Retrograde Extraperitoneal Laparoscopic Prostatectomy (RELP). A Prospective Study about 1,000 Consecutive Patients, with Oncological and Functional Results

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Purpose: Usual laparoscopic surgery of localized prostate cancer uses antegrade dissection. We describe and evaluate the original RELP (Retrograde Extraperitoneal Laparoscopic Prostatectomy).

Materials and Methods: A prospective cohort of 1005 patients with clinically localized cancer prostate who were operated on from December 1999 to September 2013, in Lyon (France), and followed up to 172 months (median: 60 months). Patients encountered a RELP procedure, a totally extra-peritoneal approach with a retrograde dissection from the apex to the bladder neck, and ascending dissection of the erectile neurovascular bundles, facilitated by the 30° optic telescope. Adjunctive treatments were: immediate radiotherapy (9.2%), salvage radiotherapy (13.4%), androgen deprivation therapy (10.8%), chemotherapy (1.4%), no treatment (75.8%).

Results: The mean age was 63.4 years, the Gleason score was 4+3 or worse in 24.9%, there were 2.3% unifocal tumors. The pathology stages were pT2A (8.71%), pT2B (2.80%), pT2C (69.0%), pT3A (13.1%), and pT3B (6.41%). There were 60.8% negative margins (R0) in total (90.1% for basal locations, and 75.8% for apical locations). The mean operating time was 115 minutes for the last 100 patients. The BPFSR (biological progression free survival rate, PSA $\leq$ 0.10 ng/ml) was 71.9% at 5 years, and 61.4% at 10 years. The cancer specific survival rate was 99.4% at 5 years, and 98.3% at 10 years. After 12 months, 88.6% of patients did not require an incontinence pad, and 67.0% retained the pre-operative quality of their erection.
Conclusion: RELP yields good oncologic results and quality of life, as good as robot-assisted surgery.

Keywords: functional results; laparoscopy; oncological results; prostatectomy; prostatic neoplasms; retrograde extraperitoneal laparoscopic prostatectomy

INTRODUCTION

The first laparoscopic prostatectomies were performed via an intra-peritoneal and ante-grade route in 1992 by Schuessler et al.,[(1)] and in 1997 by Gaston et al..[(2)] Then, several teams have amplified these approaches.[(3–5)] In 1997, Raboy et al. performed laparoscopic prostatectomy using an extra-peritoneal approach with ante-grade dissection.[(6)] In 1999, the extra-peritoneal approach was being developed simultaneously by Bollens et al.,[(7)] using ante-grade dissection, and in Lyon (France),[(8,9)] where we introduced an original, not only completely extra-peritoneal approach, but also with a retrograde prostate-semino-rectal dissection combined with the ascending dissection of the erectile neurovascular bundles, from the apex up to the bladder neck, commonly used in conventional surgery and which, paradoxically, had not been described until then in laparoscopic surgery. Rassweiler et al.[(10)] initiated a retrograde dissection via the intra-peritoneal route.
Radical prostatectomy was proven perfectly adapted to the treatment of prostate cancer, but laparoscopic procedures were initially performed via an intra-peritoneal route, contrary to the more logical and natural approach to the planes of anatomical dissection used during conventional open surgery, and were associated with certain risks that can be avoided by preserving the peritoneum.[(11)]
We then developed a simplified retrograde extra-peritoneal laparoscopic technique. This technique, while providing a largely sufficient dissection space (**Figure 1**), enables the initial approach to the apico-urethro-fascial, sphincteral, erectile and rectal junction, then prostato-semino-rectal cleavage up to the bladder neck, combined with the ascending dissection of the erectile neurovascular bundles (**Figure 2**). This technique exactly renders the open procedure, and enables the surgeon to focus immediately on the essential step on which oncologic risks (apical dissection) and functional consequences (neuro-vascular bundles and sphincter preservation) depend (**Figure 3**).
We already published 47 cases in 2002,[(8)] and 143 cases in 2003.[(9)] The objective is to present the oncologic and functional results of the first 1,000 patients operated with this technique.

