

# A pilot study of robotic uterine and vaginal vault manipulation: the ViKY Uterine Positioner<sup>TM</sup>

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**Abstract** A pilot study of uterine and vaginal vault manipulation using a new surgical robot—the ViKY Uterine Positioner<sup>TM</sup>—enrolled 36 cases comprising 31 hysterectomies, two myomectomies, two sacrocolpopexies and one excision of severe endometriosis performed between July 2010 and February 2012 in a tertiary referral District General Hospital in the UK. Mean age was 48 years, body mass index 25.7 kg/m<sup>2</sup> and uterine weight 231 g. Nine cases were foot-controlled and 27 by Bluetooth voice control. ViKY UP<sup>TM</sup> docking time once V-Care<sup>TM</sup> was inserted was 4.3 min. The device caused no peri-operative complications. Adequate mobilization, visualization and range of movement was possible in 81, 78 and 61 % of cases, respectively, with most of the problems arising in cases with uterine weight >350 g. ViKY UP<sup>TM</sup> was detached and an assistant was required in three cases, whilst V-Care<sup>TM</sup> came out of the uterus in one case. The learning curve led to various adjustments including optimizing patient position, increasing the device range of movement and adjusting device sensitivity. As a result, problems were minimized in our last nine cases. Adding robotic uterine manipulation is the obvious next step to give the gynecologist the ultimate control and stability of the uterus during robotic-assisted surgery without having to lift their head from the viewfinder or rely on a remotely

situated perineal assistant. ViKY UP<sup>TM</sup> is the first device to deliver this. Pilot study results did not demonstrate compromised safety, and the device appears to be effective and easy to learn.

**Keywords** Uterine manipulation · ViKY UP · Minimally invasive

## Introduction

During an open abdominal hysterectomy, clamps are placed on the uterine cornua, allowing easy manipulation of the uterus. However, the development of conventional laparoscopy and robotic surgery has required new techniques for manipulating the uterus. Usually, a uterine manipulator is placed vaginally and controlled by an assistant during the procedure. Robotic-assisted gynecological surgery is increasing rapidly particularly in the USA [1] and, as with any minimally invasive surgery technique, efficient and safe manipulation of the uterus is extremely important. The main current technique requires manual repositioning of the uterus by the perineal assistant, who may not be able to efficiently respond to commands or hold the uterus stable due to inexperience, lack of coordination, poor commands by the surgeon or even tiredness and boredom. Furthermore, the presence of a perineal assistant necessitates extra operating room staff and space. In robotics these problems are compounded by more difficult communication since the surgeon is remote from the bedside with no direct visualization of the perineal or bedside assistant's maneuvers. These issues have been partly overcome by fixed platforms which attach to the bed or nearby and which hold the main uterine manipulator in a fixed position and can be easily adjusted manually [2].

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However, the optimum situation would be for the console surgeon to be in full control of uterine positioning and maintaining uterine stability. The solution needs to allow the surgeon accurate, effective and secure movement, whilst not having to lift their head from the viewfinder, or move their feet from the console pedals to operate an additional foot pedal. The ViKY Uterine Positioner™ (EndoControl Medical, La Tronche, France) is a new device that provides uterine manipulation through a robotic arm remotely controlled by the console surgeon to achieve the aims outlined above. The ViKY UP™ device was initially designed as a compact motorized laparoscope holder for conventional laparoscopic surgery controlled by either foot pedal or voice activation. It received FDA approval as a laparoscopic camera manipulator in December 2008 and since that time has been used to facilitate minimally invasive surgery in many specialties. The same technology can now be applied to uterine manipulation in robotic-assisted hysterectomies and other gynecological surgeries that require displacement of the uterus out of the anatomical location to optimize the view of the operating surgeon.

## Materials and methods

Data were included for 36 women who underwent non-consecutive routine benign gynecological surgery at The Royal Surrey County Hospital, Guildford, Surrey, UK between July 2010 and February 2012. The clinic is a tertiary referral clinic for complex benign gynecology set in a District General Hospital in the UK. Initially a sample size of 20 cases was selected but various technique modifications in the pilot study led to a final “steady state” technique at 36 cases.

There were no specific inclusion or exclusion criteria and all patients undergoing routine benign surgery requiring uterine manipulation were eligible. The majority of cases were hysterectomy cases as these were specifically required for an FDA approval study that was being carried out simultaneously.

