# Retrospective case control study on the evaluation of the impact of augmented reality in gynecological laparoscopy on patients operated for myomectomy or adenomyomectomy

## Running head: Impact of augmented reality in laparoscopy

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**ABSTRACT**

The objective of this study is to evaluate the safety of using augmented reality (AR) in laparoscopic (adeno)myomectomy, defined as an increase in operating time shorter than 15 min. A total of 17 AR cases underwent laparoscopic myomectomy or adenomyomectomy with the use of AR and 17 controls without AR for the resection of (adeno)myomas. The non-inferiority assumption was defined by an operative overtime not exceeding 15 min, representing 10% of the typical operative time. The 17 AR cases were matched to 17 controls. The criteria used in matching the two groups were the type of lesions, the size and the placement. The mean operative time was 135 ± 39 min for AR cases and 149 ± 62 min for controls. The margin of non-inferiority was expressed as a difference in operative time of 15 min between the case and control groups. The mean difference observed between AR cases and controls was -14 min with 90% CI [-38.3;11.3] and was significantly lower than the non-inferiority margin of 15 min (p=0.03). This negative time difference means that the operative time is shorter for the AR cases group. Intraoperative data revealed a volume of bleeding ≤ 200 mL in 82.3% of AR cases and in 75% of controls (p=0.62). No intra or postoperative complications were reported in the groups. The use of augmented reality in laparoscopic (adeno)myomectomy does not introduce additional constraints for the surgeon. It appears to be safe for the patients, with an absence of additional adverse events and of significantly prolonged operative time.

**KEYWORDS:** laparoscopy, augmented reality, myomectomy, adenomyomectomy

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## INTRODUCTION

Minimally-Invasive Surgery has revolutionized abdominal surgery and has become the most effective method, with greater clinical benefits compared to open surgery. For gynecological surgery, the minimally-invasive approach and notably laparoscopy has become the gold standard for many indications including myomectomy and adenomyomectomy [1]. While the benefits for the patient are major, the main problems for surgeons in using minimal-invasive surgery techniques are hand-eye disconnection, reduced depth perception due to the two dimensional (2D) image display on the flat screen and limited haptic feedback [1, 2]. In most cases, a 2D laparoscope is used, although 3D laparoscopes are becoming increasingly popular, particularly with robot-assisted surgery [3]. Uterine myomas are the most common tumours in women of reproductive age, making myomectomy a frequent surgical procedure [4]. Localising myomas is particularly difficult when the surface of the uterus is unchanged or in cases of multiple occurrences [5]. The surgical strategy to incise the uterine serosa at the initial stage of myomectomy remains highly subjective. Choosing the incision zone adequately eases the access to the myomas, reduces the number and size of incisions, and the risk of postoperative adhesions being formed [6]. Localising adenomyosis is even more difficult. Adenomyosis is defined as the invasion of endometrial glands within the myometrium [7]; its focal and localised form is known as adenomyoma [8]. Adenomyomas are usually small, soft and positioned deep in the uterine muscle which limits the tactile feedback felt by the

surgeon. Whilst preoperative MRI allows one to localize the lesions, their intraoperative localisation remains highly challenging.

Augmented reality (AR) is the principle of adding virtual information to real images by means of image fusion. It can be used as a surgical guidance technology by blending a digital twin reconstructed from preoperative MRI with the surgical camera images in real time. For the surgeon, this overlaying of preoperative imaging information provides an enhanced surgical environment, augmented with otherwise unavailable information [9, 10].

The AR device we have tested was developed by our research team. It works following four main phases, as reviewed in [11]. Phase1 is preoperative. The uterus is segmented in an MRI and its deformation properties are modelled, leading to the reconstruction of its digital twin, including the target tumours, named the preoperative 3D model. Phases 2 to 4 are intraoperative. In phase 2, the camera is calibrated and the uterus surface is reconstructed in 3D from the surgical images, leading to the intraoperative 3D model [11–13]. In phase 3, a 3D registration is performed to align the uterus' preoperative 3D model to the intraoperative 3D model. The preoperative 3D model is adapted in location and shape to fit the intraoperative 3D model, using the uterus' biomechanical properties. In phase 4, the uterus is tracked in real time in the live surgical video using a computer vision technique and the preoperative 3D model is overlaid via AR. Phases 3 and 4, namely registration and tracking, are the most challenging ones, as the uterus deforms owing to the pneumoperitoneum and is then substantially mobilized by surgery.

