



## Does Mesh Application by Using Inside-Out and Outside-In Techniques during Transobturator Tape Surgery Change the Success?

Transobturator Bant Cerrahisinde İçten Dışa ve Dıştan İçte Teknik Kullanılarak Meş Uygulaması Başarıyı Değiştirir mi?


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### ABSTRACT

**Aim:** This study aimed to evaluate the effect of transobturator tape (TOT) surgery, which is performed in the treatment of stress urinary incontinence (SUI) in women, using the inside-out or outside-in technique on the success of the surgery.

**Material and Methods:** Sixty-five women diagnosed with SUI and for whom it was decided to perform TOT surgery were included in this prospective randomized study. Participants were divided into two groups, 32 women underwent TOT surgery using the inside-out technique and 33 women underwent TOT surgery using the outside-in technique. The surgical data of patients, the 3-month incidence of complications, pre-, and postoperative scores of the incontinence impact questionnaire (IIQ-7), and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) were recorded. Objective, subjective, and inadequate treatment rates were determined for the evaluation of the success of the treatment.

**Results:** When the two groups were compared, there was no statistically significant difference in terms of age, body mass index, parity, menopause status, duration of incontinence, and preoperative IIQ-7 and ICIQ-SF scores. There were no statistically significant differences between surgical durations, length of hospital stay, early surgical complications, and postoperative 3<sup>rd</sup> month IIQ-7 and ICIQ-SF scores. There were no statistically significant differences between the two groups in terms of objective, subjective, and inadequate treatment rates.

**Conclusion:** TOT surgery is successful with both techniques in patients with SUI. Choosing the technique with which the surgeon is experienced and feels most confident will increase the success of TOT surgery regardless of the technique.

**Keywords:** Transobturator tape; suburethral slings; urinary incontinence; stress.

### ÖZ

**Amaç:** Bu çalışmanın amacı kadınlarda stres üriner inkontinans (SÜİ) tedavisinde uygulanan transobturator bant (TOT) cerrahisinin içten dışa veya dıştan içte tekniği kullanılarak yapılmasının cerrahinin başarısına etkisini değerlendirmektir.

**Gereç ve Yöntemler:** Bu ileriye yönelik randomize çalışmaya SÜİ tanısı alan ve TOT ameliyatı yapılmasına karar verilen 65 kadın dahil edildi. Katılımcılar iki gruba ayrıldı, 32 kadına içten dışa teknik kullanılarak TOT ameliyatı, 33 kadına ise dıştan içte teknik kullanılarak TOT ameliyatı yapıldı. Hastaların cerrahi verileri, 3 aylık komplikasyon insidansları, ameliyat öncesi ve sonrası idrar kaçırmanın etki anketleri (incontinence impact questionnaire, IIQ-7) ve Uluslararası İnkontinans Değerlendirmesi Anketi-Kısa Formu (International Consultation on Incontinence Questionnaire-Short Form, ICIQ-SF) skorları kaydedildi. Tedavinin başarısının değerlendirilmesinde objektif, subjektif ve yetersiz tedavi oranları belirlendi.

**Bulgular:** İki grup karşılaştırıldığında yaş, vücut kitle indeksi, parite, menopoz durumu, inkontinans süresi, ameliyat öncesi IIQ-7 skorları ve ICIQ-SF skorları açısından istatistiksel olarak anlamlı fark yoktu. Ameliyat süreleri, hastanede kalış süreleri, erken dönem cerrahi komplikasyonlar ve ameliyat sonrası 3. ay IIQ-7 ve ICIQ-SF skorları arasında istatistiksel olarak anlamlı fark saptanmadı. Objektif, subjektif ve yetersiz tedavi oranları açısından iki grup arasında istatistiksel olarak anlamlı fark yoktu.

**Sonuç:** TOT cerrahisi SÜİ olan hastalarda her iki teknikle de oldukça başarılıdır. Cerrahin deneyimli olduğu ve kendini en güvende hissettiği tekniği seçmesi, teknik ne olursa olsun TOT ameliyatının başarısını artıracaktır.