Initially a V-Care™ manipulator is placed as normal in the uterus. Following this, a reusable arm bracket is connected to the right side of the operating table to which the ViKY UP™ robot is attached, giving it a stable platform close to the perineum. ViKY UP™ is then attached to V-Care™ by a simple connecting adaptor (Fig. 1).

All of the surgeries were performed by a single experienced gynecological robotic surgeon using the da Vinci™ S HD robotic system. Two different sizes of ViKY UP™ ring were used, the small initially and the medium in all subsequent cases (Fig. 2). Manipulation of the uterus was achieved by either by a foot control console placed

adjacent to the main robotic console or by Bluetooth™ voice control using a single ear transmitter/receiver worn by the console surgeon, thereby allowing uterine manipulation without lifting the head from the console. In the case of vault manipulation for sacrocolpopexy, the tip of the V-Care™ was removed so that manipulation was achieved by movement of the colpotomizer component of the V-Care™. Initially the console surgeon performs a once-only recording of their voice profile to allow effective voice recognition for all subsequent cases, though during the study two upgrades of the voice recognition software were implemented.

The system allows the console surgeon to move the uterus in individual movements up and down, in and out, left and right. Furthermore, up to three saved positions can be recorded to allow easy return of the manipulator to specific points chosen by the surgeon. After setting up and adjusting the ViKY UP™, the uterus can be repositioned by pressing a foot pedal or simple verbal commands without the need for a perineal assistant. Safety is ensured by a surgeon-initiated “stop” override voice command or foot-switch “stop” override, and by an inbuilt override that stops the device if any external pressure is felt on the device due to contact with the patient or any other surrounding objects.

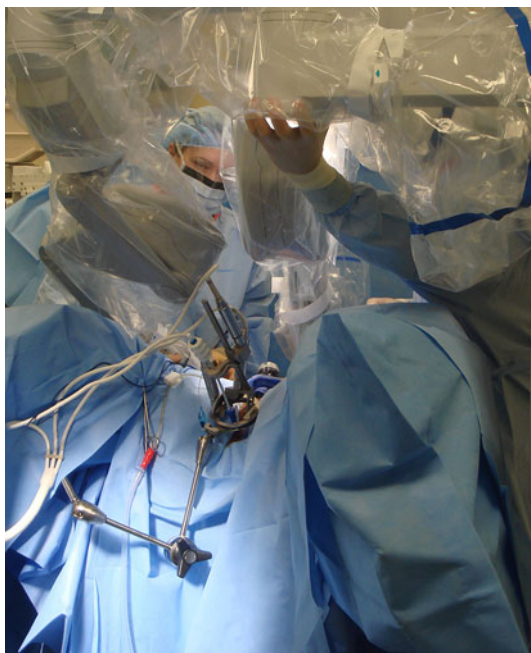
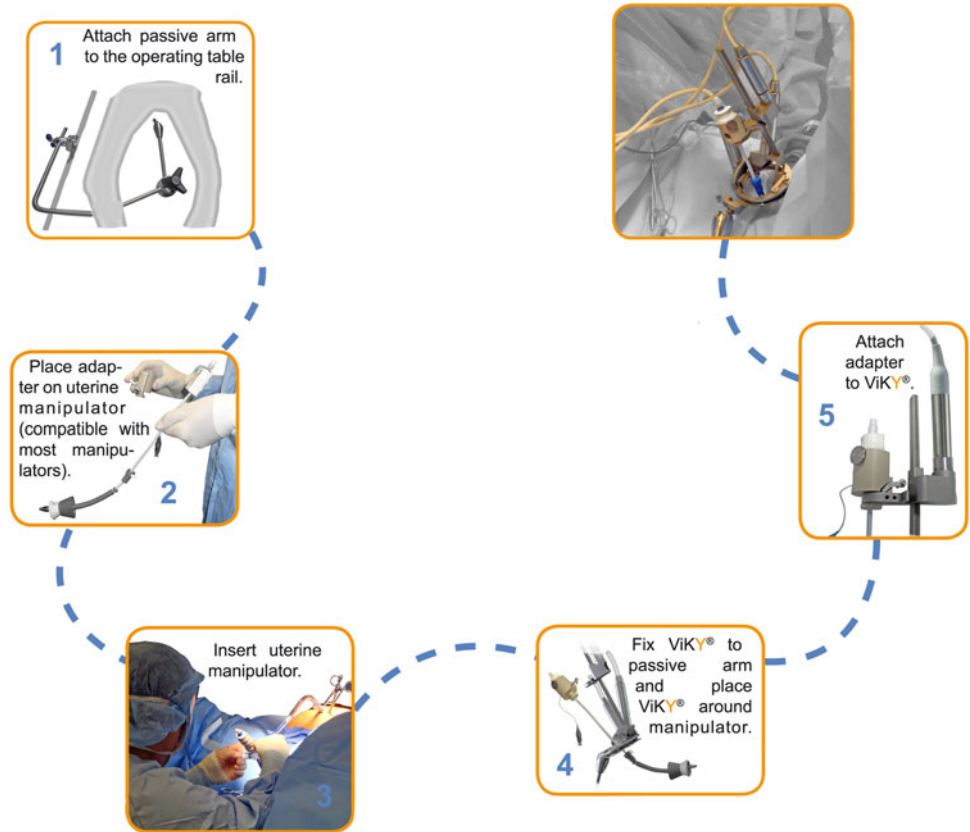
The object of this study was to prospectively collect data in a pilot observational case series to demonstrate the safety and effectiveness of ViKY UP™ for uterine or vaginal vault manipulation during robotic-assisted gynecological surgery.