Surgical navigation, including recent AR techniques, was historically developed in surgical fields involving rigid or semi-rigid structures (neurosurgery, otolaryngology, maxillofacial and orthopedic surgery) [9]. Surgical AR assistance is marginal in laparoscopy due

to the deformation and large movements of the soft organs of the abdominopelvic cavity. The use of AR has recently been reported in visceral surgery for adrenalectomy [14] and urological surgery for partial nephrectomy [15] and prostatectomy [16]. However, it remains under-researched in gynecological surgery. On the basis of a myoma model involving a 3D printed uterus and a pelvic-trainer, we showed in previous work that AR was a promising tool in gynecology [10], considerably improving accuracy in the initial localization of myomas, irrespective of their location and size. The feasibility of this technique was then demonstrated in the operating room for myomectomy and adenomyomectomy [17, 18].

The aim of this study was to demonstrate as primary endpoint that the use of AR in laparoscopic myomectomy and adenomyomectomy does not significantly impact the operative time. Specifically, the non-inferiority assumption was defined by an operative overtime not exceeding 15 min, representing 10% of the typical operative time. Secondary objectives were exploratory, aiming (i) to compare secondary endpoints (bleeding, postoperative pain, and intra and postoperative complications) between cases and controls and (ii) to gather information for larger randomized studies.

## METHODS

**IRB approval** was obtained on 01/06/2022 as IRB00013412.

### Patients and methods

This retrospective study concerned patients treated by laparoscopy for myomectomy or adenomyomectomy between May 2016 and September 2021. The inclusion criteria were adult patients, with a fertility preservation indication, presenting one or several intrauterine

myomas or adenomyomas not exceeding 12 cm in size or whose total size (sum of all myoma sizes) did not exceed 14 cm, which corresponds to the maximum size recommended for a laparoscopic approach [19], accessible by laparoscopy (with or without the use of AR) and confirmed by preoperative MRI (validated by the specialist radiologist). The consensus in the literature and the French recommendations from CNGOF (Collège National des Gynécologues-Obstétriciens Français) recommend a laparoscopic approach for myomas with an intramural or subserosal location and a diameter between 8–10 cm [19–21] extending up to 12 cm [22] or even 15 cm [23]. Some authors consider a threshold of 14 cm (determined by summing the greatest diameter of all myomas to be removed) as the limit for the feasibility of laparoscopic myomectomy [24]. The histological diagnosis of myomas or adenomyomas was confirmed by anatomopathological analyses. The criteria for non-inclusion were FIGO stages type 0 and 8 for myomas, as the AR system was not designed to handle these types, and patients whose medical follow-up did not allow sufficient data collection for the study. Patients who refused data collection for research were also excluded.

The collected data were 1) demographic data (age, BMI, parity and gestity), 2) preoperative data (medical and abdominal surgery antecedents, type, size (largest axis), number, location of myomas and adenomyomas (from MRI data) and myoma FIGO stage, preoperative symptoms and VAS (Visual Analogue Scale) of pelvic pain), 3) operative data (date of surgery, surgeon (junior or senior), bleeding (200 mL was selected as the cutoff because it is the average bleeding rate reported in our center and in the literature during myomectomy) [25–27], operative time, complications, conversion to laparotomy, length of stay, surgeon satisfaction (evaluated by the question: “has the use of AR helped you in your procedure, and if so, how?” with categorization of the answers)), 4) postoperative data (VAS

of pelvic pain (collected at the postoperative visit immediately after surgery, namely within 6 weeks of surgery), recurrences of (adeno)myomas and desire and number of pregnancies (collected at the last contact with the patient, corresponding to a median postoperative follow-up for all patients of 18 months)). Each patient had a postoperative consultation every 6 months. Recurrence was defined as a recurrence of symptoms and/or myoma (assessed at each follow-up ultrasound if pregnancy was desired). Of the 11 surgeons who performed the study procedures, 3 were juniors and 8 were seniors (a senior surgeon is defined as having over 4 years experience in advanced laparoscopy).

**Surgical technique and Augmented Reality**

The surgical technique for both controls and AR cases has previously been described [28], and can be subdivided in 10 steps: (1) surgical planning by the realization of a good cartography of the myoma(s) or adenomyoma(s), based on the preoperative T2-weighted MRI and FIGO classification system (PALM-COEIN) [18, 29]; (2) classical laparoscopic surgery materials including monopolar section device and bipolar grasper; trocar placement adapted to the size of the tumors; (3) preventive hemostasis performed using an occlusion technique of uterine vessels; (4) hysterotomy performed using a monopolar device and adapted to the size and localisation of the tumors; (5) dissection and traction performed to enucleate the tumors; (6) bipolar hemostasis performed only if necessary; (7) verification treatment completeness; (8) number of suture layers adapted to the depth of the defect; (9) tumors removed from the patient by extraction; and (10) if necessary, adhesion prevention using anti-adhesion barrier. For AR cases, the outer surface of the uterus, uterine cavity, and myoma(s) or adenomyoma(s) were segmented in the preoperative T2-weighted MRI **(Figure 1)** by the radiologist**.** This

