

User's Voice

Benefits of Using the KOELIS Trinity® for MRI-targeted Biopsy in Prostate Cancer Diagnosis*

*Original version in Japanese, translated in English by: Forte Science Communication

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Learn more in [page 8](#)



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Learn more in [page 9](#)

Introduction

The KOELIS Trinity® Diagnostic Imaging Workstation is a general-purpose ultrasound diagnostic imaging system for managing prostate cancer from diagnosis to treatment. The KOELIS Trinity® fuses MRI scans with 3D ultrasound images of the prostate to indicate on-screen the location of the lesion identified on MRI. The result is more precisely targeted biopsies.

Here we talk with Dr. Tsutomu Tamada of the Department of Radiology and Dr. Yoshiyuki Miyaji of the Department of Urology of Kawasaki Medical School Hospital, as the first adopters of the KOELIS Trinity® in Okayama Prefecture. Both frequently use the system to diagnose prostate cancer in their patients. We asked these two what problems they encountered in diagnosing prostate cancer before adoption, the circumstances surrounding adoption, and the benefits that the KOELIS Trinity® has brought.

Questions

Q. Where did you hear about the KOELIS Trinity®?

Dr. Tamada: I encountered a fusion biopsy system that incorporated images from ultrasound and MRI during my study program in the United States in 2016. The system impressed me, providing better diagnostic precision than conventional systematic transrectal ultrasound-guided prostate biopsy and conveniently allowing biopsy under local anesthesia. My experience with the system made me want to use it in Japan. After I returned to Japan, I participated in hands-on KOELIS Trinity® seminars.

Q. Can you tell me what prompted you to adopt the KOELIS Trinity®?

Dr. Miyaji: In the diagnosis of most cancers, suspicious lesions that appear on endoscopic, CT-guided, or ultrasound-guided observations are sampled.

Prostate cancer is biopsied differently. As recommended in the relevant guidelines, a systematic biopsy is generally performed for patients suspected of having prostate cancer based on a serum prostate-specific antigen (PSA) level exceeding 4.0 ng/mL. This biopsy involves using a biopsy needle to uniformly collect samples under ultrasound guidance from 10–12 sites, primarily in the peripheral zone as well as in the transitional zone.

However, in patients with early prostate cancer, the lesion is often not imaged under ultrasound guidance. This means that likely sites of prostate cancer can be found with MRI, but not ultrasound.

Since likely sites of cancer cannot be punctured under ultrasound guidance, 10–12 samples must be uniformly biopsied from the prostate.

The imprecise detection and grading of conventional systematic biopsies results in problems including the underdiagnosis of clinically significant cancer and the overdiagnosis of clinically insignificant cancer, in turn resulting in overtreatment.

The physical burden placed on patients by collecting tissue samples from many sites is not the only issue. A negative pathology result, in which cancer is not detected, can result from a technical failure to biopsy the cancer lesion, necessitating repeated biopsy procedure and causing further physical and mental anguish (Figure 1).

The KOELIS Trinity®'s most attractive features

- Greater diagnostic precision means more patients served
- More patients served means greater bed utilization

Dr. Tamada: The KOELIS Trinity® is a prostate biopsy system with an elastic fusion design concept that integrates 3D transrectal ultrasound and multiparametric MRI (mpMRI). An MRI-targeted lesion is incorporated into fused 3D ultrasound images, leading to greater diagnostic precision through more accurate MRI-targeted biopsy.

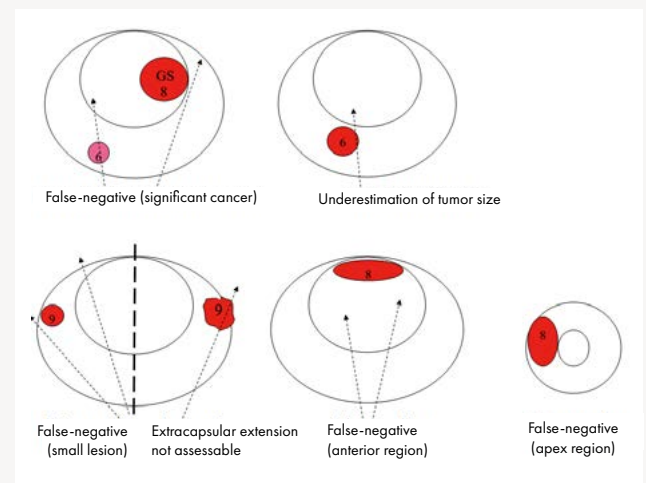
This higher diagnostic precision and the higher number of prostate biopsies it leads to are attractive to hospitals. Here at Kawasaki Medical School Hospital, a prostate biopsy entails a stay of 2 days and 1 night. More prostate biopsies mean greater bed utilization, which is a substantial plus for the hospital.

