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3D laparoscopic prostatectomy: A prospective single-surgeon learning curve in the first 200 cases with oncologic and functional results

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ABSTRACT

Background: Studies for 3D-laparoscopic prostatectomy (3D-LRP) learning curve and surgical results are lacking. Combining 3D vision to LRP attenuates differences compared to Robotic assisted laparoscopic prostatectomy (RALP) with similar mini-invasiveness but lower costs.

Materials and methods: Two hundred consecutive men with localized prostate cancer underwent 3D-LRP at Seinäjoki central hospital between 2013 and 2018. Oncological and functional results were documented. Long-term functional evaluation was done using EPIC-26 survey. Clavien-Dindo classification was used to assess complications during first 3 months. All operations were performed by a single surgeon (M.R.) with no experience of LRP or 3D-LRP. The learning curve was assessed by evaluating urethral anastomosis- and total operative time. Perioperative and postoperative data was collected prospectively during surgery and at subsequent control visits up to minimum of 1 year.

Results: A plateau in anastomosis time was reached after 30 cases and in operative time after 60 cases. Median operative time was 114 min (78–258 min) and median time for anastomosis was 25 min (11–90 min). Median blood loss was 150 ml (10–800 ml); 93.5% of the patients were discharged within the first 3 days. Clavien-Dindo $\geq$3a complications occurred in 6.5%. Positive surgical margins occurred in 23%. One-year after the operation, 93.3% had PSA $\leq$ 0.1; 91.9% of the patients were dry or used one daytime pad. EPIC-26 scores were as follows: Urinary incontinence 79.25 (14.5–100), urinary irritative/obstructive 93.75 (31.25–100), bowel 100 (33.33–100), sexual 36.17 (0–100) and hormonal 95 (37.5–100).

Conclusion: The learning curve for 3D laparoscopic prostatectomy is comparable to RALP, which makes it a cost-effective alternative with comparable oncological and functional results.

Introduction

The golden standard surgical treatment in localized prostate cancer (Pca) has long been open retropubic radical prostatectomy (ORP) [1]. However, surgery trends towards minimally invasive procedures which have advantages of reduced bleeding and shorter hospital stays compared to ORP have created alternative options [2,3]. Robotic assisted laparoscopic prostatectomy (RALP) has claimed its position as the most common surgical method when treating localized PCa. The advantages of RALP compared to ORP are well documented [4]. Post-operative catheterization time and hospital stay are shorter. Oncological and functional results are equal to ORP. The main disadvantage in RALP is higher direct treatment-related costs [1]. Positive surgical margins and major surgical complications are more common in ORP, whereas mean operative time in RALP is longer. No significant difference between techniques is found in the rate of erectile dysfunction or incontinence after surgery [5].

Laparoscopic radical prostatectomy (2D-LRP) has a long learning curve [6]. In 2D-LRP, blood loss and hospital stay are higher compared to RALP. Post-operative recovery of erectile dysfunction and incontinence are slower. However, positive surgical margins, rate of major complications, operative time and need for blood transfusions are comparable [5]. The 2D-LRP method has progressed from the early days and different surgical methods have been presented [7,8]. However, the efficacy and safety of 2D-LRP have been questioned due to concerns over its technical difficulty, risk of complications and undefined benefits over open surgery [5]. Nevertheless 2D-LRP has the same advantages of mini-invasiveness as RALP without 3HD-vision.

The studies on the learning curve for RALP are heterogeneous. The outcomes for plateau determination are different between studies. Usually, the plateau for operation time and estimated blood loss are reduced after 100–200 cases and a minimum 40–50 cases are required to reach the plateau. Overall complications are reduced when the surgeon gains

experience and the learning curve plateaus [9]. Performance in the robot-assisted procedure is significantly enhanced when using stereoscopic vision instead of monoscopic vision when performing tasks of increasing complexity. The advantage persists beyond the learning curve. The learning curve for complex procedures performed under stereoscopic vision is much flatter [10].

In a 4th generation 3D vision system, the surgeon uses ergonomic glasses and innovated technology when performing laparoscopy [11]. The system allows superior depth perception and higher resolution compared to earlier systems. Complicated urological procedures are easier compared to 2D vision, as orientation in the pelvis is improved [12]. The challenges encountered with 2D-LRP can be overcome with better and more accurate vision to the operation field. These technical advantages bring the laparoscopic technique closer to RALP.