preoperative phase was performed for each patient in the case group, using an interactive segmentation software, namely the Medical Imaging Interaction Toolkit (MITK; German Cancer Research Center) [30], to produce the respective preoperative 3D models. For controls, the preoperative MRI was re-read prior to surgery. For each surgical procedure, a standard laparoscopic technique and a standard laparoscopic set were used with a 0° laparoscope (Spies; Karl Storz). During each laparoscopy for AR cases, the AR software was used to visualize the myomas or adenomyomas according to the medical indication and the above-described three intraoperative phases were performed [17, 18]. The software runs on a standard consumer-grade computer with an Intel i7 processor (Intel, Santa Clara, CA) and an Nvidia Graphics Processing Unit (Nvidia, Santa Clara, CA). The AR system evaluated in this study is based on a previously validated pipeline, developed and published by our team [11, 17, 31]. Its technical implementation—including the steps of 3D model generation, intraoperative registration, and real-time tracking—has already been described in detail and tested in preclinical settings. For the present clinical evaluation, we used the same system without modifying the core algorithms. the workflow includes a preoperative segmentation of the uterus and lesions from MRI, followed intraoperatively by a dense 3D reconstruction of the uterine surface from a short exploratory video (the intraoperative 3D model was reconstructed using the SfM (Structure from Motion) technique by capturing a small number of images of the uterus taken from different viewpoints). A non-rigid registration aligns the preoperative model to the intraoperative geometry, using biomechanical constraints and contour information (figure 1). The final tracking step operates in real time (approximately 25 fps (frames-per-second)) on the monocular laparoscopic stream, using a tracking-by-detection method based on SIFT keypoints and robust pose estimation. The augmented visualization is

displayed as a semi-transparent overlay on a dedicated screen in the operating room. Because all processing relies solely on the laparoscopic video, synchronization is inherently ensured by design.

**Statistics**

The statistical analyses were performed on all the available AR cases (n=17). A control sample (n=40) was collected to allow identification of controls comparable to the AR cases, by propensity matching (n=17). One to one pairing was planned and controls matched according to size of myoma, type of lesions and myoma stage (to match the different FIGO stages, we grouped them as follows: FIGO 1 is the submucosal placement ; FIGO 2-5 is the intramural placement and FIGO 6-7 is the subserous placement). For each of the 17 AR cases, optimal pair matching was performed, by minimizing the sum of absolute pairwise distances in the matched samples. This step resulted in one control matched to each AR case in term of myoma size, type of lesions and myoma placement

The data are expressed as numbers and percentages, N (%) for qualitative variables, and as means (standard-deviation) or medians and interquartile range [Q1;Q3] for quantitative variables, according to the statistical distribution. The assumption of normal distribution was analyzed using the Shapiro-Wilk test.

Concerning the primary endpoint analysis, a non-inferiority design was considered with the margin defined as a non-increase of 10% in typical operative time, representing 15 min. Beyond this threshold, the benefit–risk ratio may no longer support the use of AR in this surgical setting. The upper limit of a two-sided 90% CI would exclude a difference of more

than 15 min to determine non-inferiority; a one-sided paired Student test was thus performed. Several studies have examined the relationship between operative duration and postoperative complications. In a comprehensive systematic review and meta-analysis by Cheng et al. [32], prolonged operative time was consistently associated with an increased risk of complications across various surgical specialties. In the subgroup analysis focusing on obstetrics and gynecology, an 86% increase in complication risk was observed for longer operative durations (adjusted OR = 1.86; 95% CI: 1.43–2.42; $p < 0.001$), with average procedure times ranging from 2.8 to 4.2 hours. This effect was more prominent at the upper end of the duration spectrum. These findings are corroborated by Visser et al. [33], who identified operative time as one of the top three surgery-related predictors of complications, and by Procter et al. [34], who showed that complication risk—especially for infections—increased incrementally with each 30-minute increase in operative time, but only became markedly significant beyond 60–90 minutes in laparoscopic cholecystectomy. In light of this literature, we considered a relative increase in operative time of up to 10% to be clinically acceptable when integrating augmented reality (AR) software in laparoscopic myomectomy. While this 10% threshold is somewhat arbitrary, it corresponds to a practical safety margin of approximately 15 minutes, which remains well below the complication-prone thresholds identified in the studies above. Moreover, the potential intraoperative benefits provided by AR—such as enhanced visualization and anatomical guidance—may reasonably justify this limited extension of operative time. Importantly, it is expected that when AR will be used as surgical guidance means in the future, one of its impact will be to reduce the procedure duration.