The hospital has conducted many retrospective studies on the clinical benefit of prostate MRI. The fact that we were unable to include systematic biopsy patients in certain studies was another reason why we wanted to purchase the KOELIS Trinity®.

1) Clinical Practice Guidelines for Prostate Cancer. 2018 Edition. Japanese Urological Association. Medical Review Co., Ltd. Tokyo, 2018.

Figure 1. Problems with systematic prostate biopsy

Systematic prostate biopsy can underdiagnose significant cancer and overdiagnose insignificant cancer, leading to excessive treatment.



Q. Which models did you consider in your search for a biopsy system? And what features of the KOELIS Trinity® were appealing to you?

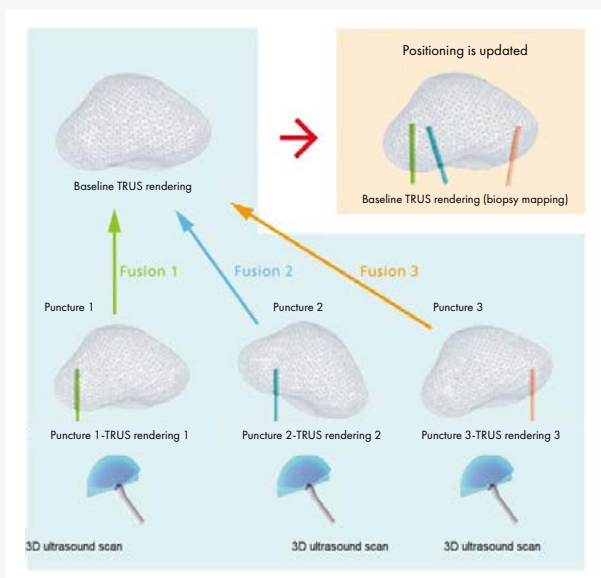
Dr. Tamada: We considered the KOELIS Trinity® and models from Company A and Company B in our selection process. We undertook an in-house demonstration with the KOELIS Trinity® and the Company A model on 12 and 6 patients, respectively. Dr. Miyaji and I went to other hospitals to see the Company A and B models and hear about how they are operated and about their diagnostic precision.

During our comparison of the systems, we noticed that the KOELIS Trinity® had numerous features. The most appealing feature was the ability to conduct more precise MRI-targeted biopsies with the KOELIS Trinity®'s elastic fusion technology. The 3D scanning capability of the KOELIS Trinity®'s 3D ultrasound probes lets you create a baseline 3D volume-rendered representation of the prostate before beginning the biopsy procedure. Another 3D rendering is created and fused with the baseline 3D rendering with each biopsy sampling, even after the biopsy procedure has started. The system displays an image that accurately reflects the locations of biopsies (Figure 2). The KOELIS Trinity® tracks changes in the shape of the prostate as it moves, automatically compensating for organ bending and deformation in the fusion process. The device is compact and easy to handle, and anesthesia is easily administered with local anal sphincter and periprostatic nerve block.

Figure 2. 3D ultrasound imaging and biopsy mapping of the prostate

A 3D scan of the prostate is taken before beginning the biopsy procedure to serve as a baseline 3D volume-rendered prostate representation.

A 3D scan is taken with each puncture and fused with the reference rendering to indicate biopsy positioning.



Why the hospital chose the KOELIS Trinity®

- Elastic fusion technology provides more accurate MRI lesion representation
- The KOELIS Trinity®'s 3D ultrasound probes track deformations of the prostate (OBT Fusion®)
- The KOELIS Trinity® is a compact, integrated ultrasound system

Q. How did you pitch the KOELIS Trinity® to hospital management?

Dr. Tamada: I worked closely with Dr. Miyaji and other urologists to formulate a presentation.