Studies on the learning curve and the outcomes of 3D laparoscopic prostatectomy (3D-LRP) are lacking. We wanted to describe the learning curve of a single surgeon in 3D-LRP and evaluate the oncological and functional results in this first 200-patients series.

Materials and methods

Study population

The study population consisted of the first 200 consecutive men that underwent 3D-LRP for localized PCa at Seinäjoki central hospital between 19 December 2013 and 20 September 2018. Data was collected prospectively. Men with PCa and eligible for surgical treatment by TNM classification, Gleason score, age, PSA and own will were included. All patients were operated on by a single surgeon (M.R.) who had performed over 100 ORPs and 50 laparoscopic kidney operations, but no 2D-LRPs. Preoperative factors such as age, prostate size, PSA, urinary continence, clinical T stage, Gleason score and tumor extent based on MRI imaging were collected. Prostate size was evaluated using transrectal ultrasound or MRI. Clinical T-stage was classified using Digital rectal examination (DRE), biopsy results and MRI. The decision to perform lymphadenectomy on high-risk patients was based on D'Amico risk classification for prostate cancer [13].

Intraoperative factors

Intraoperatively the time used for procedural phases such as Troacar placement, prostate detachment and lymphadenectomy were documented. Urethral anastomosis time was measured from the first needle incision to completion of anastomosis. Total operative time and blood loss were documented at the end of the procedure. Nerve sparing was classified as complete, unilateral or non-nerve sparing according to the surgeon. Anastomosis was done with a continuous suture using Van Velthoven technique [14].

Perioperative factors

After surgery patients were monitored in the urological ward. The data of the peri- and postoperative phase was collected from patient files. Discharge day from the hospital and complications during the first 3 months after surgery were graded according to Clavien-Dindo classification and recorded [15]. Tumor and lymph node status, together with surgical margins and Gleason score of the prostatectomy sample were documented and compared to preoperative findings. The catheter was removed in the outpatient clinic after 1 week if there was no leakage of anastomosis on perioperative filling of the bladder by 200 ml saline and after 2 weeks if there was any kind of leakage. No routine cystography was done. The patients had control visits at 2–3 months, 8–12 months and 14–16 months after the surgery. At control visits urinary continence and potency were evaluated by self-report and PSA-levels were checked.

Urinary incontinence was classified into four groups: totally continent, single day-time pad (continent most of the time), sheath (no incontinence at night) or sheath (totally incontinent). Erectile function was categorized by five groups: spontaneous erections, requirement for PDE-5 inhibitors, requirement for intracavernous injections, no function, patient not interested in sexual function.

EPIC-26 questionnaire was sent to participants in October 2019 to evaluate long-term functional results. At the time of reply the minimum time from the operation was 1 year 1 month and the maximum time was nearly 6 years. The EPIC-26 points were calculated using scoring instructions [16]. HRQL-domain scores for urinary incontinence, urinary irritative/obstructive, bowel, sexual and hormonal symptoms were calculated and transformed to a 0–100 scale.

The learning curve was assessed by evaluating the development of anastomosis time and total operative time during the 200-patient series using linear regression method. The point was reached when the slope was zero.

All analyses were performed using IBM SPSS statistics version 25.

Results

Patient characteristics

Pre-operative characteristics are shown in Table 1. Median age at surgery was 63 years (range = 45–75) and the median prostate volume was 32.2 ml (15–120). T1c was the most common clinical T-stage, whereas T2 and T3 were equally common. The most common biopsy Gleason score was 6. Most of the patients (97%) were continent before surgery, 35.5% reported normal erectile function.

Perioperative data

Median operative time was 114 min (78–258) with median blood loss 150 ml (10–800 ml). There were no conversions to open surgery. Lymphadenectomy was performed on 46 (23%) patients. Median total operative time with lymphadenectomy was 157 min (97–258). Troacar placement took

9 min (5–34) and the prostate was detached in 53 min (31–136 min). Median time for anastomosis was 25 min (11–90). Most patients (93.5%) were discharged from hospital within the first 3 postoperative days; 58% and 87.5% of the patients were discharged by first and second postoperative day, respectively. Highest Clavien-Dindo complication class was 3b (1.0%). Clavien-Dindo classification ≥ 3a occurred in 13 (6.5%). There was one rectal injury, which was noticed during surgery and repaired intra-operatively. The results have been presented in Tables 4 and 5.