The secondary endpoints were not analyzed on an assumption of non-inferiority. The two groups (AR cases vs. controls) were compared using a paired Student t-test or Wilcoxon test for quantitative variables according to the distribution and a McNemar test for categorical variables. Appropriate effect sizes were also estimated to determine the effect of one variable on another: Cohen's d for the Student t-test, r-value for the Wilcoxon test and Cohen's g for the McNemar test. The analysis of longitudinal data (different VAS at the following time-points evaluation: preoperative visit, postsurgery H1, H3 and H6, hospital discharge and postoperative visit) was carried out using a mixed model, taking into account the time and patient effect as random factors. The normality of residuals was analyzed as aforementioned.

Cross-sectional analysis was performed with the R 4.0.3 software (the R Foundation for Statistical Computing, Vienna, Austria). For secondary objectives, the statistical tests were carried out with a two-sided type I error at 5%. No correction for multiple testing was applied. The interpretation of these results may be considered as exploratory.

## RESULTS

The 17 AR cases were matched to 17 controls. The matching criteria were type of lesions (9 (52.9%) myomas and 8 (47.1%) adenomyomas for the two groups), myoma size (the median was 33 mm [26;60] for AR cases and 40 mm [25;55] for controls) and myoma placement for myomas (80% and 77.8% of myomas were intramural and 20% and 22.2% subserous for AR cases and controls respectively) (**Table 1**). The mean age was 32.7 ± 4.3 years for AR cases and 33.4 ± 3.8 years [30;36] for controls (p=0.59) (**Table 1**). Previous abdominal surgery was reported for 10 (58.8%) AR cases and 12 (70.6%) controls.

Preoperative data revealed 7 (41.2%) patients with multiple myomas in the AR case group and 5 (29.4%) patients in the control group (p=0.68) **(Table 1).** Most myoma locations were anterior (35.3%) and lateral (41%) for AR cases and fundal (41.2%) for controls (p=0.32). The most common preoperative symptom was pelvic pain for both groups (70.6%).

Intraoperative data revealed a mean operative time of 135 ± 39 min for AR cases and 149 ± 62 min for controls **(Figures 2A and 2B)**. The mean difference in operative time between AR cases and controls was -14 min with 90% CI [-38.3;11.3] which was lower than the 15 min non-inferiority margin (p=0.03). This negative time difference means that the operative time is shorter for the AR cases group, while a positive time difference would mean otherwise. **(Figures 2A and 2B).**

The reported bleeding volumes were ≤ 200 mL in 82.3% of AR cases and in 75.0% of controls (p=0.62) **(Table 2**). In the AR case group, one conversion to laparotomy was reported in a patient with posterior adenomyosis which was very difficult to access. The surgical specimen was extracted by mini-laparotomy and the opening made it possible to check by palpation that there was no residual adenomyosis. No intra or postoperative complications were reported in either group **(Tables 2 and 3).** In the control group, 2 patients were treated for endometriosis at the same time as undergoing myomectomy. No system or equipment breakdown were reported. Failure of the 3D intraoperative reconstruction phase using SfM was reported in 2 cases, for which augmented reality could not be generated.

In terms of surgeon satisfaction, in 15 (88.2 %) AR cases, AR was reported as useful during the procedure. Among these positive cases, for 15 (100%) procedures, the surgeons mentioned a

help in visualizing (adeno)myomas, and for 8 (53.3%) a help in guiding them to structures of interest.

Among the AR cases, 29.4% of patients reported no pelvic pain with 58.8% of patients reporting VAS ≤ 7 at the preoperative visit **(Figure 3).** Among the controls, 11.8% of patients reported no pelvic pain and 53% of patients reported VAS ≤ 7 at the preoperative visit. The median VAS score for pelvic pain fell from 7 [0;8] and 6 [4;8] (preoperative visit) to 3 [2;4] and 3 [1.75;4.25] (3 hours after surgery) and 0 [0;0] and 0 [0;0] at the postoperative visit (within 6 weeks after surgery), for AR cases and controls respectively. The analysis by mixed model showed no significant statistical difference between the two groups, with only a time effect: pain was lower at the postsurgery visits than at the presurgery visits.

Postoperative data (the median postoperative follow up was 18 [4;35.5] for all patients) revealed no recurrence of myoma for AR cases and only 1 (5.9%) for controls (p=1.00). In the AR case group, among 11 patients (64.7%) who expressed pregnancy desire, 6 (35.3) became pregnant **(Table 3)**, while in the control group, of the 12 patients (70.6%) who expressed pregnancy desire, 5 (29.4%) became pregnant (p=1.00).

The results of the effect sizes presented in tables 2 and 3 are in line with the above results and show, in addition to the non-significance of the tests, the small effects of the variables between the control and case groups.