I started the presentation by discussing the findings from research we had conducted on prostate mpMRI here and then presented the workings of fusion biopsy systems used overseas, stressing why we needed the system. Other basic points I covered were the rising number of patients with prostate cancer in Japan, existing problems with systematic biopsy, the significance of prostate cancer biopsy, the capacity to detect significant cancer on mpMRI, specific procedures for MRI-targeted biopsies, and the PI-RADS criteria for MRI-based diagnosis.

I also shared a 12-case demonstration of the KOELIS Trinity®, showing how MRI-targeted biopsy with the KOELIS Trinity® detected cancer at false-negative locations in systematic biopsy and how the system allows highly precise grading (Figure 3).

Dr. Miyaji: I discussed the post-purchase procedures through prostate cancer diagnosis that I formulated with Urology and Radiology and worked to dispel management's concerns regarding costs by showing them revenue projections on how purchasing the KOELIS Trinity® would increase the number of prostate biopsies and robot-assisted radical prostatectomies (RARPs) we performed (Table 1).

Management concluded that purchasing the KOELIS Trinity® would lead to more prostate biopsies and RARPs, make us the first adopter in Okayama prefecture, and would help the hospital become a regional center for prostate cancer treatment. They decided to purchase the KOELIS Trinity® in August 2018.

Figure 3. Cases in KOELIS Trinity® demonstration

- a: A small tumor is revealed only on fusion biopsy
- b: Fusion biopsy Gleason score (GS) more accurately represents the diagnosed grade (prostatectomy GS) than that from systematic biopsy

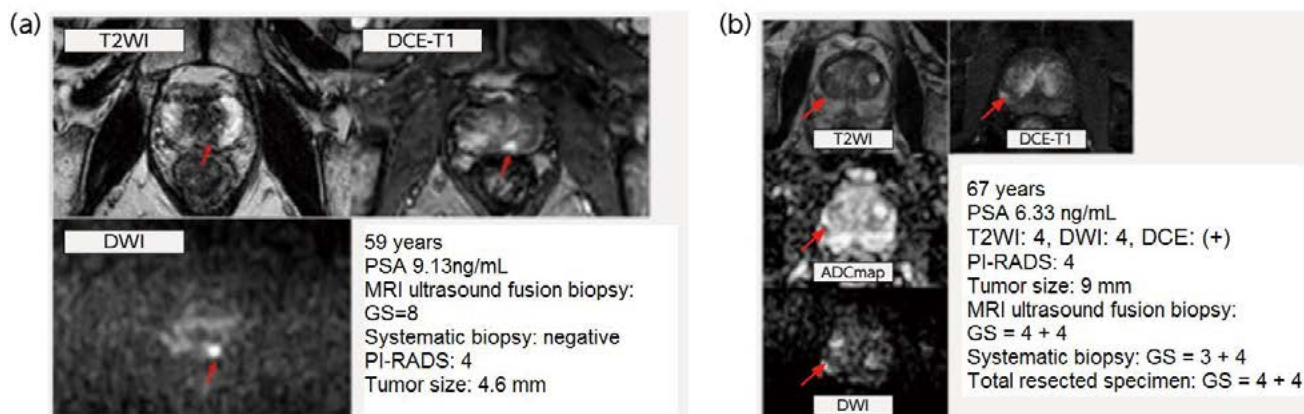


Table 1. Revenue projections

- Assumes that only patients with clinically significant MRI findings are biopsied
- Assumes that biopsy numbers increase 10% annually (20% in 2018 alone)
- Assumes a 20% year-over-year increase in prostatectomies (assuming 30% increase in 2018 and 25% increase in 2019)

Basic Items

Procedure name/cost	
MRI	¥30,000
Biopsy	¥100,000
LRP	¥1,400,000
RAR P	¥1,600,000

Trends in case numbers

	MRI	Biopsy	Surgery	Surgery	Proceeds	Increase
2014	200	131	42	32%	¥77,900,000	
2015	200	116	26	22%	¥54,900,000	
2016	200	97	35	36%	¥64,700,000	
2017	200	100	35	35%	¥65,000,000	
2018	200	120	46	38%	¥92,900,000	¥27,200,000
2019	240	132	58	44%	¥113,200,000	¥21,000,000
2020	250	145	73	50%	¥138,800,000	¥25,600,000
2021	260	160	88	55%	¥164,600,000	¥25,800,000
2022	270	176	106	60%	¥195,300,000	¥30,700,000
					Total	¥130,300,000