**Anahtar kelimeler:** Transobturator teyp; subüretal slingler; üriner inkontinans; stres.

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## INTRODUCTION

Urinary incontinence is an important problem that reduces a woman's quality of life considerably and can cause them to withdraw from social life when it progresses (1,2). The incidence of incontinence and prolapse is increasing with the increase in the average life expectancy and the serious increase in obesity. With the widespread use of the internet and social media, more and more women have learned that treatment is possible. The fact that society is more informed about treatment options has increased the rate of hospital admissions, making stress urinary incontinence (SUI) a problem that we have started to see more often in our clinic (3,4).

The gold standard in the treatment of SUI is mid-urethral sling surgery, and when the long-term results are considered, it has a cure rate of 70-90% (5). As an alternative to this, to reduce bladder damage and provide wider support to the mid urethra, transobturator tape (TOT) surgery was described for the first time by Delorme (6) in 2001 by placing an external-to-inside tape. In 2003, a new technique was defined by de Leval (7), with tape application from the inside to the outside. Both techniques have been successfully applied in urogynecology and urology clinics for years. The bladder, obturator nerves, and blood vessels may be injured during the passage through the obturator foramen during TOT surgery. Similarly, passage through the adductor tendons and into the skin is thought to cause postoperative groin and thigh pain (8).

In surgical procedures, success depends on the surgeon's compliance with the technique and the perfect application of the technique, as much as the surgical technique itself. For this reason, surgeons should be in search of techniques that will make them feel safer in terms of complications and will not have difficulty in performing them. Most of the time, the complications that may occur are not caused by the technique itself, but by mistakes made in the application of the technique (9,10). Therefore, it is important to develop surgical techniques that we know to be successful in a way that will provide ease of application to surgeons.

Although studies have compared these two techniques, the results are limited. In our study, we aimed to compare these two techniques by comparing the postoperative objective and subjective treatment success and complication incidences of women with SUI.

## MATERIAL AND METHODS

Our study was a prospective randomized double-blind case-control study. Before starting the study, approval was obtained from the ethics committee of Gaziosmanpaşa Training and Research Hospital (Date: 23/11/2022, Number: 121). All participants were included in the study by invitation and written informed consent was obtained from each if they agreed to participate in the study.

### Sample Size

In the power analysis made before the study, it was found appropriate to include a minimum of 16 women in each group, a total of 32 women, to be able to observe a difference with an effect size of 0.5 (high degree) and 80% power and 5% type I error. The calculation was made using the Chi-square test in G\*Power 3.1.9.7 program. A total of 65 women were included in the study who were applied to

the urogynecology outpatient clinic of Gaziosmanpaşa Training and Research Hospital.

Participants who were diagnosed as having SUI and for whom it was decided to perform TOT surgery were included. Detailed physical and urogynecological examinations of all participants were performed. Complete urinalysis, urine culture, voiding diary, Q test, and cough test results were recorded. Before the surgery, the patients were asked to rate their incontinence perceptions from 1 to 10, and the scores were recorded. All participants were asked to complete the Incontinence Impact Questionnaire (IIQ-7) (10) and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) (11), which were validated in Turkish.

Patients diagnosed as having true SUI, confirmed by history, physical examination, and tests, and patients without a cystocele greater than stage 1 were included in the study. Women who had undergone incontinence surgery before, those with neurologic diseases that might affect bladder functions, women with mixed-type or urge incontinence, patients who would undergo hysterectomy for gynecologic reasons, women with urinary system anomalies, those who were planning a pregnancy, patients who need additional surgery in addition to an incontinence surgeon, those with indications for surgery, and patients with cystocele and rectocele were excluded from the study. All patients were undergoing their first procedure.

The patients were divided into two groups according to the surgical technique to be used, but the patients were blind to which technique they would receive. Patients were randomized to the groups by the evaluating urogynecologist in the outpatient clinic; all patients had surgery performed by the same urogynecologist. After the surgery, follow-ups and evaluations were made by another gynecologist who was blind to the surgical technique in the early and late postoperative period.