## DISCUSSION

The purpose of using AR in surgical management of myomas is to optimize surgery by visualizing subsurface structures including the myomas in real time, using virtual 3D models reconstructed from preoperative imaging data. More specifically, the use of AR may improve

surgical procedures involving intramural adenomyomas or myomas that cannot be easily located during conventional laparoscopy. It should be noted that there is no reliable localization technique in conventional laparoscopy. In particular, ultrasound is difficult to use in laparoscopy, MRI being the most sensitive imaging technique for the identification of myomas (particularly for the detection of small myomas) and in differentiating myoma from adenomyosis.

In our study, the surgeons were asked an open-ended question regarding how they felt using AR, the majority reporting that without AR, adenomyomectomy would have been highly challenging. AR allowed them to precisely localize the myomas using transparency and provided guidance for the procedure. The study also confirmed that AR is even more useful for adenomyoma, which are smaller and at deeper spots than myomas, as reported by the surgeons.

While augmented reality (AR) could be of particular interest to junior surgeons, especially for improving anatomical recognition and facilitating access to myomas, notably by optimizing the number and size of uterine incisions [10], the current study does not allow for a robust evaluation of its benefits for this group. Indeed, the limited number of procedures performed by junior surgeons (and only within the case group) precludes meaningful statistical analysis. However, one of the long-term objectives of the AR system is precisely to support junior surgeons in achieving surgical decision-making and efficiency comparable to that of senior colleagues, particularly regarding incision planning. The system is designed to be intuitive and requires minimal training, making it accessible to less experienced users. Validating the system first among senior surgeons appears to be a logical step. Future studies should specifically target junior surgeons to assess whether AR effectively accelerates their learning curve and

improves surgical outcomes in this population. Although AR shows potential for enhancing patient management in the treatment of myomas, by allowing for more precise incisions based on tumor location, its clinical benefits remain to be clearly demonstrated. Further investigations are necessary to confirm these advantages. In a preclinical model, we previously showed that AR improved the mean accuracy of incision localization by a factor of approximately 20 [10].

Adenomyomas are generally soft and positioned deep in the uterine muscle, thus limiting the tactile feedback felt by the surgeon. As the boundary between the lesion and normal tissue can only be felt by palpation, open surgery is frequently required. This lack of tactile feedback provides an explanation for why small adenomyomas may often be left in place after laparoscopy, with reported recurrence of pelvic pain, abnormal bleeding and/or dyspareunia after surgery [17]. Furthermore, this is a likely explanation for why small to medium-size intramural myomas and those that do not modify the uterus' outer shape may be left in place more often after laparoscopy when compared to laparotomy. Finally, recurrence is reported to be more likely following laparoscopic myomectomy than laparotomy [5, 18]. 5 years after laparoscopic myomectomy, the recurrence rate is reported in the literature to reach 50% or more [35, 36]. Robotic myomectomy also requires technical improvements since the residual fibroid volume is described as up to five times greater than after laparotomy [37].

Due to a large variance in operative times for myomectomy and adenomyomectomy in the literature, a non-inferiority margin of 10% of operative time, equivalent to 15 min, was deemed by the surgeons to be the most clinically relevant. Despite our small sample size and its high variability, non-inferiority was demonstrated. Our results showed that the use of AR

during myomectomy and adenomyomectomy did not significantly extend intervention time. This result should be further improved, in particular by reducing AR set-up time, and by developing machine learning research to create, for example, a surgical dataset for the automatic detection of surgical tools or anatomical structures [31]. This study also shows that the use of AR did not lead to increased bleeding, postoperative pain, intra or postoperative complications or recurrences compared to classical laparoscopy.

The use of AR with mobile and deformable organs such as the uterus is as yet poorly documented when compared to surgery involving rigid structures [9]. Research on the use of AR has been more extensively reported in kidney surgery [38], notably involving the Minimally-Invasive Partial Nephrectomy technique. Partial nephrectomy has become the standard of care for localized kidney tumors despite its continued association with serious complications (up to 12%) [39]. Although AR offers the promise of improved surgical outcomes and decreased morbidity, published research is missing, and more clinical studies are consequently necessary if results are to be conclusive [38]. The various AR stages have also been highly challenged (particularly the registration stage) due to the deformability and mobility of the kidney, comparable to that of the uterus [38, 40]. Though the path towards autonomous actions in surgery may be long, computer vision technology is continuing to develop fast [41].

The main limitations of our study concern the patient sample size (17 AR cases and 17 controls) and the retrospective nature of the study. However, the chosen statistical method of matching allowed us to find 17 controls that corresponded precisely to the 17 AR cases on essential criteria (type, size and placement of lesions), and then to compare the two groups. A prospective randomized trial would lend additional support to our study design and to explore

with satisfactory statistical power secondary endpoints of this work, such as bleeding or complications. The intraoperative 3D reconstruction in our system relies on a technique known as Structure from Motion. SfM is a robust and widely used method across various application domains, including quality control. However, during our study, it failed in 2 out of 17 cases owing to an overly limited camera motion and the lack of distinct visual features.

