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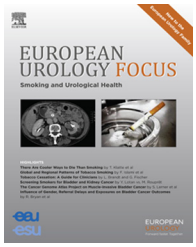

Surgery in Motion

Minilaparoendoscopic Single-site Pyeloplasty: The Best Compromise Between Surgeon's Ergonomy and Patient's Cosmesis (IDEAL Phase 2a)

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Abstract

Background: Laparoendoscopic single-site (LESS) surgery and minilaparoscopy (ML) represent the evolution of laparoscopy for the treatment of urologic diseases.
Objective: To describe the technique and report the surgical outcomes of minilaparoendoscopic single-site dismembered pyeloplasty (MILESS-DP), a new technique overcoming the technical limitations of LESS and ML, and equally combining the advantages of both these surgical procedures.
Design, setting, and participants: Twenty consecutive patients underwent MILESS-DP for ureteropelvic junction obstruction.
Surgical procedure: The SILS port was inserted through a transumbilical incision and two 3-mm trocars were inserted in the ipsilateral midclavicular line. The sequence of steps of MILESS-DP is comparable to standard laparoscopic dismembered pyeloplasty.
Measurements: The end points of this study were: (1) feasibility; (2) safety; (3) efficacy; and (4) cosmesis, evaluated using a body image questionnaire.
Results and limitations: All patients were symptomatic (100%) and three (15%) had concomitant kidney stones. (1) Feasibility: a conversion to either standard laparoscopic technique or open technique did not occur in any case. Median operative time was 147.3 min (interquartile range [IQR]: 110–195 min); (2) safety: no intraoperative complications were reported. Only in two patients (10%), a urinoma was postoperatively identified and conservatively treated with an ureteral stent. The median difference in post- and preoperative creatinine and haemoglobin was +0.55 mg/dl and -0.76 mg/dl (IQR: -0.20/-1.20 mg/dl); (3) efficacy: the median postoperative hospital stay was 4.4 d (IQR: 4–9 d). The overall success rate was 95% at the follow-up; (4) cosmesis: all patients were enthusiastic with the appearance of the scars; the median body image score and the median cosmesis score were 19.95 (IQR 19–20) and 23.95 (IQR 23–24), respectively. The limitations of this study are the limited series and short follow-up.
Conclusions: Our phase 2a studies demonstrate that MILESS-DP is a safe and reproducible procedure with excellent cosmetic outcomes and short-term clinical outcomes in the hands of a surgical team with experience in laparoscopy.
Patient summary: Minilaparoscopy using 3-mm instruments and laparoendoscopic single-site using a single abdominal incision, still present several technical drawbacks which limit their reproducibility in urology. In order to overcome these technical limitations and equally combining the advantages of both these surgical procedures, we ideated a hybrid technique which we defined minilaparoendoscopic single-site. This study aims to demonstrate that minilaparoendoscopic single-site pyeloplasty is a safe and reproducible procedure with excellent cosmetic outcomes and short-term clinical outcomes in the hands of a surgical team with experience in mini-invasive surgery.

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1. Introduction

The idea of performing surgical procedures with no scar has gained attention in the urological community over the last 5 yr [1]. Typically, major laparoscopic surgery involves the use of several (three to five) ports inserted through transperitoneal or retroperitoneal access [2]. Recent developments in laparoscopy have been directed towards further reducing morbidity and improving the cosmetic outcomes. These include the use of mini-laparoscopic instruments [3], use of natural orifices [4], and use of transumbilical access [5–7].

The idea of performing a laparoscopic procedure through a single abdominal incision was developed with the aim of minimising postoperative pain and expediting postoperative recovery [4]. Laparoendoscopic single-site surgery (LESS) has significantly evolved over the last few years, with a wide range of surgical procedures successfully performed applying this novel technique [8,9].

Nevertheless, its actual role in the field of minimally invasive urologic surgery remains to be determined because peculiar features of LESS represent significant challenges for the surgeon compared with standard laparoscopy [10]. Actually, the chief technical problems associated with this technique pertained to the lack of triangulation of the instruments, with their management in a parallel fashion, internal and external instrument collision, and absence of retraction [6]. Some authors tried to reproduce the triangulation during LESS surgery, by hiding the incisions in strategic less visible area (small strategic laparoscopic incision placement) [11] or by placing the trocars through a single umbilical incision (single-incision triangulated umbilical surgery) [12]. Nevertheless, the surgical application of both these surgical procedures has been limited in literature.