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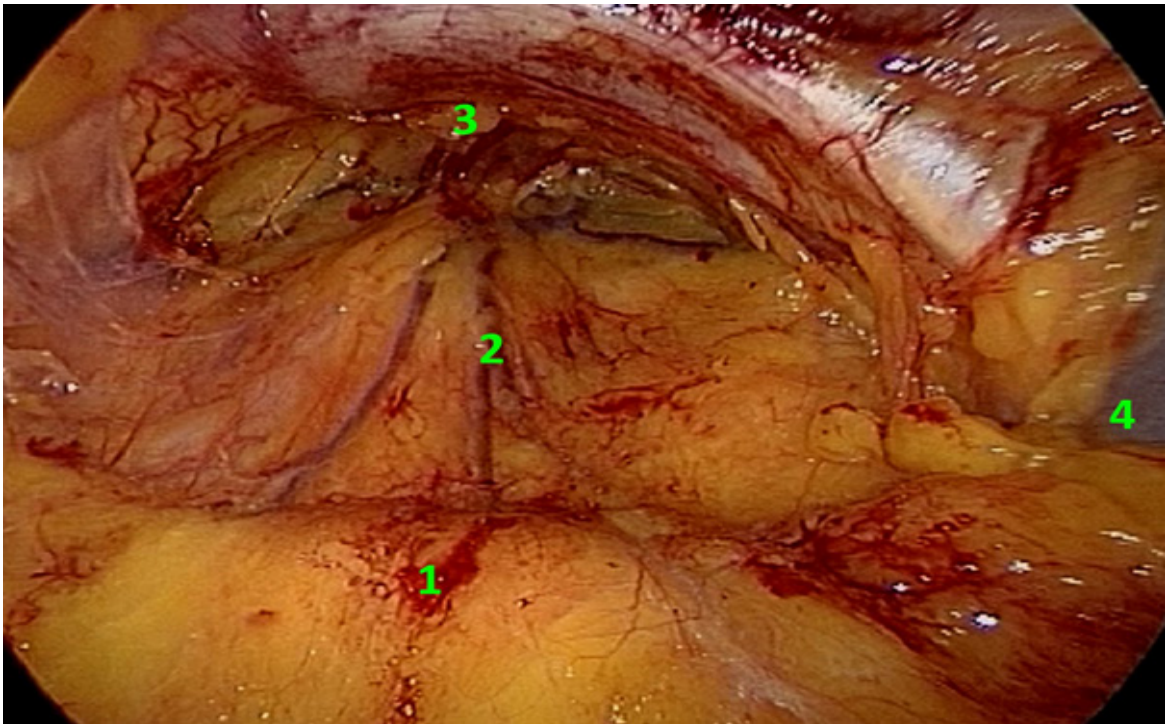

Figure 1. Pelvis exposure with the RELP technique (1: peritoneum, 2: bladder, 3: prostate, 4: neurovascular ilio-obturator axes).

MATERIAL AND METHODS

Population

From December 1999 to September 2013, a total of 1,005 patients with a clinically localized prostate cancer were operated in the CLUB, a private center in Lyon, using the RELP technique. Five patients were excluded (4 per-operative conversions, and one death due to cardiac failure). The 1,000 remaining patients were all included, followed-up, and analyzed.

We collected data about their characteristics at the inclusion (surgeon, date, age, preoperative prostate specific antigen PSA, and erection status), the characteristics of the prostate tumor (pathological report, Gleason

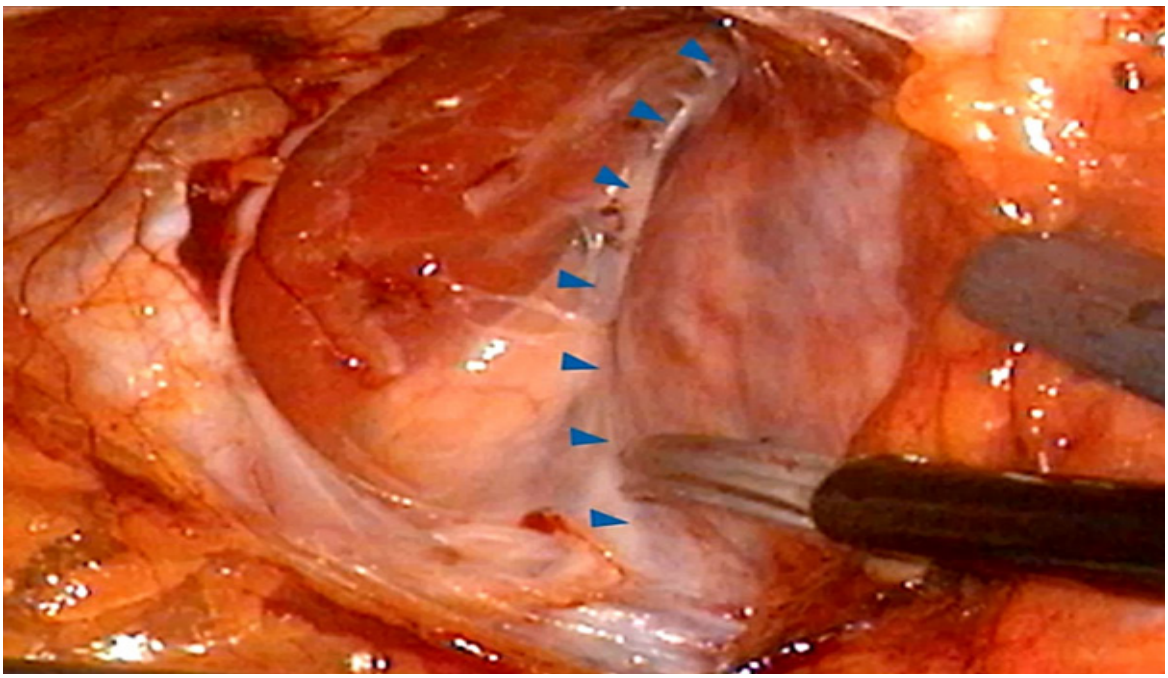

Figure 2. Initial approach to the erectile neurovascular bundles.