### Surgical Procedure

All surgeries were performed under spinal or epidural anesthesia in the dorsal lithotomy position. Thirty minutes before the surgery, prophylaxis was performed with 2 g of cefazolin. In accordance with the surgical technique, the anterior vaginal wall 1.5-2 cm sagittal was incised 1.5 cm below the urethra. The tunnel reaching the ischiopubic bone was opened using sharp and blunt dissection in the paraurethral areas. The skin was incised 1 cm lateral to the ischiopubic ramus on the line passing through the clitoris. In the first group, with the outside-in technique, a technique defined by Delorme (6) in 2001, and in the other group with the inside-out technique defined by de Leval (7) in 2003, the mesh was placed under the urethra with a specially curved trocar, close to the medial part of the obturator foramen. After the tension was adjusted, the excess mesh pieces from the skin were cut. Vaginal mucosa was sutured. The same mesh brand and material were used in both groups (Düzey SVT Helical Set, 10x450 mm thickness).

Urethral tubes were removed on the 1<sup>st</sup> postoperative day. The residual urine was measured after the first micturition. Measurement of postvoid residual urine volume (PVR), the amount of residual urine in the bladder after a voluntary void, is another noninvasive screening test for evaluating voiding dysfunction. Like uroflowmetry, PVR

measurement helps to identify patients in need of further evaluation and to evaluate treatment effect during the follow-up. Threshold values delineating what constitutes an abnormal PVR are poorly defined. However, most urologists agree that volumes of 50 mL to 100 mL constitute the lower threshold defining abnormal residual urine volume (12,13). We also accepted the residual volume of 100 ml as the limit value in our study. Patients with >100 cc and those who developed a bladder globe were re-catheterized. Patients whose residual urine was <100 cc and who did not develop early complications were discharged. All patients were called for follow-up in the 1<sup>st</sup> week, 6<sup>th</sup> week, and 12<sup>th</sup> week after the surgery. Objective treatment, subjective treatment, and unsuccessful treatment criteria recorded in the follow-ups of the patients were used to evaluate the effectiveness of the procedure. Objective treatment was defined as a negative cough stress pad test (CSPT) and complete resolution of symptoms, and subjective treatment was defined as CSPT negative on examination but persisting intermittent symptoms. The continuation of incontinence symptoms was considered an unsuccessful treatment. The IIQ-7 and ICIQ-SF questionnaires were completed again at the postoperative 12<sup>th</sup>-week follow-ups. Patients were again asked to rate their perceptions of incontinence from 1 to 10.

All authors declare that the study was conducted in accordance with the principles of the World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects.

#### Statistical Analysis

The IBM SPSS v.21 package program was used for the statistical analysis of data. The assessment of the normality of continuous variable distribution was performed using the Shapiro-Wilk test. Non-parametric analysis methods were used because the variables did not conform to normal distribution. The Mann-Whitney U test was used to compare the differences between each group. The difference between the first measurement and the second measurement was evaluated using the Wilcoxon test. Categorical data were analyzed using the Chi-square and

Fisher's exact test. A p value of <0.05 was considered a statistical significance level.

#### RESULTS

Of the 65 women who underwent sling procedures, 32 women received the inside-out technique, and 33 women had the outside-in technique. The demographic data of the patients were shown in Table 1.

When the two groups were compared, they matched each other in terms of age, parity, body mass index (BMI), menopausal status, smoking, duration of incontinence, and IIQ-7 and ICIQ-SF scores, and no statistically significant differences were found. Patients in all groups had at least one vaginal delivery. The preoperative cough stress test was performed on all patients before surgery and all were positive. There was no prolapse greater than grade 1 in any patient.

All patients were prepared for the surgery with the same procedure. The perioperative and early postoperative results of the patients were shown in Table 2.