Recently, minilaparoscopy (ML) has been rediscovered in an attempt to reduce the trauma on the abdominal wall derived from standard laparoscopic access, improving cosmetic outcome and recovery. [3]. This rediscovery has been fuelled by the availability of more reliable instrumentation and by the fact that ML allows minimal abdominal scar, meanwhile preserving the key principle of triangulation [13]. Nevertheless, the main limitations of ML are represented by the difficult-to-use instruments with larger dimensions, such as a vascular stapler, and applying this technique in patients with obesity or prior abdominal surgery [3].

In order to overcome the technical limitations of LESS and ML and equally combining the advantages of both these surgical procedures, we ideated a hybrid technique which we defined mini-laparoendoscopic single-site surgery (MILESS). In the current report, we present our technique and our preliminary experience with MILESS dismembered pyeloplasty (MILESS-DP), providing a step-by-step description of the operative technique (phase 2a according to the IDEAL methodology) [14].

2. Patients and methods

Between October 2011 and April 2014, we enrolled 20 consecutive patients who underwent MILESS-DP for ureteropelvic junction obstruction (UPJO).

All patients gave written informed consent and a prospective institutional review board-approved datasheet was constructed for this study. The end points of this study were: (1) feasibility, expressed as conversion rate; (2) safety, estimated by complication rate according to Clavien-Dindo classification [15]; (3) efficacy, consisting of the functional and symptomatologic success of surgical treatment evaluated with computed tomography urography and mercaptoacetyltriglycine-3 (MAG-3) diuretic renal scan, visual analogue scale of pain [16]; and (4) cosmesis, evaluated using a body image questionnaire, an eight-item questionnaire incorporating body image and cosmetic subscales, each with a high internal consistency (Cronbach-a of 0.80 and 0.83, respectively) [17,18] (Fig. 1). The body image scale measures patients' perception and satisfaction with their bodies after surgery, and it is calculated by reverse scoring and summing the responses to questions 1 through 5; it ranges from 5 to 20 with a higher number representing greater body image perception. The cosmetic scale assesses satisfaction with surgical scars and is calculated by simply summing responses to questions 6–8, for a score range of 3–24, with a higher score indicating greater cosmetic satisfaction [17,18].

All patients were operated by one laparoscopic surgeon (F.G.), with an experience of >100 LESS and ML procedures.

Indications to surgery were based on the results of imaging techniques, MAG-3 diuretic renal scans showing evident obstruction not solved following furosemide injection (half-life >20 min), and the presence of symptoms (eg, recurrent flank pain, fever, and recurrent upper urinary tract episodes). Exclusion criteria were a body mass index (BMI) >30 kg/m^2, an extremely large renal pelvis (ie, pelvis diameter >6 cm), pelvic kidney, and horseshoe kidney.

Median follow-up was 13.45 mo (range, 6–24 mo). After removing the double-J stent, all the patients underwent an intravenous urography and sonography. Follow-up was calculated from the date of surgery to the date of the most recent documented examination. No patient was lost to follow-up. Clinical successful outcome was defined as complete resolution of preoperative flank pain and radiographic successful outcome was defined as no radiologic evidence of obstruction at computed tomography urography, an adequate renal excretion, and preserved or improved ipsilateral renal function on MAG-3 diuretic renal scan, which was performed in all patients at 6 postoperative mo.

2.1. Surgical technique

The surgeon has been trained on dry and wet laboratories before starting the first case on humans. The sequence of steps of MILESS-DP is comparable to standard laparoscopic dismembered pyeloplasty.

2.1.1. Preoperative preparation

Prevention of thrombosis (low-molecular-weight heparin) is mandatory. Single-shot intravenous antibiosis using a cephalosporin should be administered at the beginning of the procedure.

2.1.2. Anaesthesia

MILESS-DP is performed under general anaesthesia. A recommended regimen is induction using intravenous thiopental and isoflurane as the inhalation agent. Following the induction of general anaesthesia, a nasogastric tube and transurethral catheter are placed to decompress the stomach and bladder.