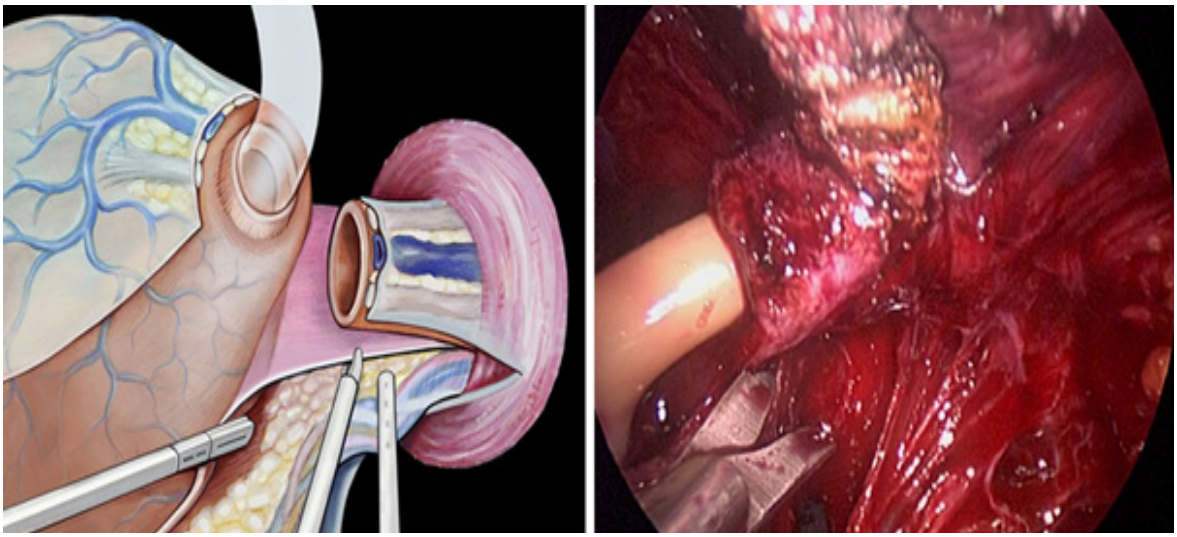

Figure 3. Retrograde apical dissections, neurovascular bundles, and sphincter preservation.

score, TNM staging), follow-up, and treatment (PSA recurrence, adjuvant treatments, complications, and intercurrent diseases). PSA recurrence was defined rigorously as a post-operative PSA value greater than 0.10 ng/ml.

The study was conducted in accordance with French regulation. As it consisted of the secondary use of routine care data, it did not require any ethical approval by an internal review board. The patients were informed their anonymized data could be reused for research purposes, and none objected. Ethnicity data could not be collected. The principles outlined in the Declaration of Helsinki were followed.

Surgical technique and postoperative protocol

The complete operative protocol is provided as online supporting information. The surgical approach for prostate dissection benefited greatly from anatomic and technical descriptions,[12–14] which made it possible to define the relationships between the apico-urethral junction and the various fasciae, the peri-urethral-musculo-sphincteral sleeves, the erectile neurovascular bundles, and the anterior wall of the rectum. The anatomic landmarks are thus better defined at the apex,[15] and the dissection planes much more natural there than at the base of the prostate to allow for easier posterior musculofascial reconstruction.[16]

The surgical team has now an experience of more than 1,500 cases operated in the CLUB. During all these procedures, a senior urologist was always present, according to the "mentoring" principle.

At the inclusion, all the patients underwent a primary prostatectomy, excluding previous radiotherapy. Af-

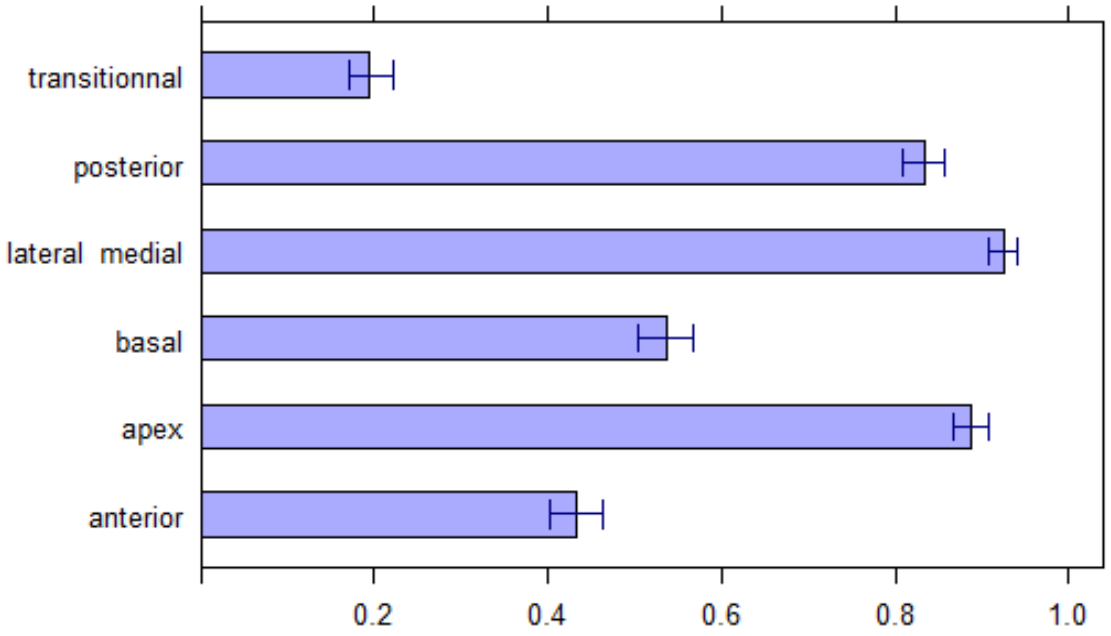

Figure 4. Proportion of patients having a given tumor location.