Q. How did patient numbers and biopsy numbers change after you purchased the KOELIS Trinity®?

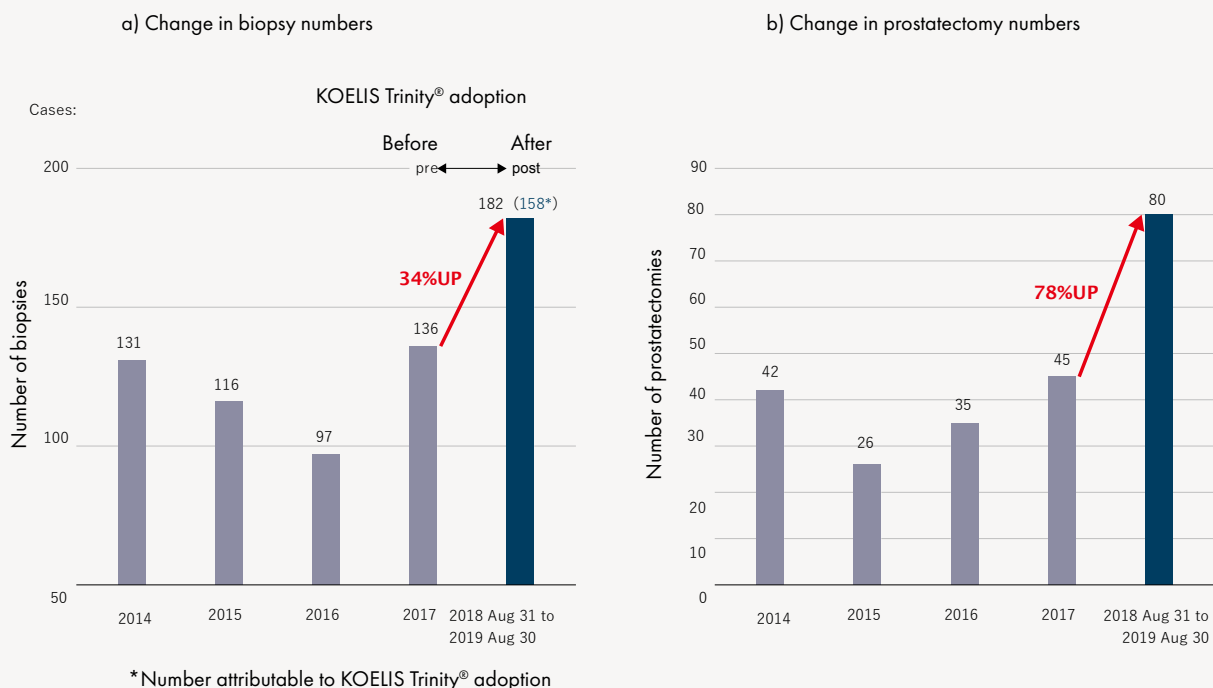
Dr. Tamada: Since we were the first adopter in Okayama prefecture, the purchase was mentioned in newspapers, websites, and regional magazines. I recall that after the purchase, more patients began to visit from Kagawa, Hyogo, and Osaka prefectures in addition to more patients from our traditional patient base in Okayama and Hiroshima prefectures. The public interest was evidently there, because many people attended the public lectures we offered after the purchase.

Dr. Miyaji: Actual biopsy numbers increased after the purchase. We performed 182 total biopsies over the 1-year period from KOELIS Trinity® adoption on August 31, 2018 to August 30, 2019. Of those, 158 (86.8%) were fusion biopsies performed using the KOELIS Trinity® (Figure 4a). I attribute this figure to referrals we got from nearby medical institutions that learned about our purchase in regional newspapers, public lectures, and regional medical conferences.

I am convinced that biopsy numbers increased because many urologists, troubled by the issues with conventional biopsy I mentioned earlier, found targeted biopsy with the KOELIS Trinity® system attractive, and because patients developed an appreciation for the benefits of the KOELIS Trinity®.

With this increase in biopsies came an increase in radical prostatectomies, from 45 to 80 (Figure 4b). This exceeded our initial projections, leaving management pleased.

