Evaluation of the safety and efficacy of the Sentire Surgical System (C1000) for robot-assisted radical prostatectomy

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ABSTRACT

Introduction: This prospective clinical study evaluated the clinical safety and efficacy of the Sentire Surgical System (C1000), a locally developed robotic surgical platform, in performing radical prostatectomy in Hong Kong.

Methods: This was a single-centre, single-arm study. Adult patients with a clinical diagnosis of localised prostate cancer planned for surgical treatment were invited to participate. Surgery was performed using the Sentire C1000 system following the standard approach. The primary endpoints were the conversion rate and the incidence of perioperative complications within 30 days. Secondary outcomes, including perioperative, pathological, oncological, and functional outcomes at 1 month after surgery, were also assessed.

Results: From August 2022 to September 2023, 20 patients were recruited. All procedures were performed without conversion. There were no intraoperative complications related to the robotic device. Minor surgical complications (Grade I-II according to the Clavien–Dindo Classification) occurred in seven patients and were managed conservatively. The mean total operative time was 184.5 minutes (standard deviation=30.0). The median estimated blood loss was 175.0 mL (interquartile range [IQR]=100.0-275.0). The median length of hospital stay was 3.0 days (IQR=2.0-4.0). Seventeen patients achieved undetectable levels of prostate-specific antigen at 1 month after surgery.

Conclusion: These initial results support the Sentire Surgical System (C1000), Hong Kong's first locally developed multidisciplinary surgical robotic platform, as a safe and effective option for radical prostatectomy, with clinical performance and outcomes comparable to existing robotic systems.

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New knowledge added by this study

- The first locally developed multidisciplinary surgical robotic system demonstrated safety and efficacy outcomes comparable to those of existing robotic systems.
- Initial clinical use in radical prostatectomy showed successful implementation, without conversion or device-related complications.

Implications for clinical practice or policy

- This locally developed surgical robotic system may offer a more affordable option for locoregional institutes and allow more patients to benefit from robotic surgery.
- Wider adoption of locally developed systems could reduce reliance on monopolised international platforms and promote technological self-sufficiency in surgical care.

Introduction

Over the past few decades, the widespread adoption of robotic surgical systems has revolutionised surgical management, particularly for radical prostatectomy.[1] Enhanced visualisation, superior dexterity, and tremor filtration enable surgeons to maintain precision in the deep pelvis with better ergonomics. These advantages contribute to lower rates of positive surgical margins and biochemical recurrence, thereby reducing the need for salvage therapy.[2] Evidence also shows that robotic surgery can significantly reduce postoperative complications and shorten the time to regain continence and potency.[3]

For the past two decades, the global market for robotic surgery has been dominated by the da Vinci Surgical System (Intuitive Surgical, Sunnyvale [CA], US). However, worldwide adoption of robotic surgery remains limited by the high costs associated with device acquisition, maintenance, and disposables.

評估於機械臂輔助式根治性前列腺切除術使用Sentire手術系統（C1000）的安全性及效用

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引言：Sentire手術系統（C1000）是香港本地研發的機械手術平台，用於進行本港的根治性前列腺切除術。本前瞻性臨床研究評估這系統的臨床安全性及效用。

方法：我們邀請了經臨床診斷患上局部前列腺癌並已計劃進行手術治療的成年患者參與這項單一中心及單組研究。手術利用Sentire C1000系統按標準方式進行。主要研究結果包括轉為開腹式手術的比率及在術後30日內出現圍手術期併發症的發生率。我們亦評估了次要結果，包括術後1個月的圍手術期、病理、腫瘤學及功能結果。

結果：我們於2022年8月至2023年9月期間招募了20名患者，全部手術均沒有轉為開腹式手術；沒有出現與該機械手術系統相關的術中併發症。七名患者出現輕微手術併發症（Clavien–Dindo第1至II級），全部均以非手術方式處理。平均總手術時間為184.5分鐘（標準差=30.0），估計血流失中位數為175.0毫升（四分三位數=100.0-275.0），住院日數中位數為3.0（四分三位數=2.0-4.0）。共有17名患者術後1個月的前列腺特異性抗原達至檢測不到的水平。