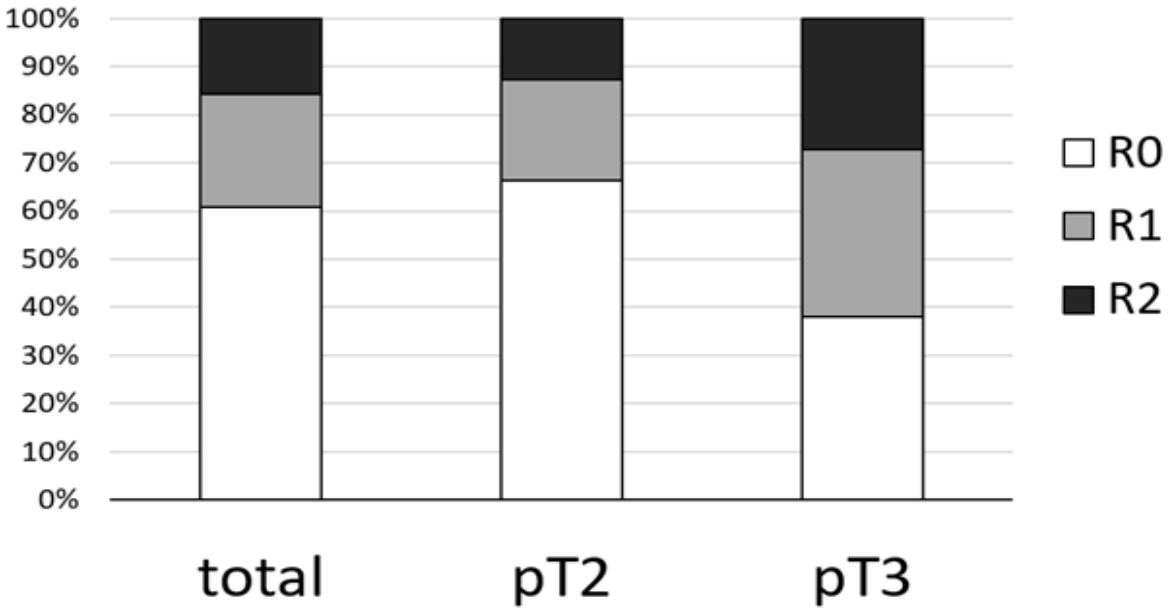

Figure 5. Margins as function of the TNM tumor stage.

ter the surgeon systematically examined the prostate macroscopically, subsequently the specialist anatomic pathologist determined the tumor margins (location, extent, dimensions and number). The tumor was qualified R0 in the absence of tumor margin, R1 if there was one focus < 3 mm, even infra-millimetric, or R2 if there was one focus ≥ 3 mm or more than one focus of any size. In case of R2 positive margins with an ascending post-operative PSA>0.10 ng/ml, an adjuvant radiotherapy was proposed within 6 to 9 months postoperatively according to the patient's acceptance. Furthermore, the patients were followed-up every 6 months, and a secondary radiotherapy was proposed for those with initial positive margins and a subsequently two times rising PSA. ADT was proposed in case of failure of radiotherapy.

Data collection

The data were collected in the course of medical consultations by the surgeons who operated the patients. A spreadsheet was used. During the study period, the data were gathered and controlled every week by the first author and, when necessary, the information was checked in the patient's paper file. A final check was carried out at the time of the statistical analysis and revealed no anomaly.

Statistical analysis

Descriptive univariate statistics were computed in the whole database. For quantitative variables, the mean and standard deviation (SD) were computed. In case of