While the current study was not designed to re-assess technical accuracy in a quantitative manner, it builds upon previously reported results obtained with the same system. In particular, Collins et al. [11] reported a Target Registration Error (TRE) below 2 mm near the fundus and increasing with depth, with values compatible with the clinical objective of assisting myoma and adenomyoma localization. In our study, this technical foundation was sufficient to provide clinically useful guidance in most cases, as reflected by the surgeons' subjective feedback. However, reconstruction failures in two cases and the variable reliability of tracking in deeper regions confirm that technical limitations remain and warrant further development. In this work, our focus was intentionally placed on the feasibility and safety of integrating AR into real surgical conditions, rather than on optimizing visual rendering or revalidating the underlying tracking algorithm. Future studies could combine objective accuracy measurements (e.g., intraoperative ground-truth tracking or CT validation) with clinical impact assessment to provide a more complete picture of AR's contribution in gynecologic surgery.

Our AR system will in the near future support a large span of uterine surgery procedures, by providing more information (in addition to the localization of structures of interest such as myomas) such as anatomical landmarks and surrounding organs (the ureters, main vessels, rectum), but also the detection of phenomena such as bleeding and coagulation smoke,

critically important for other indications such as endometriosis and oncologic procedures. Today, the application has been further developed according among others the IEC 62304 and brought to market in full compliance with the European Medical Device Regulation (MDR). In 2015, the first patient underwent surgery with the assistance of augmented reality. Subsequently, a spin-off (**SurgAR)** was founded in 2019 to leverage the laboratory's data. Four years later, the augmented reality system received CE marking.

## CONCLUSION

The use of augmented reality appears safe for patients during gynecologic laparoscopy with no additional constraints for the surgeons. Patients operated with AR experienced no additional adverse events or prolonged operative time. Further research as a prospective randomized trial would give additional support to our study results.

## Contribution to Authorship

N.B., A.C., B.P and M.DA. conceived and designed the study

P.C., A.-S.G., C.F. N.B. performed the surgical procedures

A.C., M.R., P.S., A.B., N.B. and M.DA. analyzed and interpreted the data, wrote the manuscript and approved the final version to be submitted

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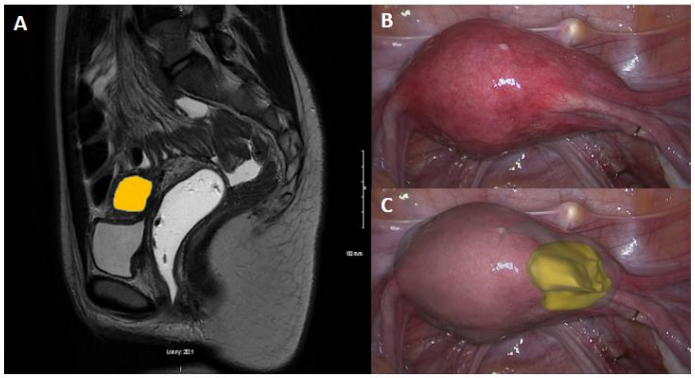
Figure 1:




A. MRI: Sagital view of adenomyoma
B. Laparoscopic view of uterus
C. Laparoscopic view of uterus with visualization of adenomyoma

Table 1: Preoperative data

| | cases (n=17) | Controls (n= 17) | p value |
|---|---|---|---|
| **Demographic data** | | | |
| Age (years) (med [Q1;Q3]) | 35 [29;36] | 33 [30;36] | 0.59 |
| Body Mass Index (kg/m2) (med [Q1;Q3]) | 25.9 [19.8;30.8] | 25.8 [19.5;28.3] | 0.6 |
| **Gestity n(%)** | | | |
| 0 | 10 (58.8) | 9 (52.9) | 1.0 |
| 1-8 | 7 (41.2) | 8 (47.1) | |
| **Parity n(%)** | | | |
| 0 | 12 (70.6) | 10 (58.8) | 0.8 |
| 1-4 | 5 (29.4) | 7 (41.2) | |
| Previous abdominal surgery n(%) | 10 (58.8) | 12 (70.6) | 0.75 |
| **preoperative data** | | | |
| **Type of lesions n(%)*** | | | |
| leiomyoma | 9 (52.9) | 9 (52.9) | - |
| adenomyoma | 8 (47.1) | 8 (47.1) | |
| **Multiple myomas n(%)** | | | |
| 1 | 10 (58.8) | 12 (70.6) | 0.68 |
| +1 | 7 (41.2) | 5 (29.4) | |
| **(Adeno)myoma size* (mm) (med [Q1;Q3])** | 33 [26;60] | 40 [25;55] | - |
| **Location of (adeno)myomas n(%)** | | | |
| anterior | 6 (35.3) | 3 (17.6) | 0.32 |
| fundal | 2 (11.8) | 7 (41.2) | |