結論：這些初步研究結果反映對於根治性前列腺切除術而言，Sentire手術系統（C1000）這個首個由香港本地研發的跨專科手術機械平台是安全及具效用的選擇，其臨床表現及結果與現有機械系統相若。

Consequently, access disparities persist worldwide, particularly exacerbating inequities in surgical care[4] in low- and middle-income countries.[5] Surgeons and trainees are also deprived of opportunities to acquire robotic skills, creating a bottleneck in the clinical application of advanced surgical technologies. To address this problem, a novel, high-performing yet affordable robotic surgical system is needed to expand access to the highest standards of surgical care.

The Sentire Surgical System (C1000) is a novel robotic surgical system developed by Cornerstone Robotics Limited (Hong Kong, China). It is the first locally developed surgical robot designed for multispecialty use. The system consists of three interconnected components: a Patient-Side Robot (PSR), a Surgeon Console, and a Vision Cart. The PSR has four robotic arms, on which an endoscope and up to three robotic surgical instruments can be mounted. The endoscope provides a high-resolution, three-dimensional image for the console surgeon. An array of instruments, including graspers, needle drivers, clip appliers, and scissors, can be installed depending on the operational requirements. The Surgeon Console includes two hand controls and a set of foot pedals, enabling surgeons to operate the surgical instruments and endoscope on the PSR, while applying energy through the surgical instruments. The Vision Cart includes a touchscreen display showing the endoscopic view for the assistant surgeon. It houses the energy source for monopolar and bipolar instruments, as well as the light and camera source for the endoscope.

This study aimed to evaluate the clinical safety and efficacy of the Sentire Surgical System by reporting outcomes from the first clinical trial for radical prostatectomy, as part of a multispecialty clinical study. Comparable safety and patient outcomes will provide supporting evidence for the continued development of this robotic surgical technology, facilitating its implementation and evaluation in further clinical trials.

Methods

Study design

This was a prospective, single-centre, single-arm study aligned with Stage 1 (Innovation) of the IDEAL (Innovation, Development, Exploration, Assessment, Long-term Study) framework.[6] The study formed part of a multi-speciality clinical investigation to evaluate the safety and efficacy of the Sentire Surgical System for robot-assisted colorectal, upper gastrointestinal, and urological surgery (radical prostatectomy).

Study population

From August 2022 to September 2023, 20 adult men with clinically localised prostate cancer and planned radical prostatectomy were recruited. The inclusion criteria were: (1) age between 50 and 80 years; (2) clinical diagnosis of non–metastatic prostate cancer; (3) body mass index <35 kg/m^2; (4) deemed suitable for minimally invasive treatment; and (5) provision of informed consent. Exclusion criteria were: (1) contraindication to general anaesthesia; (2) prior history of prostatic surgery; (3) untreated active infection; (4) uncorrected coagulopathy; (5) presence of other malignancies or distant metastases; and (6) membership in a vulnerable population.

Surgical procedure

All 20 robot-assisted radical prostatectomies were performed by four practising urological surgeons, each with extensive experience (>50 prior cases as chief surgeon). All participating surgeons had been trained in the use of the system and had prior experience performing procedures with the system on cadaveric and live porcine models.

Patient and trocar positioning

Patients were placed under general anaesthesia in the lithotomy position. A total of four robotic ports were used. First, a 10-mm endoscope port was placed supraumbilically through an open approach. After pneumoperitoneum was established, three

additional 8-mm robotic ports were inserted: one on either side of the supraumbilical port, adjacent to the left mid-clavicular line at approximately the vertical level of the umbilicus, and one along the right or left anterior axillary line, about 2 cm above the anterior iliac spine. A 12-mm assistant port was inserted opposite the most lateral robotic port, mirrored across the midline. Finally, a 5-mm assistant port was inserted between the midline and either the right or left mid-clavicular line (on the same side as the 12-mm assistant port) for suction and retraction (Fig 1).