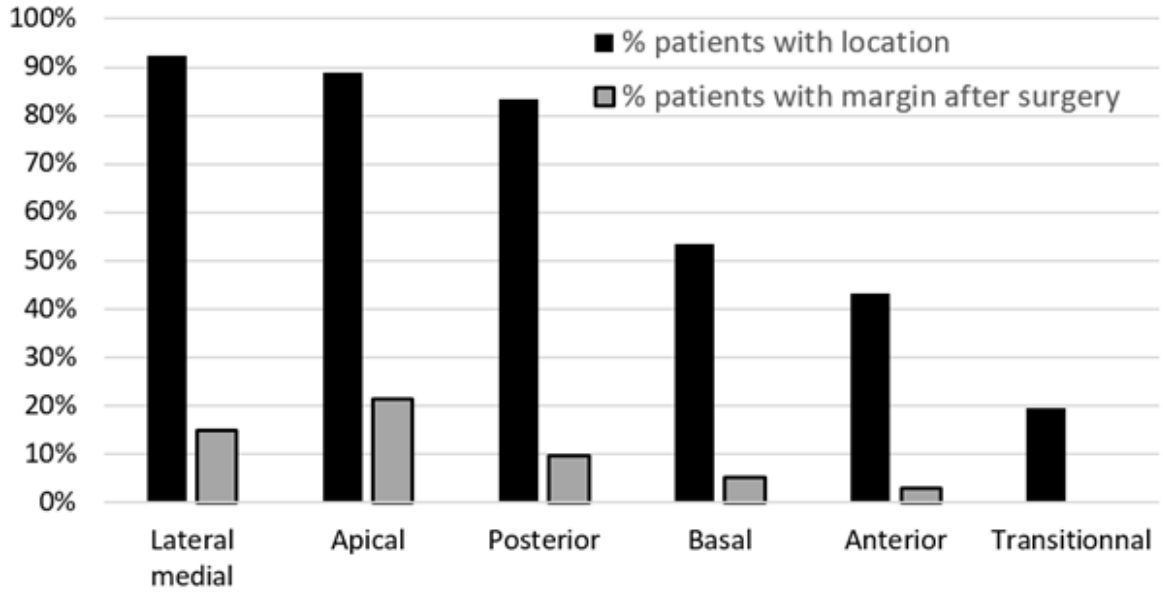

Figure 6. Proportion of patients having a given tumor location, and the corresponding margin location.

Table 1. Characteristic of the study included in this systematic review.

Follow-up	Proportion (n)	Lost to follow-up (beginning of period)
[0,30] months	36.5% (365)	0%
]30,60] months	14.6% (146)	36.5%
]60,90] months	20.0% (200)	51.1%
]90,120] months	18.7% (187)	71.1%
]120,150] months	8.4% (84)	89.8%
]150,180] months	1.8% (18)	98.1%

non-normal distribution, median, first and third quartiles were computed (respectively Q2, Q1 and Q3). For qualitative and binary variables, counts and proportions were reported.

The 95% confidence intervals of means were computed using the normal distribution when appropriate ($n \geq 30$ or normal distribution). The 95% confidence intervals of proportions were computed with the Exact Binomial Test.

The Khi² test was used to test the independency between categorical variables (with theoretical counts ≥ 5). Linear regressions were used to draw the learning curves of the surgeons.

The time-dependent events were analyzed using survival methods. Descriptive survival curves were drawn using the Kaplan-Meier estimate, with normal estimation of confidence intervals. Cox model with stepwise covariate selection was used for inferential analyses. Survival analyses were performed including all the patients who underwent surgery: the objective was to quantify the survival after the comprehensive protocol (surgery with or without adjuvant or secondary radiotherapy), and not to assess the surgery alone. We only tested covariates that were available before or immediately after the surgery, and included all of them: surgeon name, age of the patient, year, Gleason score, Gleason ≥ 7 (4+3), tumor stage, tumor volume, margins, each location of the margins (apical, basal, etc.), capsule infiltration, nerve sheaths infiltration, and presence of lymph nodes metastasis. We did not include covariates that were a consequence of the results of the surgery (e.g. radiotherapy, hormonotherapy or chemotherapy), to avoid the indication bias. A bidirectional step procedure was used to automatically filter covariates.

The post-operative erection status and the urinary continence of the patients was only evaluated for the patients who were followed up at least 12 months, for a sufficient recovery delay.

All the tests were double-sided and interpreted with a 5% significance threshold.

Data management and statistical computations were performed with R statistical computing software. Missing values were studied, but not imputed.

RESULTS

One thousand patients were analyzed and followed up during 0 to 172 months. The median follow up time was 60 months [19; 95] (**Table 1**).

Patients' background

The mean age was 63.4 (SD = 6.44). The median PSA before the surgery was 6.7 ng/ml [4.94; 9.30], with 75.4% (n = 754) having PSA<10, 18.1% (n=181) having 10 < PSA < 20, and 6.50% (n = 65) having PSA > 20. The clinical stage (only available for patients n°1 to 324) was cT1a-b for 2.47% (n = 8), cT1c for 59.3% (n = 192), cT2a-b for 34.6% (n = 112), and cT3a for 3.70% (n = 12).

Characteristics of the tumor and extension assessment

According Epstein's classification of Gleason score,[17] patients can be classified as follows: 24.1% (n=241) of group 1 (Gleason ≤ 6), 50.9% (n = 509) of group 2 (Gleason 3+4), 18.2% (n=182) of group 3 (Gleason 4+3), 5.6% (n = 56) of group 4 (Gleason 8), and 1.1% (n=11) of group 5 (Gleason 9 or 10). The score was 4+3 or worse in 24.9% (n = 249) of patients.