| | | | |
|---|---|---|---|
| posterior | 2 (11.8) | 4 (23.5) | |
| lateral | 7 (41.1) | 3 (17.6) | |
| **Placement for myomas* n(%)** | | | |
| Submucosal (Figo 1) | 0 | 0 | |
| Intramural (Figo 2-5) | 8 (80) | 7 (77.8) | - |
| Subserous (Figo 6-7) | 2 (20) | 2 (22.2) | |
| **Preoperative symptoms n(%)** | | | |
| pelvic pain | 12 (70.6) | 12 (70.6) | 1.0 |
| meno-metrorrhagia | 3 (17.7) | 7 (41.2) | 0.22 |
| infertility | 10 (58.8) | 7 (41.2) | 0.55 |

* matching parameters

- Pvalues of mcNemar test is not calculated because there is 0 discordant pairs

Figure 2A et 2B

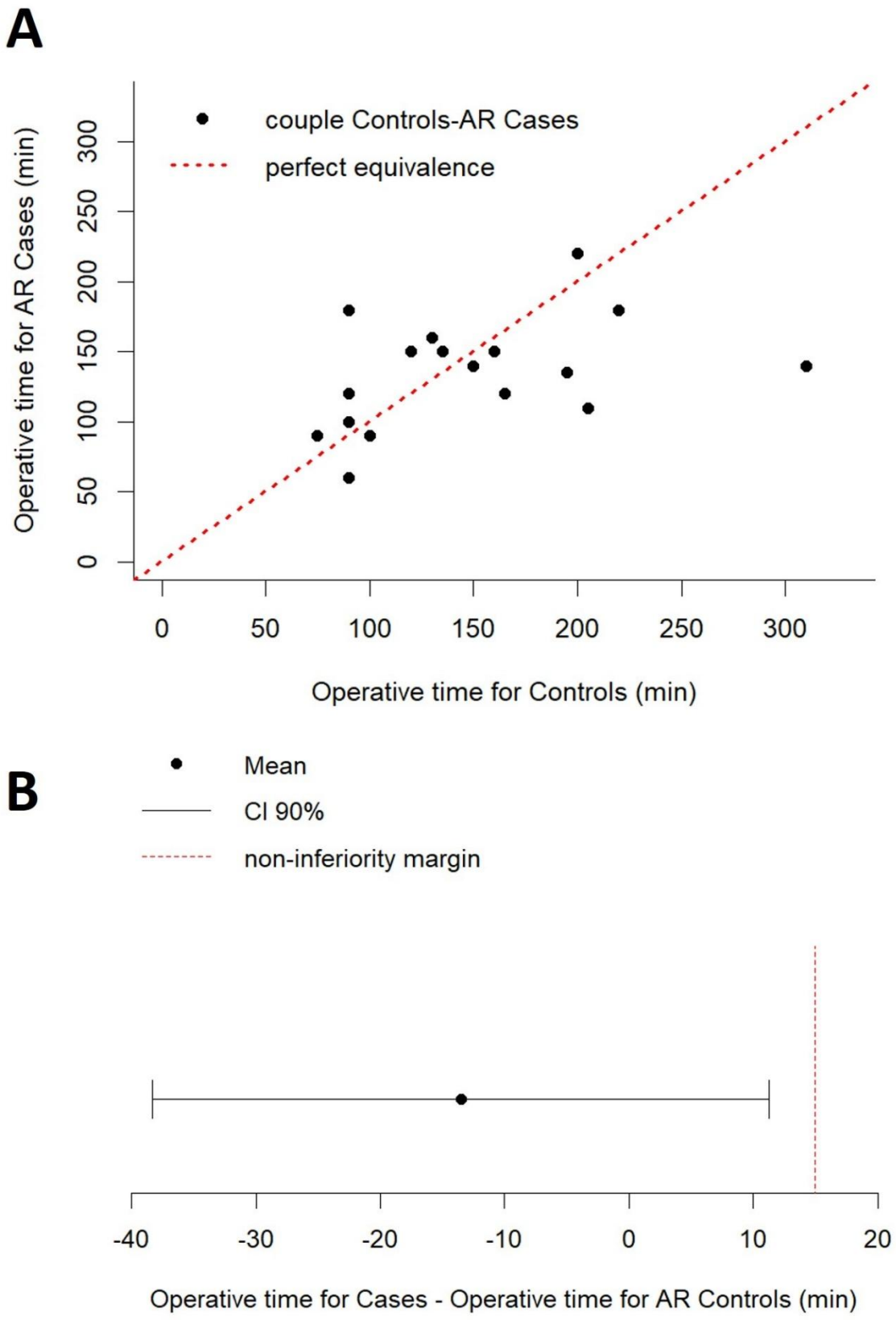



Table 2: Intraoperative data

| intraoperative data | cases (n=17) | Controls (n= 17) | p value | Effect size |
|---|---|---|---|---|
| **type of surgery*** | | | | |
| myomectomy | 9 (52.9) | 9 (52.9) | - | |
| adenomyomectomy | 8 (47.1) | 8 (47.1) | | |
| **Surgeons n(%)** | | | | |
| Senior† | 12 (70.6) | 17 (100) | 0.07 | 0.5 |
| Junior | 5 (29.4) | 0 | | |
| bleeding <200 mL n (%) | 14 (82.3) | 12 (75) | 0.62 | 0.25 |
| operating time (min) (med [Q1;Q3]) | 140 [110;150] | 135 [90;195] | 0.48 | 0.14 |
| conversion to laparotomy | 1 (5.9) | 0 | - | |
| intraoperative complications | 0 | 0 | - | |
| length of hospitalization (day) | 2 [1;3] | 3 [2;3] | 0.41 | 0.12 |
| Blood transfusion | 0 | 0 | - | |

* matching parameters

† senior : with more than 4 years' experience in advanced laparoscopy.