Learning curve assessment

Surgeon development during the 200-patient series was most evident in time required for creating the urethral anastomosis. The plateau was achieved after 30 patients. After this point no further shortening of anastomosis time was

Table 1. Patient characteristics.

	n (median)	% (min–max)	Q1–Q3
Tumor clinical characteristics			
PSA (ng/ml)	(7.7)	(1.7–49.7)	5.5–11.0
Gleason score (Biopsy), n (%)			
6	133	66.5	
7	37	18.5	
8–10	27	14.5	
Clinical T-stage, n (%)			
T1c	101	50.5	
T2$_{a-c}$	50	25	
T3	49	24.5	
Patient characteristics			
Age	(63)	(45–75)	58–67
Prostate volume (cm^3)	(32.2)	(15–120)	26–43
Urinary continence			
Dry	194	97	
Urge incontinence	5	2.5	
Stress incontinence	1	0.5	
Erectile function			
Not relevant	87	43.5	
Normal	71	35.5	
PDE-5 inhibitor	16	8.0	
Not known	26	13.0	

Cohort of 200 Finnish men with localized prostate cancer and managed with 3D laparoscopic prostatectomy.

observed (Figure 1(a)). Improvement was also seen in the total operative time. After 60 operations the total operative time was stabilized statistically (Figure 1(b)). No clear change in other parameters such as surgical margins, blood loss, continence or length of hospital stays were observed during the study. When the 200 patients were divided into four groups of 50 patients according to time the PSM were 20%, 22%, 20% and 30%. The reason for higher PSM in the last group was that the group held pT3 of 42% of the total 50 patient. In the first three groups the numbers were 36%, 10% and 20%, respectively.
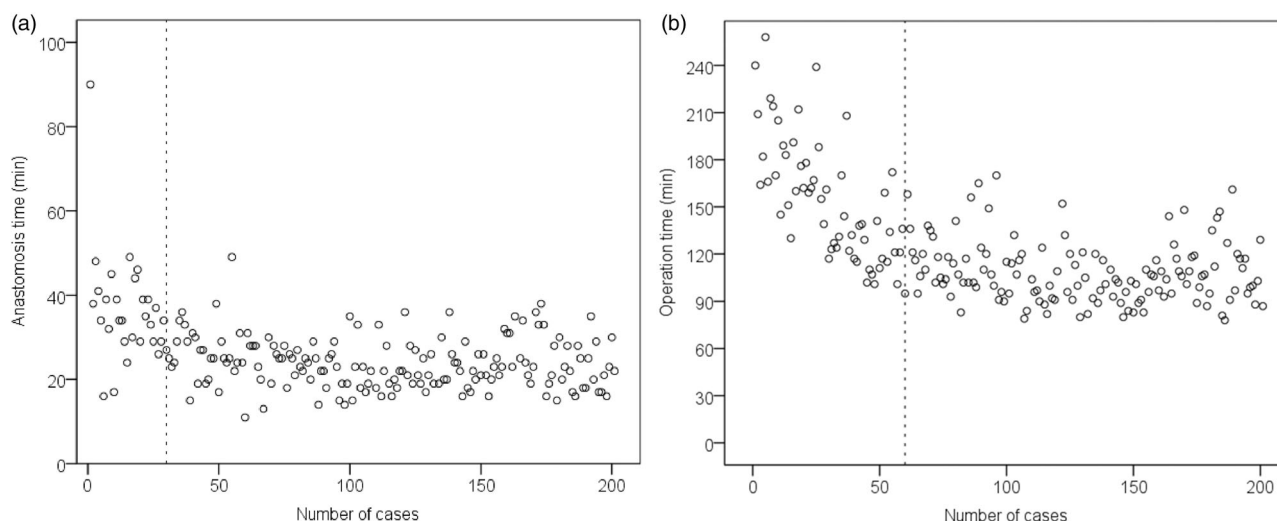
Pathological characteristics

After surgery, the most common pT classification was T2c (63.5% of patients), followed by T3a (20%), T2a (8.5%) and T3b (7.0%) (Table 2). Gleason score distribution was pG6 (40.5%), pG7 (41.0%), pG8 (10.5%), pG9 (5.0%) and pG10 (3%). Surgical margins were positive in 23% of the cases; in ≥ pT3 the PSM was 37% and with pT2 it was 17.8%. Lymph nodes were positive in 3/47 (6.4%) cases. The difference in total results of lymphadenectomies done compared to total lymph nodes (pN) is due to one lymph node which was situated on the top of the prostate and found in a single specimen of the prostate. The total number of lymph nodes gathered was not available.