The tumor volume, determined using planimetric measure, was < 25% of the prostate in 37.8% (n = 378), 25-50% of the prostate in 39.2% (n = 392), 50-75% of the

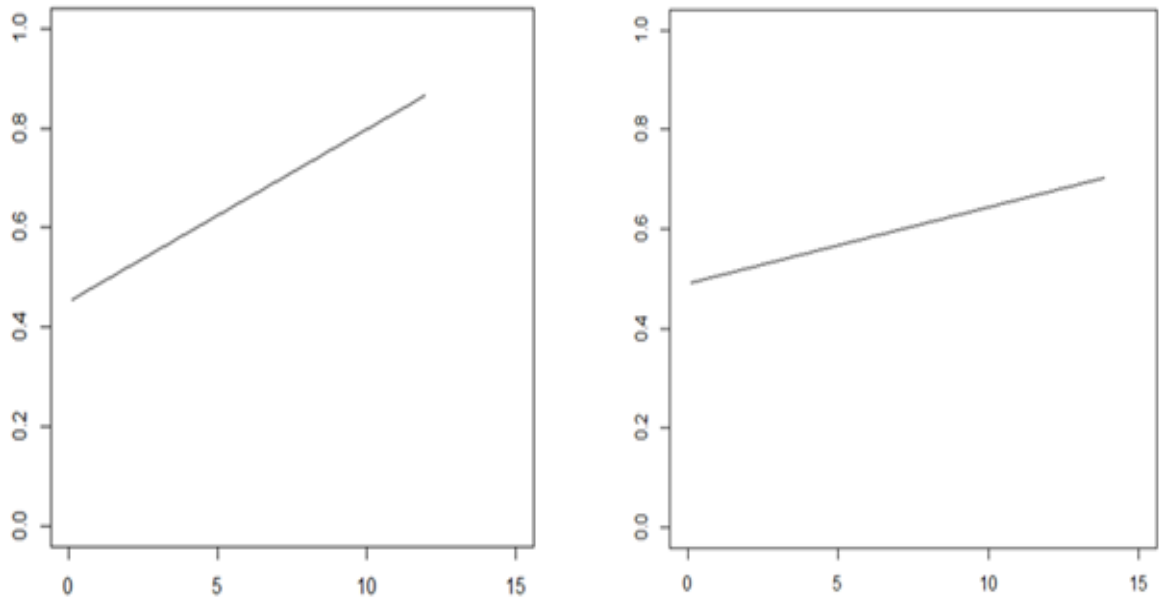

Figure 7. Learning curve (y=proportion of R0 margins, x=years, pT2 only). Left: main surgeon. Right: team of five surgeons

Table 2. Complications (out of 1005 cases)

Complications	n	Comments
Intra-operative:		
Conversion	6	4 to achieve prostatectomy (excluded)
2 for open ureteric re-implantation (included)		
Rectal injury	6	5 immediately recognised and sutured
1 secondary temporary diversion		
Ureteral section	4	2 immediate and 1 secondary open re-implantation; 1 laparoscopic suture
Ureteral stenosis	3	2 double J stent;
1 secondary open re-implantation		
Ureteral meatus eversion	1	secondary open re-implantation
Bladder wall injury	4	sutured without any consequences
Immediate post-operative:		
Death	1	cardiac failure
Anastomosis fistula	9	during more than 2 weeks
Pelvic hematoma	6	
Ureteric stenosis	3	2 treated percutaneously;
1 secondary open re-implantation		
Tardive:		
Stenosis of the anastomosis	3	
Urethral- stenosis	6	

prostate in 19.6% (n = 196), and 75-100% of the prostate in 3.4% (n = 34).

Most tumors were multifocal 87.9% (n = 879) or bifocal 9.8% (n = 98), and 2.3% (n = 23) were unifocal.

Relatively to the total number[3,810] of all the single and multifocal locations, the distribution was apical in 23.3% (n = 888), lateral medial in 24.3% (n = 925), posterior in 13.8% (n = 526), basal in 14.1% (n = 536), anterior in 11.3% (n = 113), and transitional in 5.1% (n=195). Relatively to the patients, tumor locations are presented on **Figure 4**.

The prostatic capsule was intact in 59.1% (n = 589) cases, infiltrated in 22.6% (n = 225) cases, and passed through in 18.4% (n = 183) cases.

The nerve sheaths were intact in 48.1% (n = 479) cases, penetrated in 40.6% (n = 104) cases, and passed through in 11.4% (n = 113) cases.

Regarding lymphatic involvement, 61.3% (n = 613) did not have any lymphadenectomy due to a PSA value lower than 10 ng/ml and Gleason score $\leq$ 7 (3+4). Among the 387 pelvic lymph node dissection, 99.2% (n = 384) were negative, and 0.78% (n = 3) were positive. According to the TNM pathological classification, the tumor stage was pT2A in 8.71% (n = 87) cases, pT2B in 2.80% (n = 28) cases, pT2C in 69.0% (n = 689) cases, pT3A in 13.1% (n = 131) cases, and pT3B in 6.41% (n = 64) cases. There was no pT0 stage.

The margins of the tumor were R0 in 60.8% (n = 608), R1 (one focus < 3 mm, including margins < 1mm) in 23.6% (n = 236), and R2 (one focus $\geq$ 3 mm or more than one focus of any size) in 15.6% (n = 156). Those proportions were respectively 66.3%, 20.9%, and 12.8% for pT2 tumors, and 37.9%, 34.9%, and 27.2% for pT3 tumors (p = 1.5e-12). (**Figure 5**)

The patients had an apical margin in 21.5% (n = 215), a lateral medial margin in 15% (n = 150), a posterior margin in 9.7% (n = 97), a basal margin in 5.3% (n=53), and an anterior margin in 3.1% (n = 31) (an individual patient may account for several margin locations. (**Figure 6**)

The "success rate", defined as the proportion of patients without margins for a given location among patients

