Clinical Overview

The ALF-X Robotic Surgical System, which has been granted a CE Mark for use in laparoscopic surgery across General, Gynecology, Urology, and Thoracic surgery, was developed to provide robotic benefits unavailable with other surgical systems, with operational costs similar to many traditional laparoscopic procedures. Specifically, ALF-X provides:

- Multi-port system with independent instrument arms that allow for standard laparoscopic port placement and replicate familiar laparoscopic instrument motion
- 3DHD eye-tracking camera control allows for simultaneous movement of camera and instruments
- Open console retains surgeon's line-of-sight with the sterile field and audio/visual communication with surgical team
- Haptic technology: provides the surgeon with force-sensing during critical tasks such as dissection and suturing, determines a low-force instrument fulcrum point for minimal torque on incision site, and provides a safety stop if force limits are exceeded.
- Broad offering of 5mm instruments: may be used with standard laparoscopic trocars and standard insertion techniques for simple patient repositioning and instrument exchange
- Reusable instruments and minimal disposables for a cost of ownership comparable to standard laparoscopy

The impact of these features on the capacity of the ALF-X system to enhance laparoscopic surgery were studied in the following series of peer-reviewed publications. In total, 146 gynecological procedures for both benign and malignant disease were performed at the Gemelli University Hospital in Rome.1,2 Key learnings from the studies included:

- Similar safety and efficacy profile to standard laparoscopy1,2,13,14
- Surgeons reported that the haptic technology allowed them to feel tissue consistency and suture tension, enhancing their adaptation and confidence1,2
- Docking time (attachment of instruments and determination of fulcrum point) stabilized between five and ten minutes after a 4-5 case learning curve1, with a median docking time of 7 minutes2 and a significant reduction in operating time for multiple procedures over the study period1,2
- Similar cost/procedure to standard laparoscopy16,17

PRE-CLINICAL & BENCHTOP STUDIES

Experimental data from animal models supported the applicability of the ALF-X system in complex laparoscopic procedures: cholecystectomy, partial nephrectomy, nephrectomy, left and right pulmonary lobectomies and lymphadenectomies, pleuropericardial fenestrations, esophageal and tracheal isolation and suture, thymectomies, and vesicoureteral anastomosis. In benchtop assessments of the ALF-X learning curve, the authors concluded that the relatively short learning curve observed may be associated with retention of familiar laparoscopic movements. Additionally, surgeons confirmed force-sensing during critical suturing activities.

CASE SERIES ON MONOLATERAL OVARIAN CYST REMOVAL

In the initial clinical case series12, Gueli Aletti et al. reported a series of 10 patients treated using the ALF-X system for the presence of monolateral ovarian cyst without a preoperative assessment suspicious for malignancy. The cysts were removed with an ovary-sparing technique with respect to conservative surgical principles. The median operative time was 46.3 minutes and median lesion diameter was 5 cm (range, 4–12). Median VAS score was 5.2 at 2 hours and 3.8 at 24 hours and no patients experienced postoperative wound hematoma, wound infection or delayed bleeding. Patients without postoperative complications were discharged at 1 or 2 days after the procedure. There were no complications reported at 30 days of follow-up. The authors concluded that ALF-X laparoscopic enucleation of benign ovarian cysts with an ovary-sparing technique is feasible, safe, and effective.

FEASIBILITY AND SAFETY PROFILE OF ALF-X HYSTERECTOMY FOR BENIGN AND MALIGNANT DISEASE

A following study demonstrated the feasibility and safety profile of ALF-X hysterectomy for benign and malignant disease.13 Eighty women underwent total ALF-X hysterectomy with or without bilateral salpingo-oophorectomy with or without pelvic lymphadenectomy. The procedures were performed by 11 different surgeons who were well-trained in
laparoscopy but novices with ALF-X. The median operative times (140 minutes (range, 58-320) with hysterectomy only and 197 minutes (range, 129-290) with pelvic lymphadenectomy) tended to be longer than for standard laparoscopy and similar to other forms of robotic surgery; nevertheless a decrease in ALF-X operating time was observed. The median docking time for this case series was 8 minutes (range, 3-25). Intraoperative conversions (3 (3.7%) to standard laparoscopy, and 2 (2.5%) to laparotomy) and early post-operative clinical results (1 patient (1.2%) was readmitted in the early postoperative period) were noted to be similar to those reported for standard and other forms of robotic-assisted laparoscopy. The authors recommended follow-up comparative and cost-analysist studies.

RETROSPECTIVE COHORT - ALF-X VS. LAPAROSCOPY FOR EARLY-STAGE ENDOMETRIAL CANCER
A retrospective cohort study was then performed with 89 patients affected by early stage endometrial cancer who underwent elective surgical staging. Among them, 43 underwent ALF-X staging, and 46 underwent conventional laparoscopic staging. There was no significant difference between groups at baseline. All selected patients underwent laparoscopic staging with radical hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymphadenectomy, if required. There were no intraoperative complications reported for either group and there was no significant difference in conversions between groups. Operating time with ALF-X was significantly greater than with laparoscopy; however, this was the first application of ALF-X system for the surgical management of patients with endometrial cancer. Critically, the number of lymph nodes removed was equivalent between approaches, with no recurrences detected in the series at the time of the report. The authors conclude that their results support the surgical adequacy of the ALF-X for radical oncologic purposes.

COST ANALYSIS
The cost of ownership of robotic systems, including acquisition cost, maintenance, and instrument cost, is often cited as the greatest drawback to robotically-assisted surgery. It was hypothesized that the ALF-X would allow for a more cost-effective robotic surgery program, in light of its unique offering of instruments that are reusable and can be used with conventional 5 mm trocars. Cost analysis was performed on 81 patients who underwent ALF-X robotic hysterectomy at a single center in Europe. According to micro-costing technique, surgical team costs, materials, and operating theatre usage were recorded during each surgical intervention. The analysis confirmed that ALF-X procedures with reusable instrumentation require a low consumption of robotic materials. While the ALF-X instruments are used in these procedures were, strictly speaking, reusable, when amortizing the instruments over only the 81 patients studied, the procedure cost/patient came to only €3391.82, with €673.09 per patient in instrument costs. Given the fully reusable nature of the ALF-X instruments used in this case, the operational costs of an ALF-X robotics program could be considered similar to many traditional laparoscopic procedures.

SUMMARY
These initial clinical data series support the clinical and economic feasibility of ALF-X surgery for various benign and malignant conditions. The 146 gynecological procedures performed using ALF-X at the Gemelli University Hospital Case series indicated that use of this device allowed for similar safety and efficacy profiles, as compared to standard laparoscopy. The surgical staff learning curve for ALF-X robotic docking time stabilized between 5-10 minutes after a rapid 4-5 case learning curve, with a median docking time of 7 minutes. Surgeons reported that the haptics allowed them to feel tissue consistency and suture tension, enhancing their adaptation and confidence, which may have been linked to a significant reduction in operating time for multiple procedures over the study period. Additionally, a cost analysis supports that the reusable instruments and minimal disposables required for ALF-X provide a cost of ownership comparable to standard laparoscopy. In conclusion, ALF-X provides robotic benefits unavailable with other systems, with operational costs similar to many traditional laparoscopic procedures.
REFERENCES