Functional and oncological outcomes

At first, second and third control visit, 93.9%, 93.4% and 91.1% of the patients had PSA < 0.2, respectively (Table 3).

At the first control visit, 38.1% ($n = 75$) were completely continent; 40.6% ($n = 80$) were using a single daytime pad and 20.8% ($n = 41$) used a sheath but were continent overnight. Only one patient was totally incontinent. In the second control visit 126 patients were dry (68.1%), 44 (23.8%) patients were using a single daytime pad and 13 (7.0%) patients used a sheath at daytime. Two (1.3%) patients were

Figure 1. (a) Learning curve of Urethrovesical anastomosis (UVA). (b) Learning curve of total operative time (TOT).

Table 2. Pathological characteristics of prostatectomy specimens.

	n	%
pT (Tumor classification)		
T2a	17	8.5
T2b	2	1.0
T2c	127	63.5
T3a	40	20.0
T3b	14	7.0
pG (Gleason score)		
6	81	40.5
7	82	41.0
8	21	10.5
9	10	5.0
10	6	3.0
Surgical margins (all cases)		
Negative	154	77
Positive	46	23
pT2		
Negative	120	82.2
Positive	26	17.8
≥ pT3		
Negative	34	63.0
Positive	20	37.0
pN (Lymph nodes)		
Negative	44	22.0
Positive	3	1.5

Cohort of 200 Finnish men with localized prostate cancer and managed with 3D laparoscopic prostatectomy.

Table 3. Functional and oncological outcomes after surgery.

	n	%
Continence (after surgery)		
2–3 months		
Dry	75	38.1
Single daytime pad	80	40.6
Sheath (Continent overnight)	41	20.8
Sheath (Incontinent)	1	0.5
10–12 months		
Dry	126	68.1
Single daytime pad	44	23.8
Sheath (Continent overnight)	13	7.0
Sheath (Incontinent)	2	1.1
16–18 months		
Dry	109	72.7
Single daytime pad	28	18.7
Sheath (Continent overnight)	7	4.7
Sheath (Incontinent)	3	2.0
Psa (ng/ml)		
2–3 months		
0.0	180	90.9
<0.2	6	3.0
≥0.2	12	6.1
10–12 months		
0.0	170	87.2
<0.2	12	6.2
≥0.2	13	6.7
16–18 months		
0.0	141	82.9
<0.2	14	8.2
≥0.2	15	8.8
Erection (after surgery)		
2–3 months		
No function	94	47.5
Function	13	6.6
p.o treatment	45	22.7
I.c treatment	27	13.6
No information	19	9.6
10–12 months		
No function	40	21.6
Function	22	11.9
p.o treatment	51	27.6
I.c treatment	44	23.8
No information	28	15.1

Cohort of 200 Finnish men with localized prostate cancer and managed with 3D laparoscopic prostatectomy.

Table 4. Intraoperative parameters and post-operative complications.

	Median	Min–Max	Q1–Q3
Operative time, All cases (min)	114	78–258	99–137
Operative time without lymphadenectomy (min)	106	78–240	95–120
Operative time with lymphadenectomy (min)	157	97–258	131–171
Lymphadenectomy time (min)	27	12–87	22–36
Blood loss (ml)	150	10–800	75–200
Troacar placement time (min)	9	5–34	8–12
Prostate detachment time (min)	53	31–136	45–62
Anastomosis time (min)	25	11–90	20–30
Release day from hospital (days after surgery)	1.79	1–13	1–2

	n	%
• Day 1	116	58
• Day 2	59	29.5
• Day 3	12	6.0
Total of patients released from hospital during 3 first postoperative days	187	93.5
Clavien-Dindo 3 months		
• Grade1	16	8.0
• Grade 2	7	3.5
• Grade 3a	11	5.5
• Grade 3b	2	1.0

Cohort of 200 Finnish men with localized prostate cancer and managed with 3D laparoscopic prostatectomy.