The patients were called for follow-up in the 1<sup>st</sup> week, 6<sup>th</sup> week, and 12<sup>th</sup> week after the surgery. The effectiveness of the surgery was evaluated through examinations of the patients at the 3<sup>rd</sup>-month follow-up. There was a significant improvement in all scores and patient symptoms after surgery independent of the technique. When the two techniques were compared in this improvement, it was observed that there was no significant difference between the two groups in terms of IIQ-7 and ICIS-SF scores, incontinence perception scores (Table 3), objective treatment, subjective treatment, and inadequate treatment rates (Table 4).

Both the preoperative incontinence perception values and the postoperative incontinence perception values did not differ significantly according to the groups (p=0.849, and p=0.325, respectively). Preoperative and postoperative incontinence perception values were different in the inside-out TOT group (p<0.001). Preoperative and postoperative incontinence perception values in the outside-in TOT group were also statistically significantly different (p<0.001).

**Table 1.** Demographic data of the patients

	TOT Inside-Out (n=32)	TOT Outside-In (n=33)	p
<b>Age</b> (years), mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	62.28±8.07 64 (57-66) [47-78]	61.09±8.17 61 (55-67) [46-78]	0.557 <sup>a</sup>
<b>BMI</b> (kg/m <sup>2</sup> ), mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	30.64±5.85 30 (26-34) [21.87-44.1]	29.66±5.74 29 (24-30) [17.72-42.31]	0.442 <sup>a</sup>
<b>Parity</b> , mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	2.38±1.07 2 (2-3) [1-5]	2.48±1.00 3 (2-3) [1-5]	0.514 <sup>b</sup>
<b>Incontinence duration</b> (years), mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	2.5±1.69 2 (1-3) [1-7]	2.21±1.56 2 (1-3) [1-6]	0.367 <sup>b</sup>
<b>Number of vaginal birth</b> , mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	1.09±2.30 1 (1-2) [0-3]	1.12±2.33 1 (1-2) [0-3]	0.723 <sup>a</sup>
<b>Vaginal birth</b> , n (%)	26 (81.3)	28 (84.8)	0.699 <sup>c</sup>
<b>Cesarean</b> , n (%)	6 (18.8)	5 (15.2)	0.740 <sup>c</sup>
<b>Menopause</b> , n (%)	4 (12.5)	3 (9.1)	0.708 <sup>d</sup>
<b>Smoker</b> , n (%)	2 (6.3)	3 (9.1)	0.514 <sup>d</sup>

TOT: transobturator tape, SD: standard deviation, Q<sub>1</sub>-Q<sub>3</sub>: 25<sup>th</sup>-75<sup>th</sup> percentile, <sup>a</sup>: Student's t-test, <sup>b</sup>: Mann-Whitney U test, <sup>c</sup>: Chi-square test, <sup>d</sup>: Fisher's exact test

The change in the preoperative and postoperative incontinence perception values did not differ according to the groups ( $p=0.696$ ).

Objective, subjective, and inadequate treatment rates were shown in Table 4, and no significant difference was detected between the groups.

## DISCUSSION

In the current study, the effect of using the inside-out and outside-in TOT techniques, which are two different techniques of the same surgery, on the success of the surgery was evaluated in patients with SUI. When the data of our study were evaluated, no superiority of either method over the other could be determined statistically.

Although many surgical techniques have been described in the treatment of SUI, TOT surgery stands out because of its minimal invasiveness, low cost, low complication rates, and high success rates (14). There are many studies in the

literature comparing the inside-out and outside-in techniques with each other. In a study by Liapis et al. (15), although there was no statistically significant difference in treatment success, they found the outside-in technique disadvantageous in terms of vaginal mucosa perforation and bladder damage, and showed that the inside-out technique was disadvantageous in terms of vascular injury and nerve damage. In our study, vaginal sulcus perforation developed in patients during surgery, and the mesh was corrected by retracting and repositioning during the procedure. However, there was no significant difference between the two techniques in terms of sulcus perforations. This difference may be due to the difference in the number of cases.