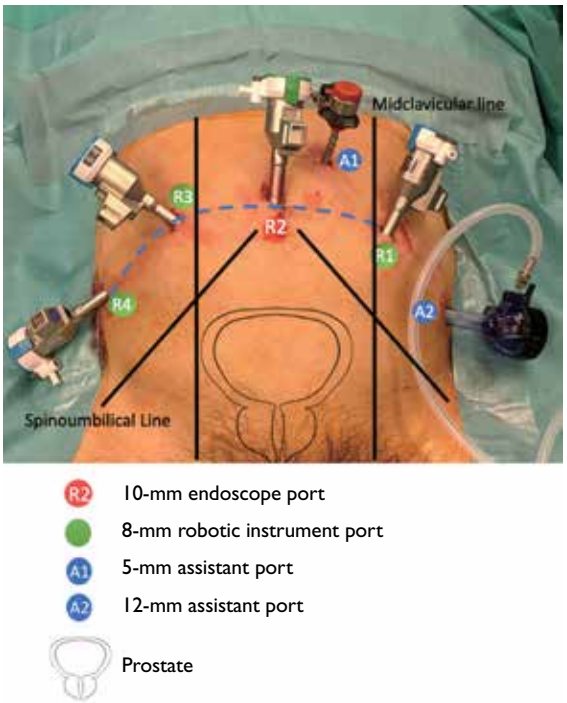

FIG 1. Port placement for prostatectomy

Docking

Following port placement, the patient was placed in the Trendelenburg position. The PSR of the Sentire Surgical System, which consists of four robotic arms extending from a central column, was positioned between the patient's legs. Figure 2 shows photos of the operating room during radical prostatectomy.

Instruments

For most radical prostatectomy procedures, a 0° endoscope was used throughout. One surgeon alternated among the 0°, 30° up (for initial bladder detachment), and 30° down endoscopes (for bladder neck dissection) according to their preference. Bipolar Maryland Forceps (Cornerstone Robotics Limited, Hong Kong SAR, China) were used in the left hand, Monopolar Curved Scissors (Cornerstone Robotics Limited, Hong Kong SAR, China) in the right hand, and ExtraGrasp forceps (Cornerstone Robotics Limited, Hong Kong SAR, China) on the fourth robotic arm for traction. Left-hand and right-hand instruments were exchanged for the Large Needle Driver during vesicourethral anastomosis and other suturing tasks. The right-hand instrument could also be replaced with the Large Clip Applier for vessel ligation.

Operation

Each operation was performed using the standard transperitoneal anterior approach. Briefly, bladder dissection was carried out in the areolar tissue plane between the peritoneum and transversalis fascia after the peritoneum had been incised at the lateral borders of the urinary bladder. Dissection continued caudally to develop the retropubic space. Preprostatic fat was removed for enhanced anatomical localisation. Dissection of the endopelvic fascia was then performed. The dorsal venous complex was ligated according to surgeon preference. Bladder neck dissection followed, then dissection of the vas deferens and seminal vesicles. The posterior plane of the prostate was then dissected, continuing to the prostatic apex. Lateral dissection was performed next, with the degree of nerve sparing determined by preoperative erectile function, tumour location, and tumour grade. Apical dissection was performed and the urethra was then divided.

Haemostasis was secured by further suturing of the dorsal venous complex, if not previously completed. If indicated, pelvic lymph node dissection was performed at this stage. Posterior Rocco's stitch reconstruction was carried out, followed by vesicourethral anastomosis with continuous sutures. After confirming watertightness, a pelvic drain was placed via the most lateral robotic port. The robot was then undocked and specimens were removed in a specimen bag through an extended camera port incision. Wounds were closed using standard techniques.