Table 5. Type of postoperative complications (Clavien- Dindo ≥ 3a).

	n (%)
Clavien-Dindo 3b	
Surgical site hematoma	2 (1.0%)
Clavien-Dindo 3a	
Abscess of the surgical site	1 (0.5%)
Seroma of the surgical site	2 (1.0%)
Rupture of fascia and inherniation of small intestine to laparoscopic port wound	1 (0.5%)
Leakage of anastomosis	4 (2.0%)
Hematuria	1 (0.5%)
Postoperative hemorrhage	1 (0.5%)
Hydronephrosis (unilateral)	1 (0.5%)
	13 (6.5%)

Cohort of 200 Finnish men with localized prostate cancer and managed with 3 D laparoscopic prostatectomy.

incontinent. During the third control visit, 109 (72.7%) patients were continent and 28 (18.7%) patients were using a single daytime pad. Seven patients (4.7%) used a daytime sheath and three patients (2.0%) were totally incontinent.

In the first control visit only 13 (6.6%) patients were able to have a normal erection. The majority had no function (47.5%) or were using PDE-5 inhibitors (22.7%) or intracavernous alprostadil injections (13.6%). During the second and third control visit the proportion of patients having a normal erection, using PDE-5 inhibitors or injections were 11.9%, 27.6%, 23.8% and 11.5%, 27.2% and 24.5%, respectively. At the third control visit, 33 (22.4%) patients felt that the subject was not relevant to them.

Health-related quality-of-life (HRQoL)

Most participants (76%) answered the EPIC-26 form. After evaluating the answers, the domain scores could be calculated as follows: Urinary incontinence for 149 participants (98%), urinary irritative/obstructive for 146 (96%), bowel for 145 (95.4%), sexual for 150 (98.7%) and hormonal for 147 (96.7%). EPIC-26 scores were as follows: Urinary incontinence

was 79.25 (14.5–100), urinary irritative/obstructive was 93.75 (31.25–100), bowel was 100 (33.33–100), sexual was 36.17 (0–100) and hormonal was 95 (37.5–100).

Discussion

As the 2D-LRP started to generalize in the urological field the main objective was to achieve similar results with mini-invasive technique [2,17]. Soon it was discovered that the prostatectomy done with laparoscopy was demanding and the learning curve was steep [8,18]. RALP started in the US and got its position as the most used surgical method when treating Pca. The competence was achieved more rapidly when compared to 2D-LRP [3,19]. The advantage of RALP compared to 2D-LRP was 3D vision and articulated wrist-like instruments [20]. RALP became the preferred method of prostate cancer surgery in most centers as the technique evolved [3]. Since it has been found that short- and long-term outcomes are not superior to ORP [21].

3D vision has been generalized in laparoscopy and it has been shown to give benefits in urological procedures compared to 2D laparoscopy [22]. The role of 3D vision in laparoscopic prostatectomy is uncertain and there are only a couple of studies regarding it [11,23,24]. 3D-LRP offers benefits over 2D-LRP, which can be seen in a recent review by Bertolo et al. [25]. Their total operative time was 35 min shorter compared to 2D laparoscopy. 3D vision was a significant predictor for shorter time spent on urethrovesical (UVA) anastomosis. Operative time, estimated blood loss (EBL) and recovery of continence after 3 months were significantly better in 3D-LRP compared to 2D-LRP. 3D laparoscopy gives better visibility with improved depth of perception [23]. Bove et al. [11] described the first study in urologic literature to compare the advantages of 4th generation 3D vision over traditional 2D vision in LRP. The preliminary study suggested a trend of improvement in blood loss and early postoperative recovery of continence. Statistically significant differences for 3D laparoscopy were seen in mean operative time and anastomosis time.

No comparison between RALP and 3D-LRP or learning curve studies regarding 3D-LRP have been published. The current clinical trend in management of low-risk PCa towards active surveillance reduces the number of patients treated with surgery so the learning curve length is a relevant issue as new surgeons are trained in the future [26]. In a public healthcare system the treatment options should also be cost-effective [21].