In a systematic review and meta-analysis examining prospective studies conducted by Madhuvrata et al. (16) between 1966 and 2011, these two methods were compared and no significant difference was found in

**Table 2.** The per-operative and early postoperative results of the patients

	TOT Inside-Out (n=32)	TOT Outside-In (n=33)	p
<b>Surgical time</b> (minutes), mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	22.69±4.38 20 (20-25) [16-32]	22.21±4.04 20 (20-25) [16-32]	0.801 <sup>a</sup>
<b>Hospital stay</b> (day), mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	1.09±0.30 1 (1-2) [1-2]	1.12±0.33 1 (1-2) [1-2]	0.723 <sup>a</sup>
<b>Vaginal mucosa perforation</b> , n (%)	6 (18.8)	3 (9.1)	0.303 <sup>b</sup>
<b>Groin pain</b> , n (%)	1 (3.1)	0 (0.0)	0.492 <sup>b</sup>
<b>Mesh erosion</b> , n (%)	3 (9.4)	3 (9.1)	0.999 <sup>b</sup>
<b>Urinary catheter (&gt;24 hours)</b> , n (%)	3 (9.4)	6 (18.2)	0.475 <sup>b</sup>
<b>De novo urge incontinence</b> , n (%)	2 (6.3)	2 (6.1)	0.999 <sup>b</sup>
<b>Transient residual urine elevation</b> , n (%)	6 (18.8)	7 (21.2)	0.804 <sup>c</sup>

TOT: transobturator tape, SD: standard deviation, Q<sub>1</sub>-Q<sub>3</sub>: 25<sup>th</sup>-75<sup>th</sup> percentile, <sup>a</sup>: Mann-Whitney U test, <sup>b</sup>: Fisher's exact test, <sup>c</sup>: Chi-square test

**Table 3.** Comparison of scores before and after surgery

	TOT Inside-Out (n=32)	TOT Outside-In (n=33)	p <sub>group</sub>	p <sub>general</sub>
Preop incontinence perception, mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	7.0±1.19 7 (6-8) [5-9]	7.06±1.06 7 (6-8) [5-9]	0.849	0.696
Postop incontinence perception, mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	1.22±0.75 1 (1-1) [0-4]	1.42±0.90 1 (1-1) [0-4]	0.325	
	<b>p<sub>time</sub></b>	<b>&lt;0.001</b>	<b>&lt;0.001</b>	
Preop IIQ-7 score, mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	15.66±1.10 16 (15-16) [14-18]	15.48±1.18 15 (14-16) [14-18]	0.509	0.763
Postop IIQ-7 score, mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	0.91±1.01 1 (0-1) [0-3]	0.94±0.97 1 (0-1) [0-3]	0.654	
	<b>p<sub>time</sub></b>	<b>&lt;0.001</b>	<b>&lt;0.001</b>	
Preop ICIQ-SF score, mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	13.00±1.19 13 (12-14) [11-15]	13.03±1.31 13 (12-14) [11-15]	0.925	0.393
Postop ICIQ-SF score, mean±SD, median (Q <sub>1</sub> -Q <sub>3</sub> ) [min-max]	1.66±1.49 1 (0.25-2.75) [0-5]	2.12±1.60 2 (1-3) [0-5]	0.216	
	<b>p<sub>time</sub></b>	<b>&lt;0.001</b>	<b>&lt;0.001</b>	

p<sub>group</sub>: Mann-Whitney U test, p<sub>time</sub>: Wilcoxon test, p<sub>general</sub>: Repeated Measures ANOVA (time-group interaction)

**Table 4.** Objective, subjective, and inadequate treatment rates

	TOT Inside-Out (n=32)	TOT Outside-In (n=33)	p
<b>Objective treatment</b> , n (%)	31 (96.9)	31 (93.9)	0.999 <sup>a</sup>
<b>Subjective treatment</b> , n (%)	1 (3.1)	1 (3.0)	0.999 <sup>a</sup>
<b>Inadequate treatment</b> , n (%)	0 (0.0)	1 (3.0)	0.492 <sup>a</sup>

TOT: transobturator tape, <sup>a</sup>: Fisher's exact test

terms of treatment success and recurrence in 12-month follow-up. Groin and thigh pain was nonsignificantly more common with the inside-out route. Only vaginal angle injuries were significantly more common with the outside-in route.