2.1.3. Operative setup and patient positioning

In all patients, a double-J ureteral stent is preoperatively positioned retrograde and is removed approximately 6 wk after surgery. The patient is then placed in the semilateral decubitus position with the side of the lesion elevated at 60°. The ipsilateral arm is secured using an arm board and the contralateral arm is fixed beside the trunk and well-padded to avoid lesions of neural structures. Additional fixation is done using cloth tapes

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1. Are you less satisfied with your body since the operation?
   1 no, not at all
   2 a little bit
   3 quite a bit
   4 yes, extremely

2. Do you think the operation has damaged your body?
   1 no, not at all
   2 a little bit
   3 quite a bit
   4 yes, extremely

3. Do you feel less attractive as a result of your disease or treatment?
   1 no, not at all
   2 a little bit
   3 quite a bit
   4 yes, extremely

4. Do you feel less feminine/masculine as a result of your disease or treatment?
   1 no, not at all
   2 a little bit
   3 quite a bit
   4 yes, extremely

5. Is it difficult to look at yourself naked?
   1 no, not at all
   2 a little bit
   3 quite a bit
   4 yes, extremely

6. On a scale from 1 to 7, how satisfied are you with your incisional scar?

1 (very unsatisfied)	2	3	4 (not unsatisfied/not satisfied)	5	6	7 (very satisfied)

7. On a scale from 1 to 7, how would you describe your incisional scar?

1 (revolting)	2	3	4 (not revolting/not beautiful)	5	6	7 (beautiful)

8. Could you score your own incisional scar on a scale from 1 to 10 using the scale below? (circle)

1 (revolting)	2	3	4	5 (not revolting/not beautiful)	6	7	8	9	10 (beautiful)

Fig. 1 – Body image questionnaire and cosmetic subscales [16,17].

across the hips and the legs. Great care should be taken to generously pad all rests and cloth tapes. When the patient is positioned securely, the table is rolled to a classical flank position to verify the stability of the system. The surgeon and the assistant stand to the contralateral side of the interested kidney (ie, UPJO left, surgeon at the right side).

2.1.4. Instruments

The SILS trocar (Covidien formerly Tyco Healthcare GmbH, Neustadt/Donau, Germany) is a specialized multilumen with two 5-mm working-channels and one 12-mm channel. A 30° lens high-definition laparoscopic camera (Karl Storz, Tuttlingen, Germany) with 5-mm diameter and 50 cm length is inserted through one of the 5-mm channels of the SILS trocar and frees the other 5-mm channel and the 12-mm channel for the simultaneous insertion of instruments with diameter $\geq$5 mm (ie, suction and irrigation cannula, spoon forceps, 5-mm grasping forceps for retraction). Two 3.5-mm trocars are used to introduce dissector, scissors, and the needle-holders.

2.1.5. Placement of the SILS port and of the 3-mm trocars

With the patient in a 60° position, a mini laparotomy (5 cm) is performed for the insertion of the SILS trocar. The endoscopic camera is introduced and two 3.5-mm trocars are inserted in the ipsilateral midclavicular line (Fig. 2). Any additional trocar was used during the procedure.

2.2. MILESS-DP

The peritoneum is incised along the Toldt's line using 3.5-mm electrosurgical scissors and grasping forceps. After mobilisation of the colon, the ureter is identified above its cross over the iliac vessels (Fig. 3). The proximal ureter and the renal pelvis were completely mobilised. The renal pelvis is dismembered with the proximal ureter and the stenotic segment was resected (Fig. 4). In the case of a crossing vessel, a dismembered pyeloplasty with transposition of the ureter ventral to the vessels is performed. Stone removal is also feasible using a 10-mm spoon forceps introduced though the SILS port. The ureter is then spatulated

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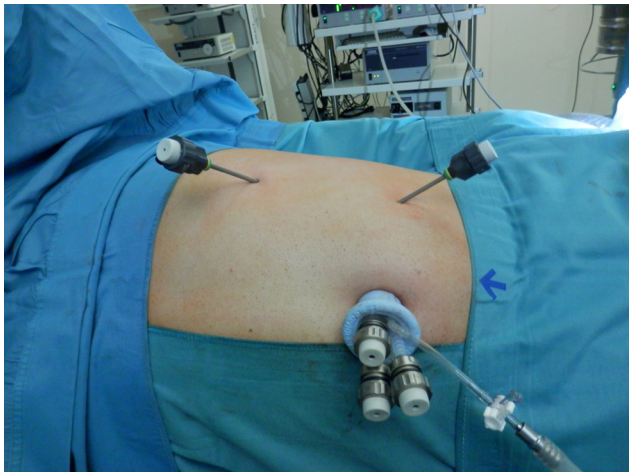


Fig. 2 – Placement of the SILS port and of the 3.5-mm trocars (minilaparoendoscopic single-site).