In this novel single-surgeon series of 3D-LRP the learning curve for UVA and total operative time were faster than previously reported for 2D-LRP or RALP in the literature. In this study the learning curve was seen with a statistical plateau in anastomosis time with 30 patients and with 60 patients in total operative time. A systematic review by Abboudi et al. [9] on the RALP learning curve showed that a significant change in OT is achieved after 100 cases. The learning curve for urethrovesical anastomosis time (UVAT) was only measured in one study by O'Malley et al. [27], with 10 cases required to reach the plauteu. The learning curve studies on

2D-LRP are heterogeneous and the outcome for learning has been measured often with PSM, complications, or prostate cancer recurrence [9]. The mean operation times with a large patient series have adjusted to 156 min [8] and to 250.5 min in the Rassweiler et al. [7] study. The 200 patients in the group did not show statistical plateauing in PSM, blood loss, hospital stay or early complications. These outcomes may be more related with patient- and tumor characteristic than with surgeon experience. A larger study population will be needed to estimate whether these parameters improve in bigger patient series.

The operative time and blood loss are comparable to what was seen with initiation of the RALP study in Finland. In this study the skin-to-skin time was 183 min and blood loss 212 ml [1]. The results are better that what is seen in the Yaxley et al. [4] study with results for the RALP of operation time 202 min and estimated blood loss 443.74 ml. The total amount of PSM in our study was 23%, with $\geq$ pT3 the PSM was 37% and with pT2 17.8%. These results are better to those seen with an initiation of RALP study in Finland. The early oncological results are comparable [1].

The number of Clavien-Dindo $\geq$ 3a complications in our study was 6.5%. If we look at an earlier review article by Novara et al. [28], on RALP complications our results adjust to a range of 0.5–7%, which is seen in RALP studies. It is notable that our cut point for complications was 3 months postoperatively. The functional results are slightly inferior to those seen with RALP initiation in Finland, but comparable to early results with RALP in Sweden [29].

Functional outcomes after radical prostatectomy are of critical importance for future quality-of-life. Many non-randomized studies have shown the benefit of RALP for urinary continence and for sexual function with follow-up between 12 and 24 months. On the other hand, there are several studies that show no difference between ORP and RALP on functional outcomes when the follow-up is up to 36 months [30]. In our study the long-term evaluation of functional outcome was made using a validated EPIC-26 questionnaire. The results on continence are comparable with previously published ORP, 2D-LRP and RALP results in the literature [30,31].

The strength of our study was that we described implementation of a new method to clinical practice in a new environment. The surgeon had no previous experience from 2D-LRPs, the conditions were standardized and the surgical team was mainly the same in all operations. The patients were the first 200 consecutive patients that were treated with 3D-LRP during the study period so there was no patient selection. The complications were registered and reported according to established Clavien-Dindo classification. The learning could be seen first in the anastomosis time and later in the total operative time. The development is not only surgeon's improvement but reflects progression of the whole surgical team. Accurate and diligent measurement of different phases of the procedure allows precise estimation of the progress.

The weakness of our study is that the majority of the operated men had Gleason 6 cancer based on diagnostic

biopsies, reflecting clinical practice at the time. Such low-risk cancers would nowadays be managed mainly with active surveillance, which may limit the generalizability of our results to current clinical practice. However, most patients with Gleason 6 cancers were young, had many positive cores in biopsies or were not willing to start or to continue previous active surveillance. In the final pathologist report the proportion of Gleason 6 decreased from 66.5% (133) to 40.5% (81), which shows clearly the diagnostic challenge encountered during the survey. The development of the prostate MRI and fusion biopsies has improved diagnostic accuracy since. It remains unclear whether the results will be generalizable to situations where prostate carcinoma with medium- or high-risk PCa are treated with surgery. The self-reported evaluation of the continence and potency are likely biased towards better outcomes as in the beginning they were recorded at the operating surgeon's outpatient clinic. We aimed to reduce this subjectivity by adding objective EPIC-26 survey to estimate functional results in the long-term.

Conclusion

3D-LRP has a fast learning curve in UVA and operation time. The oncological and functional results in our study are comparable to previous literature seen with RALP. 3D-LRP offers similar benefits of mini-invasiveness as RALP with a fraction of the cost.

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