Figure 4. Comparison of biopsy numbers (a) and prostatectomy numbers (b) before and after KOELIS Trinity® adoption



Q. What concrete benefits has the KOELIS Trinity[®] brought?

Dr. Tamada: The excellent performance of the elastic fusion technology and satisfying precision of the system lived up to our expectations. We compared the percentage of positive cores and the ratio of positive core length to tissue length in systematic biopsies (12 samples) and MRI-targeted biopsies (4–5 samples on average) performed with the KOELIS Trinity[®] in 135 patients with high PSA levels who showed positive findings on pre-biopsy MRI. These MRI-targeted biopsies exhibited a significantly higher percentage of positive cores for both overall and significant cancer (Figure 5), and positive core length was significantly longer (Figure 6). We have not calculated data on Gleason scores (GS), which is used for grading, but we have the impression that the scores for biopsy specimens and total prostatectomy specimens do not differ much. These figures convinced us that MRI-targeted biopsy with the KOELIS Trinity[®] provides better diagnostic efficiency than systematic biopsy, because it allows cancer to be detected with fewer samples that contain a greater proportion of cancer tissue.

We also made a discovery in terms of diagnostic imaging. The KOELIS Trinity[®] pinpoints prostate cancer directly beneath the capsule (sub-capsular lesion) and linear prostate cancer not defined in PI-RADS. We plan to submit a paper on these lesions.

Figure 5. Percentage of positive cores in KOELIS Trinity[®] biopsies

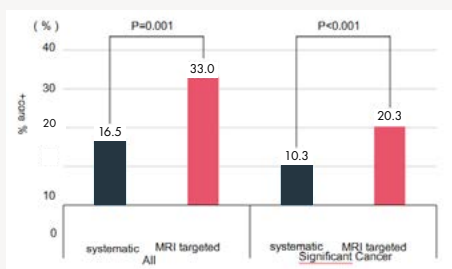
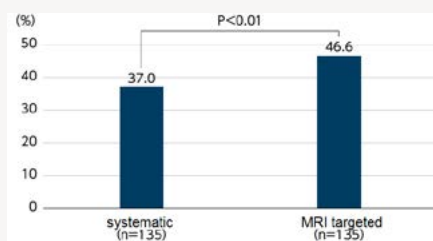


Figure 6. Positive core lengths in KOELIS[™] biopsies



Dr. Miyaji: Biopsy procedures for patients with cancerous findings in MRI here at the hospital now take a bit longer because we perform targeted biopsy in 2 locations for each lesion of a PI-RADS category of 3 or greater in addition to conventional systematic biopsy in 12 locations, but we are able to get patients in and out of the KOELIS Trinity[®] operating room in an average of 30 minutes. Less than 20 minutes is required for some patients. Overall, care is unaffected.

Reasons include:

- 1. Our targeted biopsy technique has improved with experience.
- 2. Radiology uploads MRI data into the KOELIS Trinity[®] before the biopsy procedure, so we can begin with the target lesion already input.
- 3. The patient now receives local anesthesia in the lithotomy position, eliminating the need to reposition the patient as in conventional caudal epidural block.

To maintain the quality of biopsy procedures, Dr. Tamada or I were present to supervise operators using the KOELIS Trinity[®] until they became familiar with the new system. We gradually increased the number of operators from 1 initially. Now 4 urologists perform biopsies with the KOELIS Trinity[®]. Typically, a physician experienced in systematic biopsies is able to smoothly perform the procedure after handling about 10 cases.

We had 3 patients showing a positive result from systematic biopsy who were false-negative in KOELIS Trinity[®] target biopsy, likely due to fusion errors. Since we encountered these 3 cases during the 3-month period after purchasing the KOELIS Trinity[®], we consider this as mostly a matter of overcoming the learning curve.

Benefits the KOELIS Trinity[®] has provided

- Improved detection capability, longer core length, and discovery of lesions with new shapes

Q. Could you tell me about any expectations you have for the KOELIS Trinity®?

Dr. Miyaji: It is my position that in low-risk patients, active surveillance is an effective way to prevent suffering and decreases in QOL caused by prostatectomy and radiotherapy. I think this approach should be actively used, especially for clinically insignificant cancer.

However, many urologists are reluctant to choose active surveillance, because the criteria for active surveillance are poorly defined and issues with monitoring procedures and the reliability of active surveillance remain.

If we find a close match in the Gleason scores of KOELIS Trinity®-targeted biopsy specimens and prostatectomy specimens in Japanese patients, KOELIS Trinity®-targeted biopsy findings could be used as a criterion for selecting active surveillance.