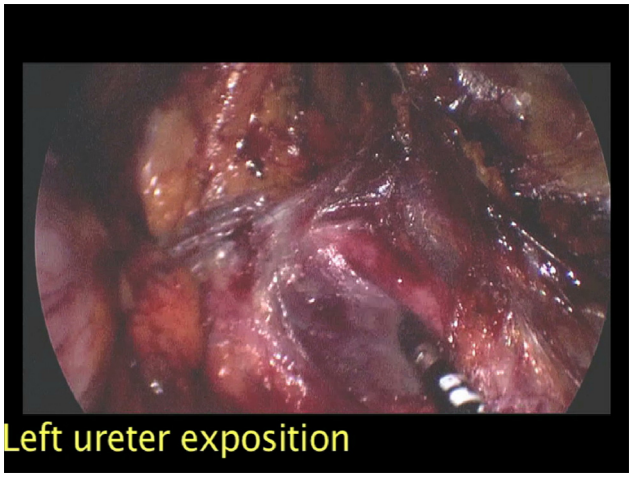
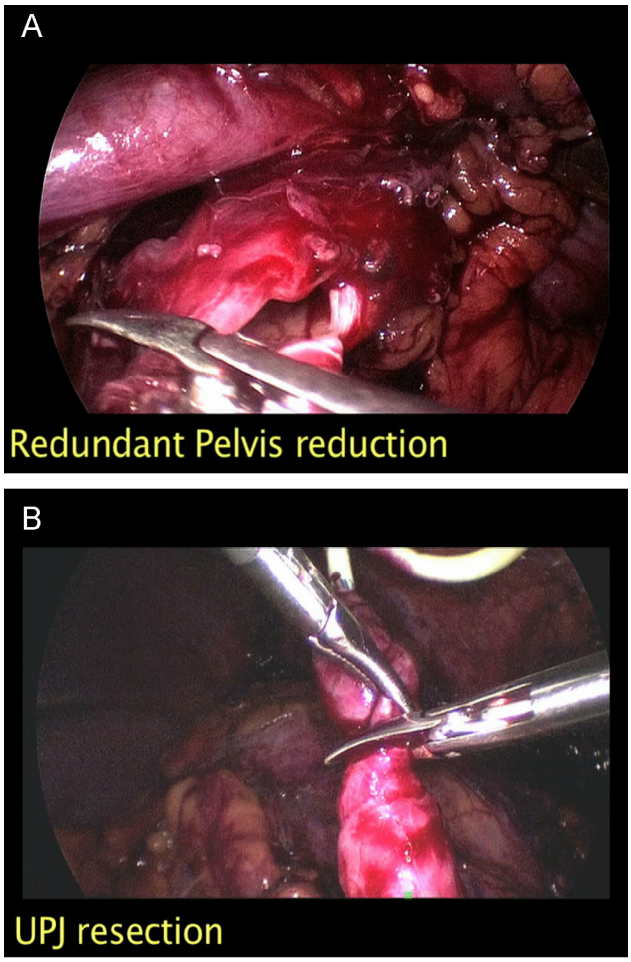


Fig. 3 – Exposure of the ureter.



UPJ = ureteropelvic junction.

Fig. 4 – Images showing (A) reduction of the pelvis and (B) ureteropelvic junction resection.

longitudinally. The renal pelvis is resected and the pyeloplasty is performed according to the Anderson-Hynes technique. The anastomosis is performed with interrupted 4-0 Vycril sutures, starting from the deepest point of the spatulated ureter and from both flap corners of its end with the corresponding sites of the renal pelvis (Fig. 5). After completing the posterior wall, the 7-F stent is replaced in the pelvis and the anterior wall of the anastomosis is completed with a running 4-0 Vycril suture. At the end of the procedure, once complete homeostasis is achieved, a15-F Robinson drain is placed though one 3-mm trocar into the pararenal space. The 3-mm trocars are removed under laparoscopic visualisation, the SILS port is then removed, the fascia is then closed with an interrupted 2-0 Vycril suture. The skin is approximated with an intracutaneous suture and with skin glue (Fig. 6).