Figure 3

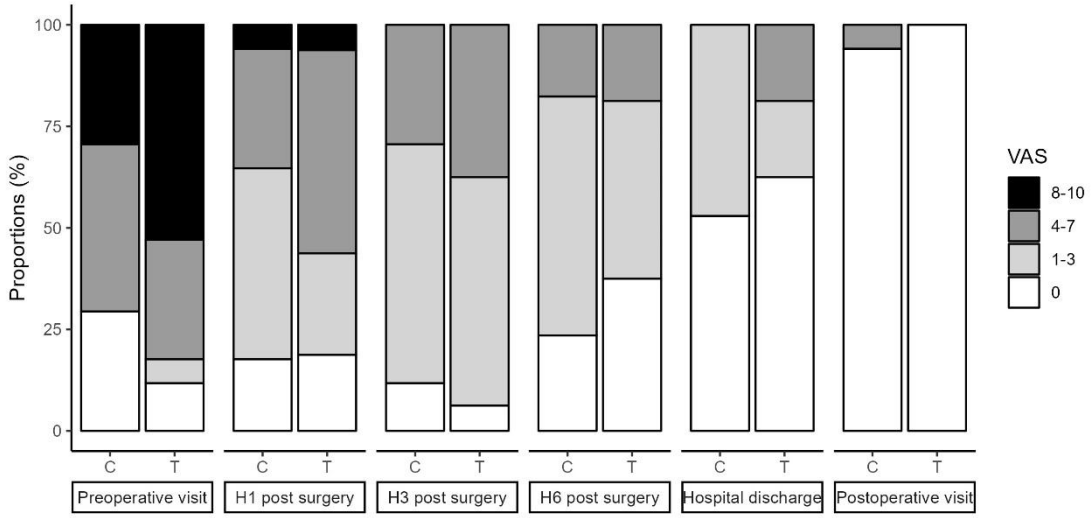



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Table 3: Postoperative data

| n(%) | Cases (n=17) | Controls (n= 17) | p value | Effect size |
|---|---|---|---|---|
| Postoperative complications | 0 | 0 | - | |
| Recurrence | 0 | 1 (5.88) | - | |
| Pregnancy desire | 11 (64.71) | 12 (70.59) | 0.57 | 0.12 |
| Pregnancy achieved | 6 (35.29) | 5 (29.41) | 1.00 | 0.07 |

**Figure legends**

**Fig. 1**: Using a preoperative 3D model as digital twin reconstructed from T2-weighted magnetic resonance imaging (MRI) (A), presentation of the augmented reality guidance system for uterine adenomyoma localization during gynecologic laparoscopy (B,C).

A. MRI: Sagittal view of adenomyoma

B. Laparoscopic view of the uterus without the AR system

C. Augmented laparoscopic view of the uterus and visualization of adenomyoma with the AR system

**Fig. 2** : Non-inferiority of operative time.

A. The plot shows operative time value for AR cases (x-axis) and controls (y-axis).
B. The plot shows the mean difference in operative time with their 90% confidence interval and the non-inferiority margin.

**Fig. 3**: Visual Analogue Scale: Pelvic pain

For AR cases, 29.4% of patients reported no pelvic pain, 58.8% of patients reported a VAS ≤ 7 at the preoperative visit. For controls, 11.8% of patients reported no pelvic pain, 53% of patients reported a VAS ≤ 7 at the preoperative visit.