Study endpoints

Primary endpoints included the conversion rate and the incidence of perioperative complications within 30 days. Conversion was defined as an emergent change to a conventional laparoscopic or open approach. Intraoperative events and postoperative complications during the hospital stay and within 30 days of discharge were recorded. The severity of complications was graded according to the Clavien–Dindo Classification. Whether complications were anticipated was determined based on their consistency with the current investigational plan or consent form. In the event of postoperative complications, the relationship to the Sentire Surgical System, the surgical procedure, and the

FIG 2. Intraoperative images of the Sentire Surgical System (C1000) during radical prostatectomy. (a) Robotic arms docked for the procedure. (b) Assistant surgeon position. (c) Surgeon Console. (d) Anaesthesiologist position

patient's underlying condition was documented, along with actions taken and outcomes.

Secondary endpoints included perioperative and pathological outcomes. Perioperative outcomes included total operative time, docking time, total console time, estimated blood loss, time to resume regular activity, length of hospital stay, time of drain and removal, time of urethral catheter removal, visual analogue scale (VAS) pain scores at 14 and 30 days, and use of pads for urinary incontinence at 14 days and 30 days. Pathological outcomes included surgical margins, lymph node metastasis, tumour involvement, pathological tumour stage, number of lymph nodes harvested, and postoperative prostate-specific antigen (PSA) level.

Statistical analyses

Data are presented in a descriptive manner. Continuous variables are reported as means with standard deviations (SDs) or medians with interquartile ranges, whereas categorical variables are presented as percentages. All analyses were performed using SPSS (Windows version 25.0; IBM Corp, Armonk [NY], US).

Results

Twenty patients were enrolled in the trial, and all successfully underwent robot-assisted radical prostatectomy using the Sentire Surgical System. The mean age was 68.5 years (SD=4.1) and the mean body mass index was 24.2 kg/m^2 (SD=2.8). Two patients had a history of abdominal surgery: Case 3 had undergone open appendicectomy, and Case 11 had undergone laparoscopic cholecystectomy. Seventeen patients underwent radical prostatectomy only, while three also underwent lymphadenectomy. The mean prostate volume was 40.7 cc (SD=17.8). Nine patients had a Gleason score of 6, nine had a score of 7, and two had a score of 8. Five patients were classified as low-risk, 11 as intermediate-risk, and four as high-risk. Two patients received neoadjuvant hormonal therapy due to concerns about prolonged waiting times during the coronavirus disease 2019 period; their mean initial PSA level dropped from 16.2 ng/mL to 2.19 ng/mL. The mean preoperative PSA level for patients who did not receive neoadjuvant therapy was 15.2 ng/mL (SD=20.8) [Table 1].

All operations were completed without conversion. There were no intraoperative

TABLE 1. Demographics of the study population (n=20)*

Age, y	68.5±4.1
BMI, kg/m²	24.2±2.8
ASA grading	
I	1
II	16
III	3
Previous intra-abdominal surgery	2
Procedure performed	
Radical prostatectomy only	17
Radical prostatectomy with lymphadenectomy	3
Prostate volume, cc	40.7±17.8
Gleason score	
3+3	9
3+4	7
4+3	2
4+4	2
Risk level	
Low	5
Intermediate	11
High	4
Neoadjuvant therapy	
Yes	2
No	18
Preoperative PSA level, ng/mL	
Before neoadjuvant therapy (n=2)	16.2
After neoadjuvant therapy (n=2)	2.19
Without neoadjuvant therapy (n=18)	15.2±20.8

Abbreviations: ASA = American Society of Anesthesiologists; BMI = body mass index; PSA = prostate-specific antigen

* Data are shown as No., mean or mean±standard deviation

complications related to the robotic device. Minor surgical complications (Grade I-II) occurred in seven patients, including four cases of wound infection, one case of urinary retention, one case of prolonged anastomotic leakage, one case of bilateral lower limb rash, and one case of left loin pain. Only five of these complications—namely wound infections and prolonged anastomotic leakage—were considered related to the surgery (Table 2).

The mean total operative time (from skin incision to closure) was 184.5 minutes, including a mean docking time of 4.2 minutes and a mean total console time of 149.7 minutes. The median estimated blood loss was 175.0 mL. Postoperatively, the median time to resumption of regular activity was 7.0 days, the median duration of drainage was 2.0 days and the median duration of urethral catheterisation was 7.0 days. The median length of hospital stay was 3.0 days. The median VAS pain score at the 14-day follow-up was 3.0, whereas at the 30-day follow-up it was 0. Pad usage for urinary incontinence was 3.5 at the 14-day follow-up and 2.0 at the 30-day follow-up (Table 3).