3. Results

Preoperative results are summarised in Table 1. The median patient age was 31 yr (range, 15–48 yr), median BMI was 25.39 kg/m^2 (range, 19–29.9 kg/m^2) and median preoperative American Society of Anaesthesiologists score was 1 (range, 1–2). Of the 20 patients, eight had a right-sided UPJO and 12 had a left-sided UPJO. No patients underwent previous UPJO surgery. All patients were symptomatic (100%) and three (15%) had concomitant kidney stones. Four patients (20%) had undergone prior abdominal

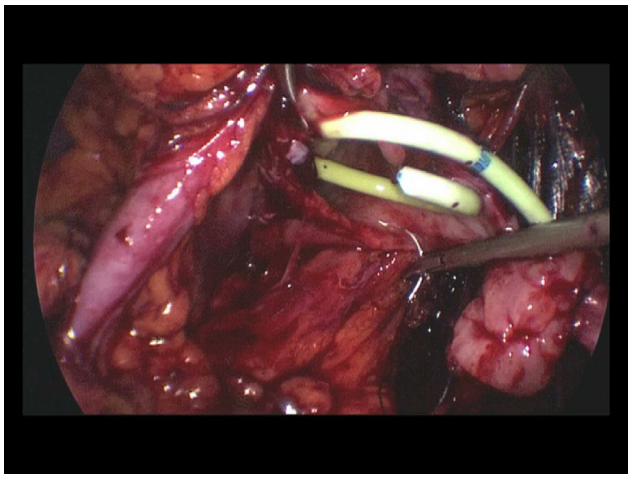


Fig. 5 – Pyeloureteral anastomosis.

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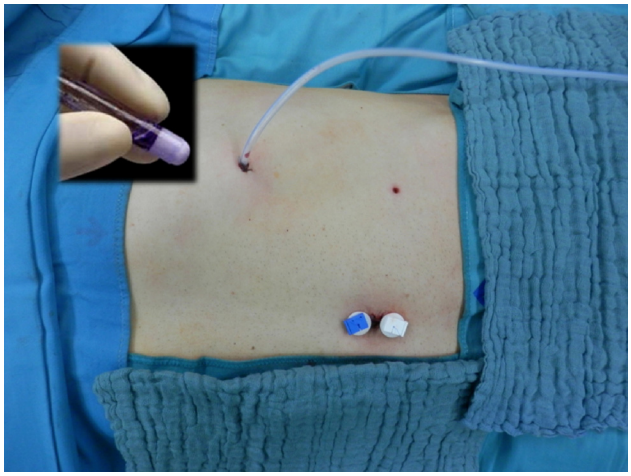

Fig. 6 – Intraoperative appearance of the surgical scar.

Table 1 – Preoperative data

	MILESS-DP
n =	20
Median age (yr), *n* (IQR)	31 (15–48)
Gender (women/men ratio)	0.82
Median BMI kg/m^2, *n* (IQR)	25.39 (19–29.9)
Left/right kidney, *n*	12/8
Concomitant kidney stone, *n* (%)	3 (15)
Prior abdominal surgery, *n* (%)	4 (20)
Crossing vessels, *n* (%)	14 (70)
Median ASA score, *n* (IQR)	1 (1–2)

ASA = American Society of Anaesthesiologists; BMI = body mass index; IQR = interquartile range; MILESS-DP = minilaparoendoscopic single-site dismembered pyeloplasty.

surgery (two patients had undergone laparoscopic cholecystectomy, one patient a laparoscopic varicolecectomy, and one patient an appendectomy).

3.1. Feasibility

A conversion to either standard laparoscopic technique or open technique did not occur in any case. The median operative time was 147.3 min (range, 110–195 min) (Table 2). Additional 5-mm or 3-mm trocars were not required. Crossing vessels with an anterior course to the ureteropelvic junction were detected in 14 cases (70%).