Data were recorded immediately after surgery on a written data sheet in the operating theatre. Demographic data included age, body mass index (BMI), weight of uterus or myomas extracted, uterine sound length and parity. Intra-operative data included: the time to connect ViKY UP™ to the V-Care™ manipulator, skin-to-skin operating time, inadvertent detachments of ViKY UP™ and the need to resort to a perineal assistant. Subjective data were collected for the surgeon's perception of the effectiveness of visualization, mobility, range of movement and voice control responsiveness. Intra-operative complication data were collected for uterine perforation, vaginal and cervical lacerations, excessive bleeding or blood transfusion and injury to bladder or bowel.

ViKY UP™ is a CE-marked product (June 2010) and therefore this study is considered to be a Post Market Surveillance study (non-interventional) and classifies as a service evaluation not requiring ethical review in the UK. This study did not incur any extra cost to the department.

For statistical analysis all data were entered into Excel™ and analyzed using simple descriptive statistics looking for and taking into account unexpected outliers in the analysis.

**Fig. 1** ViKY UP™ set-up



**Fig. 2** ViKY UP™ ring

**Results**

The 36 cases comprised 31 hysterectomies, two myomec-  
tomies, two sacrocolpopexies for vaginal vault prolapse

and one severe endometriosis excision. Mean age, BMI and  
uterine weight were 48 years, 25.7 kg/m<sup>2</sup> and 231 g (ran-  
ges 29–64, 21–39.4 and 64–1,732, respectively).

In 27 cases, ViKY UP™ was voice-controlled and in  
nine foot-controlled. Adequate visualization, mobiliza-  
tion and range of movements were possible in 81, 78  
and 61 % of cases, with most of the problems arising in  
uteri heavier than 350 g. No response problems were  
encountered in the foot-controlled cases, whilst in 2  
out of the 27 voice-controlled cases the ViKY  
UP™ occasionally failed to respond to first request.  
However, repetition of the command resulted in correct  
function.

The mean time taken to attach ViKY UP™ to the  
V-Care manipulator was 4.3 min (range 1–32). The mean  
procedure (skin to skin) duration was 142 min (range  
50–232). ViKY UP™ became detached, meaning a peri-  
neal assistant was required, in three cases (8 %), whilst  
the V-Care™ came out of the uterine cavity in one case.  
Pneumoperitoneum was well maintained in all cases and  
there was good delineation of the vaginal fornixes.

No intra-operative complications were observed for  
uterine perforation, vaginal laceration, cervical tear, or  
bladder, ureteric or bowel injury in any of the cases. In  
addition, no cases required blood transfusion and there  
were no conversions to open surgery.