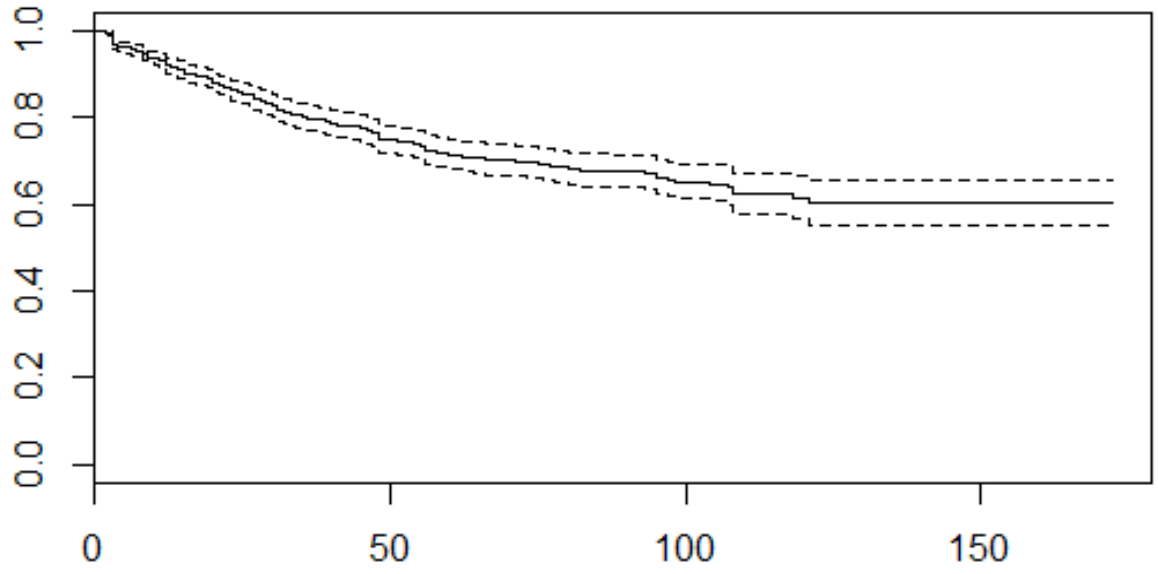

Figure 8. Biological progression free survival rate (x in months, event: PSA>0.10 ng/ml)

having that tumor location, was 100% for transitional locations, 92.8% for anterior locations, 90.1% for basal locations, 88.4% for posterior locations, 83.8% for lateral medial locations, and 75.8% for apical locations.

Surgical procedure

The mean operating time decreased from 206 minutes (patients 1 to 100 for the original surgeon), to 145 minutes (patients 225 to 324 for the original and next surgeon), and 115 minutes for the last 100 patients (patients 901 to 1000 for 4 surgeons).

The mean weight of the specimen was 42,5g (range14-125 g).

A continuous improvement of surgeon performance (Figure 7) was observed: 43.2% (n = 433) of the surgical procedures were performed by the first author from his age 55 to 68. For that cohort, the pT2A, pT2B and pT2C tumors, the proportion (y) of R0 versus R1&R2 as a function of the year (x) was estimated y = 0.0344 x + 0.454 (p = .0002, n = 348), which means the proportion of R0 increased by 3.44% every year in average.

The final team of 5 surgeons did not have equal experience. They participated as part of the team on an alternating basis. The proportion of R0 was estimated y = 0.0154 x + 0.491(p = .0005, n = 1000).

Complications and morbidity

Surgical conversion occurred in six patients. There were 15 per-operative complications, 19 immediate post-operative complications, and nine tardive complications (**Table 2**). According to Clavien classification,[18] we observed: one grade V, 15 grade IIIa, and 12 grade IIIb complications.

Other treatments and follow-up

Among the patients, 75.8% (n = 758) did not require any complementary treatment. In case of rising PSA > 0.10 ng/ml: 9.2% (n = 92) received immediate adjuvant external beam radiotherapy (EBRT); 13.4% (n = 134) secondary EBRT; 10.8% (n = 108) received ADT (androgen deprivation therapy), and 1.4% (n = 14) received a chemotherapy.

During their follow up, 23.7% (n = 237) encountered a PSA recurrence (defined as a value greater than 0.10 ng/ml), with a median value of 0.21 [0.17; 0.30] in case of recurrence.

The biological progression free survival rate (BPFSR) is presented in **Figure 8**. It reaches 96.1% [94.9; 97.4] at 1 year, 90.1% [88.1; 92.1] at 2 years, 80.5% [77.7; 83.4] at 3 years, 71.9% [68.6; 75.3] at 5 years, and 61.4% [56.8; 66.5] at 10 years.

The following covariates had an adjusted significant impact on the BPFSR:

- The margins (reference: no margin): R2 margins with HR=3.35 [2.43; 4.62] (n=151), and R1 margins with HR=2.04 [1.48; 2.80] (n=232)
- A Gleason score of 7= 4+3 or greater, with HR=1.97 [1.49; 2.59] (n = 247)
- Infiltration of nerve sheaths (reference: no infiltration): extra-capsular infiltration with HR=1.76 [1.13; 2.74] (n = 112), and intra-capsular infiltration with HR=1.45 [1.07; 1.97] (n = 399)
- Presence of lymph node metastasis, with HR=8.00 [1.10; 58.3] (n = 3)
- T3 stage of the tumor versus T2, with HR=1.55 [1.08; 2.22] (n = 192)

The following variables were found significant in bivariate analyses, but were not independent predictors in Cox model: year of surgery, tumor volume, and capsule infiltration.