3.2. Safety

Intra- and postoperative data are summarised in Table 2. No intraoperative complications were reported and the median estimated blood loss was negligible in all patients (median 87.2 ml; range, 40–120 ml). The ureteral stents were usually removed after 6 wk. Only in two patients (10%), a urinoma was postoperatively identified and a mono-J-stent was placed under radiologic guide (Clavien grade IIIb); in both patients, the urinoma was solved spontaneously and a new double-J-stent was replaced and left *in situ* for 8 wk. The median difference in post- and preoperative creatinine and haemoglobin was +0.55 mg/dl (+2/+11 mg/dl) and -0.76 mg/dl (range, -0.20/-1.20 mg/dl), respectively.

Table 2 – Intraoperative and postoperative data

	MILESS-DP
n =	20
Median operating time (min), *n* (IQR)	147.3 (110–195)
Blood loos (ml), *n* (IQR)	87.2 (40–120)
Transfusion rate (%)	0
Median difference in post-/preoperative haemoglobin (mg/dl), *n* (IQR)	-0.76 (-0.20/-1.20)
Median difference in post-/preoperative creatinine (mg/dl), *n* (IQR)	+0.55 (2/11)
Postoperative day of oral intake	1.0
Median VAS (1–10) at discharge (IQR)	1.6 (1-3)
Median analgesic requirement (mg) (IQR)	8.9 (4.4–12)
Length of stay (d) (IQR)	4.5 (4–9)
Median time to bladder catheter removal, d (IQR)	3.1 (2–9)
Median time to drain removal, d (IQR)	4.05 (2–9)
Periumbilical skin incision (cm) (IQR)	3.8 (3–5)
Conversion rate to conventional laparoscopy	0
Conversion rate to open surgery	0
Overall success rate (*n*)	95 (19)

IQR = interquartile range; MILESS-DP = minilaparoendoscopic single-site dismembered pyeloplasty; VAS = visual analogue scale.

3.3. Efficacy

The median postoperative hospital stay was 4.5 d (range, 4–9 days). The median time to catheter removal was 3.1 d (range, 2–9 d) and drain removal was 4.05 d (range, 2–9 d). Patients were mobilised and allowed to resume an oral diet from postoperative Day 1. Most of the patients had mild or no pain at discharge with a median visual analogue scale score of 1.6 (range, 1–3). The overall success rate was 95% (*n* = 19) at the follow-up. One of the two patients who had developed a postoperative urinoma (5%) had recurrent flank pain. Slowly developing reobstruction is suspected in this patient, who is currently being observed adopting a conservative therapy (12 mo follow-up).

3.4. Cosmesis

Median periumbilical skin incision was 3.8 cm (range, 3–5 cm). All patients were enthusiastic with the appearance of the scars; the median body image score and the median cosmesis score were 19.95 (range, 19–20) and 23.95 (range, 23–24), respectively (Fig. 7).

4. Discussion

Minimally invasive dismembered pyeloplasty is an acceptable alternative to open pyeloplasty, given similar intermediate-term functional outcomes and lower morbidity [19–22]. LESS is the latest evolution of minimally invasive surgery and to date has been performed for >1000 urologic

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Fig. 7 – Postoperative appearance of the surgical scar at 1-mo follow-up.

cases worldwide, <100 of these being pyeloplasties [8]. LESS pyeloplasty has been reported to yield short-term clinical outcomes similar to conventional laparoscopic pyeloplasty [23] and could potentially achieve superior cosmesis [24]. However, it is technically very challenging and is associated with a steep learning curve [25], due to the absence of triangulation and for instrument crowding [6].

In 2012, Olweny et al [24] compared their initial experience with robotic assisted laparoendoscopic single-site (R-LESS) pyeloplasty to their latter experience with conventional (C)-LESS pyeloplasty. Although two postoperative complications (Clavien 3a and 3b) occurred in the C-LESS group versus one postoperative complication (Clavien 3a) in the R-LESS group, the authors recognised the advantages associated with R-LESS versus C-LESS pyeloplasty, by reducing the physical learning curve for this complex procedure.

In a recent multi-institutional study on LESS upper urinary tract surgery, Greco et al [26] reported the necessity of an additional 3-mm trocar in 40% of cases. The authors suggested that the use of one additional port should be undertaken liberally if the surgeon is uncomfortable during LESS, embracing the concept that patient safety comes first ("do not harm"). Similarly, in a recent multi-institutional study we recently coauthored [8], use of an additional port during LESS occurred in 23% of cases.

Nevertheless, according to current terminology [27,28], the use of an additional 3-mm trocar is still considered as LESS.