Regarding pathological outcomes, 13 of the 20 patients (65%) had negative surgical margins, including the two who received neoadjuvant hormonal therapy. Seventeen patients (85%) had undetectable PSA levels 1 month after surgery, while two other patients (95%) achieved undetectable levels at 3 months. Among the three patients who underwent lymphadenectomy, the mean number of lymph nodes harvested was 9 (range=5-11) [Table 4].

Discussion

This prospective study reports the results of the first-in-human clinical trial of the Sentire Surgical System—the first locally developed multispecialty

TABLE 2. Postoperative complications

Case	Complications	Onset after surgery, d	Clavien–Dindo grading	Relevance to surgery	Outcomes
2	1. Painful defecation 2. Acute retention of urine	1. 7 2. 8	1. II 2. I	1. Possibly 2. Possibly	1. Resolved with paracetamol PRN 2. Resolved with Foley catheter insertion
4	Minor wound infection at umbilicus	7	I	Definitely	Resolved with dressing
7	1. Mild drain wound site infection 2. Bilateral lower limb maculopapular rash	1. 9 2. 14	1. I 2. I	1. Definitely 2. Not related	1. Resolved with dressing 2. Resolved without medication or surgery
8	Minor wound infection at main site	10	I	Definitely	Resolved with dressing
9	Wound infection (right assistant port)	7	I	Definitely	Resolved with daily dressing
11	Anastomotic leakage	0	1	Definitely	Resolved without medication or surgery
13	Left loin pain	6	II	Not related	Resolved with medication

Abbreviation: PRN = pro re nata (as needed)

TABLE 3. Perioperative surgical outcomes (n=20)*

Total operative time, min	184.5±30.0
Docking time, min	4.2±3.0
Total console time, min	149.7±26.4
Estimated blood loss, mL	175.0 (100.0-275.0)
Time to normal activity, d	7.0 (7.0-7.0)
Length of drain stay, d	2.0 (2.0-2.75)
Length of Foley catheter stay, d	7.0 (7.0-7.0)
Length of hospital stay, d	3.0 (2.0-4.0)
VAS pain score	
At 14-day FU	3.0 (0-5.0)
At 30-day FU	0 (0-2.75)
Use of pads for urinary incontinence	
At 14-day FU	3.5 (1.0-4.0)
At 30-day FU	2.0 (1.0-3.0)

Abbreviations: FU = follow-up; VAS = visual analogue scale
* Data are shown as mean±standard deviation or median (interquartile range)

TABLE 4. Pathological outcomes for all cases (n=20)*

	Total	Prostatectomy only	Prostatectomy and lymphadenectomy
Surgical margins			
Positive	7 (35%)	5 (25%)	2 (10%)
Negative	13 (65%)	12 (60%)	1 (5%)
Lymph node metastasis	0	0	0
Tumour involvement			
Both lobes	17 (85%)	14 (70%)	3 (15%)
Half lobe or less	3 (15%)	3 (15%)	0
Pathological tumour (T) stage			
T2a	2 (10%)	2 (10%)	0
T2b	1 (5%)	1 (5%)	0
T2c	15 (75%)	13 (65%)	2 (10%)
T3a	2 (10%)	1 (5%)	1 (5%)
PSA persistence† on day 30			
Yes	3 (15%)	2 (10%)	1 (5%)
No	17 (85%)	15 (75%)	2 (10%)
No. of lymph nodes harvested			
5	1 (5%)	N/A	1 (5%)
11	2 (10%)	N/A	2 (10%)

Abbreviations: N/A = not applicable; PSA = prostate-specific antigen
* Data are shown as No. (%), unless otherwise specified
† PSA level ≥0.1 ng/mL

surgical robot—used for radical prostatectomy. All 20 procedures were completed successfully, without conversions and device-related intraoperative or postoperative complications, demonstrating that this novel surgical system is safe and effective for robot-assisted radical prostatectomy.