## Discussion

In our experience the use of a uterine manipulator, whether it be by perineal assistant, a fixed hydraulic platform or surgical robot, makes most benign gynecological minimally invasive procedures easier. The use of the third robotic arm can also give a measure of uterine manipulation but the combination of both uterine and third arm manipulation really optimizes the ability to get the best surgical view. The third arm can also be freed up for helping with fine anatomical dissection and not just as a general retractor. Uterine manipulation also allows the uterus to be pushed into the patient more easily and consequently the ureters are displaced anatomically further from the uterine pedicles where they are otherwise at risk of compromise during hysterectomy.

Demographically, the women in our study have a relatively low mean BMI of 25.7, in comparison with that which might be seen in some other countries like the USA [3]. We did operate on women with a BMI up to 39.4 and did not find that increased BMI was a problem in terms of mobility or range of movement of the device due to direct conflict with the larger thighs of high-BMI women. Our technique evolved to ensure that thighs were abducted as much as possible to create as flat a surface as possible for placing the ViKY UP™ ring against the perineum and this also had the effect of widening the distance between the thighs and avoiding instrument conflict.

The mean uterine weight of 231 g (and one case of 1,732 g) shows that we were operating on significantly enlarged uteri and stretching the capability of the device to its limit. It did become apparent in the early stages, however, that uteri of >350 g had reduced range of movement and visualization. This in some ways is purely an inherent property of the large uterus itself, and not a reflection on the device's reduced ability to deal with the large uterus. However, the safety software in the device means that it will not torque the uterus as much into the patients' thighs as a perineal assistant would, and this results in a reduction in range of movement compared to what is achievable by a hand-held manipulator. That being said, uteri up to approximately 350 g posed no range of movement or visualization problems whatsoever.

Several strategies were implemented to overcome the large uteri issue, including switching to the larger medium-sized ring instead of the extra-small version to improve the inherent range of movement of the device. To accommodate the larger ring at the perineum, thigh abduction has to be maximized as described above. The sensitivity of the software's recognition of external contact with the patient was also decreased so that range of movement was also improved by safely allowing more torque of the device against the patient at the extremes of manipulation.

Furthermore, no device detachments occurred in the latter part of the series with these adjustments and subjectively there were no range of movement, mobility or visualization issues in the final nine cases. From a safety perspective, the ViKY UP™ performed well, as we experienced no intra-operative complications caused by the device throughout the whole pilot study.

The upgrade to third-generation voice recognition software improved responsiveness. There are still some tips and tricks that need to be observed with voice control, including the need to remember to pause before giving a command or else the system does not respond, and to adjust the voice control sensitivity scale to allow optimum response depending on the natural assertiveness of the surgeon's voice.

Further consideration is currently being given to attaching ViKY UP™ to alternative manipulators. A new adaptor connecting to the Advincula Arch™ by Cooper Surgical™ is currently being trialed to see if this improves range of movement with large uteri.

In terms of set-up, the learning curve is fast and ViKY UP™ docking time does not add more than a mean of 4.3 min to the operating time. It is easy and intuitive to use and assemble. Since modifying the technique, we have found the ViKY UP™ to be an important addition to our surgery. Da Vinci™ surgery gives improved view, precision and ergonomics and it seems the logical next step to include stable, surgeon-controlled uterine manipulation to the package to improve the surgeon's rhythm and view and to remove the problem of communication with a perineal assistant. In addition, as the ViKY UP™ can also be used as a laparoscopic camera holder, it has more than one role in the department, making it more cost-effective. The cost of the device in the USA will be about US\$75,000. Cost data were not collected to assess potential savings resulting from not requiring a perineal assistant.

This pilot study does have some limitations. The fact that cases were not consecutive must introduce an element of selection bias into the results. Cases were more likely to take place when EndoControl staff were present or when the case was not a teaching or demonstration case. A randomized controlled trial is required with multiple surgeons comparing the use of ViKY to a control group with a perineal assistant. Operating times, peri-operative outcomes and cost data could be compared.

## Conclusion

ViKY UP™ is the first attempt at extending the role of surgical robots to uterine manipulation, which is one of the most crucial components of gynecological minimally invasive surgery. As with any new technology, there is a learning curve that has been more pronounced for us in this

pilot study than for surgeons who will subsequently use the system. Our initial experience with the ViKY UP™ has been very encouraging. It does not appear to compromise patient safety, leads to a more fluid surgical experience for the robotic surgeon, and is the inevitable next step in the development of gynecological robotics.

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**Conflict of interest** None.

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