During their follow up, 3.1% (n = 31) patients died, including 0.9% (n = 9) who died from prostate cancer. The cancer specific survival rate was 99.7% [99.4; 1.00] at 1 year, 99.4% [98.8; 1.00] at 5 years, and 98.3% [97.1; 99.5] at 10 years.

The following covariates had a significant adjusted impact on the cancer survival:

- The tumor volume (where 1 means 75%-100% of the prostate), with HR=118.63 [2.459; 5724.24]
- T3 stage of the tumor (versus T2), with HR=10.8 [1.21; 97.4] (n = 192)

The following variables were found significant in bivariate analyses, but were not independent predictors in Cox model: year of the surgery, Gleason score, surgical margins, capsule infiltration, and nerve sheaths infiltration.

Functional Results

For the 813 patients who had follow up during of at least 12 months (with 1.3% missing values), 75.0% (n = 610) had a perfect continence, 13.6% (n = 111) had some seldom and minor leaks but did not need any protection, 5.9% (n = 48) used one light pad per day, 3.32% (n = 27) used several pads per day. Of this later group, 14/27 finally had a sling implantation. Total incontinence occurred in 1.97% (n = 16). Of this group, 15/16 had an artificial urinary sphincter implantation.

Preoperative erectile function was evaluated in 876/1000 patients via our own formal but non validated questionnaire: 81.3% (n = 712/876) of patients could obtain a normal erection without any treatment, 7.08% (n=62/876) spontaneously had an erection insufficient for penetration but were successfully treated pre-operatively for erectile dysfunction (ED), and 11.6% (n = 102) were unable to attain any erection either with or without treatment.

For the 770/876 patients with at least 12 months follow-up, the preceding percentages were respectively: 23.8% (n = 183/770), 35.1% (n = 270/770), and 41.2% (n = 317/770).

Among the 712/876 patients with normal pre-operative erectile function, 549/712 were followed at least 12 months: 29.3% (n = 161/712) retained normal erections, 37.7% (n = 207/712) had an insufficient erection but were treated successfully for ED, and 33.0% (n=181/712) had no erection with or without treatment. Thus erectile function was maintained in 67.0% (n=368/712).

Among the 33% (n = 181/712) patients who had normal erection pre-operatively but ED post-operatively, 55.2% (n = 100/181) stated that this was not a concern to them. This group was significantly older (mean age 66.6 versus 63.9, p = .0046).

DISCUSSION

This cohort has similar baseline data to previously published series,[19–21] with at least 1,000 consecutive patients and a mean follow up of 5 years.

The margins rate (pT2-pT3): 32.9 % (R1: 23.6%, even unifocal infra-millimetric, and R2: 15.6%) need a comparative analysis with others series (8.7% to 51.4%).[22,23]

We speculate that the retrograde dissection might have a significant favorable impact on the location rate (apical in 21.5% and basal in 5.3%) with a “success rate” of 75.8% for apical locations and 90.1% for basal loca-

tions.[24,25]
Our rate of systematic lymph node dissection rate (38.7%) is consistent with previously published series. (26,27)
The duration of surgery decreased regularly with experience. The rate of negative margins for the four "companion" surgeons increased by 3.44% every year.
In spite of the margins rate and a PSA threshold ≤ 0.10 ng/ml, the BPFSR remains similar to others series: 71.9% at 5 years, 61.4% at 10 years,(28) and the cancer specific survival rate is: 99.4% at 5 years, 98.3% at 10 years.
With a median follow up of 60 months, 75.8% patients have not required any complementary treatment. At 12 months follow up, 88.6% do not require any incontinence pad.(29) Of those patients with normal pre-operative erectile function, 67.0% maintain normal erectile function, with or without oral treatment.
Most importantly, this procedure is perfectly adaptable to the RARP (robotic assisted radical prostatectomy). To the best of our knowledge no report of robot assisted radical retrograde extraperitoneal laparoscopic prostatectomy (R-RELP) has been published except by this group.(30) We believe that the retrograde approach has significant advantages, as demonstrated in a detailed step by step supplemental description with video presentation published online. We hope that this article will assist interested robotic surgeons in applying this technique to their surgical armamentarium. The R-RELP is now the subject of a clinical trial.
Robotic-assisted laparoscopic prostatectomy (R-RELP) using the da Vinci system can be reproduced to an equal standard using the RELP technique.(30) Three-dimensional vision via the 30° telescope and articulated instruments, with their 90° mobility, are particularly suited to retrograde dissection, and make easier for the urologists to give up the open surgery. This is the ideal application to exploit the specific capacities of the robot to their fullest as well as with the less expansive 3D column.

CONCLUSIONS

This report demonstrates that RELP technique yields acceptable oncologic and quality of life outcomes. This technique is adaptable to RARP.

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Pierre Dubernard had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

CONFLICT OF INTEREST

The authors report no conflict of interest.

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