A prospective study of 100 women in France in 2006 showed that, in agreement with the literature, the two transobturator access routes are equally safe and do not require perioperative cystoscopic examinations (17).

Nerve damage is one of the most feared complications. Spinosa et al. (18) argued that the inside-out technique might damage the posterior terminal branch of the obturator nerve, and even the dorsal nerve of the clitoris could be affected by possible lesions but did not reveal any anatomic evidence. In the continuation, Ahtari et al. (19) performed each technique in a study on a cadaver and placed a tape. In their examinations, although the distance to the nerve was the same in both methods, the inside-out technique also passed the tape closer to the obturator canal. The outside-in technique was found to be safer in terms of nerve damage.

All follow-ups in this literature included one-year results. The 9-year follow-up by Karmakar et al. (20) included the longest follow-up period in the literature. In their study, it was revealed that the success rate showed a significant decrease compared with the 1-year results (71.6% vs. 80%). However, this was a clinically insignificant reduction compared with the 3-year results (71.6% vs. 73.1%). This means that the failure of the surgery is higher in the first years and tends to decrease as time progresses. The authors emphasized that the success rate was almost constant after 3 years.

A prospective single-blind study of 341 women conducted by Abdel-Fattah et al. (21) in 2010 also evaluated the independent risk factors for 1-year failure. In the study, no statistical difference was found between the two methods in terms of success and failure. In terms of quality of life and sexual life, the difference before and after surgery was not different for the two methods.

The fact that the anatomic space is entered with a blunt needle, working very close to important anatomic areas, and the accuracy of the placement of the tape cannot be visualized during surgery is perhaps the most distressing process for surgeons in terms of surgical technique. To illuminate this process, studies were conducted on cadavers, and the band position was tried to be confirmed by placing radiopaque bands. One of these studies was a study conducted by Hinoul et al. (22) on 10 freshly thawed cadavers. After the propylene bands were made radiopaque, they were placed by an experienced surgeon using two different techniques, then scanned using computed tomography and the route of placement was evaluated. As a result, the inner angle of the tape applied from the inside to the outside was significantly narrower compared with the other method. This meant that the two techniques did not place the tape in the same location, despite using the same anatomic space and the same material.

In a study conducted by Cordeiro et al. (23), there was no statistical difference between the technical successes of the two methods, while the rates of de novo urge incontinence and mesh erosion were the same in the two groups when different materials were used during the technical application. However, there was more erosion in

microporous bands than in macroporous bands. When the same study looked at surgical times, the inside-out technique was associated with significantly shorter surgical time. However, this may be due to their increased experience with these methods because they perform more inside-out techniques in their practice. In another study conducted by Abdel-Fattah et al. (24), 238 of 341 women were followed for 3 years and the success of both methods was found to be the same, in line with the literature.

10-year long-term results were shared in 2018 in the study of Serdinšek et al. (25), which is one of the newest studies. They did not find a significant difference in terms of objective and subjective improvement rates, and satisfaction rates.

In the most recent study to date by Kovalev et al. (26) in 2021, the two techniques were compared in many ways. They defined the outside-in technique as the method performed by taking the anatomical soft tissues as a guide, and the inside-out technique as the method in which the bone tissue is the guide. The author, who stated that the perineal pain may be due to the damage of the obturator nerve branches, determined that the branch damage was seen at 70% in the outside-in technique, while 30% was seen in the inside-out technique. In their evaluation to detect band placement with tomography, they also found the inside-out technique to be disadvantageous, which may affect the clinical results. As a result, they argued that bone tissue is a more reliable guide than soft tissue.

## CONCLUSION

Successful results are obtained with TOT procedures performed in the treatment of SUI. The perfect application of the technique is as important as the choice of technique in the success of the surgery. We believe that the choice of surgical procedure and technique should be decided after discussing the risks related to the patient in addition to the experience of the surgeon.

**Ethics Committee Approval:** The study was approved by the Ethics Committee of Gaziosmanpaşa Training and Research Hospital (23.11.2022, 121).

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