In parallel with the recent development of potentially "scarless" surgical techniques, such as natural orifice transluminal endoscopic surgery and LESS, there has been a renewed interest in the surgical community towards a rediscovery of ML. This interest has been driven by two main reasons: the boosting of manufacturers that leads to the availability of a new generation of purpose-built instrumentation [29] and the fact that ML seems to be ready for immediate implementation, as it is based on the same established principles of standard laparoscopy [3]. In urology, however, only small case series and case-control studies on ML have been reported so far [12,30–32]. A recent multi-institutional study we recently coauthored [3] represents the first large cohort reporting the outcomes of contemporary ML and providing an overview of the current applications in our surgical specialty. A large spectrum of the common urologic procedures for both upper and lower urinary tract diseases have been performed and shown to be feasible duplicating the principles of standard laparoscopy. Not surprisingly, reconstructive procedures, which do not require an additional incision to extract a surgical specimen, thus maximizing the benefits of the ML approach, were the most common. Nevertheless, the main technical problems of ML are still represented by the difficult-to-use instruments with larger dimensions (≥10 mm) and by the impossibility to apply this technique in patients with obesity or prior abdominal surgery.

Considering the necessity of a 3-mm additional trocar in LESS [27] and the technical limitations of the ML [3], a question could be raised whether or not the simultaneous use of two 3-mm trocars during LESS could equally combine the advantages of LESS and ML, by reproducing the triangulation of the instruments, without compromising the cosmetic results. This represents the principle on which we ideated the MILESS. In literature we find some study describing a hybrid LESS by using 3-mm or 5-mm or 12-mm additional trocars [33,34]. Recently, Kallidonis et al [33] described a similar hybrid technique combined with ML instruments as standard LESS equipment [33]. The authors described 30 reconstructive and oncologic cases, concluding that the combination of LESS and ML instrumentation as routine equipment of reconstructive LESS improved the intraoperative ergonomics of procedures requiring complex suturing and reconstructive tasks. Nevertheless, limitations of this study included the inability to standardise the technique according to the IDEAL model, which is required in order to describe and assess the development of each surgical innovation.

In our study, 20 patients underwent MILESS-DP. No intraoperative complications occurred. Only in two patients (10%), a urinoma was postoperatively identified, but it solved spontaneously. The overall success rate of MILESS pyeloplasty was 95% at a median follow-up of 13.45 mo. Three (15%) patients had concomitant kidney stones, which were completely removed with a 10-mm spoon forceps introduced through the SILS port; all patients were stone free after surgery. Although four patients had undergone prior abdominal surgery, patient population was generally young (median age 31 yr), nonobese (median BMI of 25.39 kg/m^2), and healthy (median preoperative American Society of Anaesthesiologists' score 1.1). Moreover, according to a stage 2a study, to better codify the technique we prefer to exclude the difficult cases. Using Dunker's methodology [17], we queried body image and cosmesis among patients who underwent MILESS-DP. All patients were enthusiastic with the appearance of the scars and both median body image score and median cosmesis score were 19.95 (range, 19–20) and 23.95 (range, 23–24), respectively.

The limitations of this study mainly are the limited series and short follow-up, although the preliminary results appear promising. Moreover, one might argue that any

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new surgical technique should be compared with the original one before one can draw any conclusions concerning its benefits. This study represents work in progress as the IDEAL model for surgical innovation [14] recommends that the next step should be evaluation of the learning curve and prospective comparison with LESS, ML, and conventional laparoscopic dismembered pyeloplasty.

5. Conclusion

Our phase 2a study demonstrates that MILESS pyeloplasty is a safe and reproducible procedure with excellent cosmetic outcomes and short-term clinical outcomes in the hands of a surgical team with experience in laparoscopy. Future prospective randomised studies comparing MILESS to LESS, ML and conventional laparoscopic pyeloplasty are required to further characterise the efficacy and reproducibility of our technique.

Author contributions: Francesco Greco 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.

Study concept and design: Greco.
Acquisition of data: Pini, Altieri, Alba.
Analysis and interpretation of data: Greco, Verze.
Drafting of the manuscript: Greco.
Critical revision of the manuscript for important intellectual content: Mirone.
Statistical analysis: None.
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Supervision: Mirone.
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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.euf.2015.09.001.

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