Since the introduction of robotic surgery in Hong Kong in 2005, its use—particularly in urology—has steadily expanded.[7] According to the latest Surgical Outcome Monitoring and Improvement Programme report (2022-2023), almost all radical prostatectomies (409 of 410 patients) were performed using robotic surgery.[8] Improved outcomes have been a key factor supporting its development.[9] However, the high cost of robotic systems considerably limits further expansion and popularisation. With the expiration of certain technological patents, new robotic systems are rapidly emerging worldwide.[10] The development of a locally based robotic system in Hong Kong represents an important milestone for the future of robotic surgery in the region.

Perioperative outcomes in this trial were favourable, with a mean total operative time of 184.5 minutes, comparable to reported times in the existing literature on both laparoscopic and robotic radical prostatectomy.[11] The short docking time reflected a smooth docking process. Most cases had acceptable blood loss, and no patients required transfusion, again comparable to the literature.[11] Despite the higher-than-expected wound infection rate, most infections were minor and managed with simple dressing. No specific cause was identified, and these events are unlikely to be related to the robotic system. Postoperative hospital stay was also short, with satisfactorily low VAS pain scores. Early functional outcomes, specifically pad usage for urinary incontinence, were also satisfactory (Table 3).

Short-term oncological outcomes also support the system's efficacy, such that 65% of patients achieved a negative surgical margin and 85% and 95% of patients showed no PSA persistence (PSA level ≥0.1 ng/mL) at 30 days and 3 months after surgery, respectively—results that are comparable to the literature.[12] In the three cases where lymphadenectomy was performed, the mean lymph node yield was 9, which is considered optimal for balancing the biochemical recurrence-free rate and complication risk.[13] These findings indicate that the system can achieve oncological outcomes in radical prostatectomy comparable to those of established robotic systems.

Compared with our previously reported outcomes using other robotic systems,[14] the performance of the current system was highly comparable. The mean operative time and hospital

stay were 184.5 minutes/3.1 days (Sentire C1000), 225.8 minutes/3.3 days,[14] (da Vinci S), and 223.7 minutes/3.0 days,[14] (da Vinci SP). These results not only demonstrate that the Sentire C1000 offers performance comparable to existing robotic systems but also confirm the ease of surgical transition. A key factor enabling this transition is the similarity of the robotic control interface—including hand controls and foot pedals, allowing surgeons to adopt the new system more readily and apply their existing robotic experience. This is akin to driving different brands of cars, where consistent interfaces such as the steering wheel and pedals enable smooth adaptation. As a result, most new robotic systems adopt similar interface designs to support seamless integration by experienced surgeons. Moreover, the PSR has a similar arm configuration and setup to the da Vinci system, which also helps both surgeons and nursing staff adapt to the setup.

As this is the initial report of the Sentire Surgical System's clinical use in radical prostatectomy, further clinical studies are warranted to evaluate its performance across a broader range of procedures.

Conclusion

Our findings indicate that the Sentire Surgical System (C1000) is a safe and effective robotic platform for radical prostatectomy. Its successful performance in this first-in-human experience supports ongoing development and broader application of this novel surgical robotic system.

Author contributions

Concept or design: CF Ng.
Acquisition of data: CH Yee, PKF Chiu, MHM Tam, FPT Lai.
Analysis or interpretation of data: FPF Lai.
Drafting of the manuscript: CF Ng, FPF Lai.
Critical revision of the manuscript for important intellectual content: All authors.

All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

As an editor of the journal, CF Ng was not involved in the peer review process. Other authors have disclosed no conflicts of interest.

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Ethics approval

The research was approved by the Joint Chinese University of Hong Kong—New Territories East Cluster Clinical Research Ethics Committee, Hong Kong (Ref No.: CREC 2021.472). It was registered on www.ClinicalTrials.gov (Ref No.: NCT05151835). Written informed consent was obtained from all patients for the publication of this research and the accompanying images.

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