Q. What do you think the future holds?

Dr. Tamada: I think we'll see an increase in the number of relatively young prostate cancer patients. Our hospital wants to adopt the option of focal therapy, which prioritizes preservation of prostate function. Although many treatment approaches are available for focal therapy, we plan to use our experience and expertise to offer local radiotherapy. I also expect that more radiologists will be tasked with interpreting MRI scans, which are now standard for patients prior to prostate biopsy. The Japan Radiological Society plans to offer hands-on workshops on MRI reading. Improving the MRI interpreting skills of radiologists is an urgent need. I intend to continue honing my skills here.

Dr. Miyaji: The greater number of biopsies and per-patient biopsy samples we've had since we purchased the KOELIS Trinity® has increased the workload of our pathologists. I think we need to consider going with MRI targeted biopsy only or reducing the number of biopsy samples from systematic biopsies to reduce their workload and the physical burden on patients.



Nonproprietary names: General-purpose ultrasound diagnostic imaging device / ex vivo handheld ultrasound diagnostic probe / ultrasound rectal probe for diagnosis / mounting device for ultrasound probe biopsy needles

Brand name: KOELIS Trinity® Diagnostic Imaging Workstation

License No.: 227AHBZX00038000

Manufacturer and seller: AMCO Inc.



Dr. Tsutomu Tamada

Director, Department of Radiology, Kawasaki Medical School Hospital

Curriculum Vitae

- May, 1993 Appointed as Resident, Department of Radiology, Kawasaki Medical School (KMS) Hospital
- April, 1995 Appointed as Clinical Assistant of Department of Radiology of KMS and Senior Resident (KMS) Hospital
- April, 1997 Began coursework at KMS Graduate School (clinical physiology and nuclear medicine)
- March, 2001 Completed coursework at KMS Graduate School
- April, 2002 Began serving as Lecturer in Department of Radiology at KMS and Deputy Head Physician at KMS Hospital.
- October, 2009 Began serving as Associate Professor of Department of Radiology at KMS and Deputy Department Director (KMS) Hospital
- April, 2016 Studied abroad as a visiting researcher at NYU Langone Medical Center in New York
- to March, 2017
- April, 2018 Serving as Professor of Department of Radiology at KMS and Department Director at KMS Hospital

Qualifications

- 2001 - Radiological Diagnosis Specialist of the Japan Radiological Society
- 2002 - Undertook Postgraduate Clinical Instructor Training Course (KMS Hospital)
- 2011 - Certified as Lung Cancer CT Screening Physician
- 2017 - Certified as Radiology Training Instructor

Memberships

- Radiological Society of North America
- International Society for Magnetic Resonance in Medicine
- European Society of Urogenital Radiology
- Japan Radiological Society delegate
- Japanese Society for Magnetic Resonance in Medicine delegate
- Japanese Urological Association: Member of the Committee on the Revision of the General Rules for Clinical and Pathological Studies on Prostate Cancer Handling Criteria, Member of the Authoring Committee for Penile Cancer Treatment Guidelines, Member of the Working Group for Prostate Focal Therapy Guidelines
- Japanese Society of Abdominal Radiology: Delegate

Specializations

- Abdominal Radiology, Genitourinary MRI Diagnosis



Dr. Yoshiyuki Miyaji

Director, Department of Urology, Kawasaki Medical School Hospital

Curriculum Vitae

March, 1988	Graduated from Okayama University School of Medicine
June, 1988	Began residency at Okayama University Hospital
July, 1989	Began residency at Department of Urology, Kure Kyosai Hospital
November, 1990	Began serving as Clinical Fellow, Department of Urology, Onomichi Municipal Hospital
July, 1992	Began serving as Clinical Fellow, Department of Urology, Kochi Municipal Central Hospital
July, 1994	Began serving as Clinical Fellow, Department of Urology, Okayama University Hospital
April, 1997	Began serving as Assistant Professor, Urologist, Okayama University Hospital
April, 1998	Began serving as Chief of Department of Urology, National Hospital Organization Iwakuni Clinical Center
April, 2006	Began serving as Instructor, Department of Urology, Kawasaki Medical School (KMS)
April, 2007	Began serving as Associate Professor, Department of Urology, KMS and Deputy Department Director, Department of Urology, KMS Hospital
April, 2019	Began serving as Specially Appointed Professor, Department of Urology, KMS and Department Director, Department of Urology, KMS Hospital

Posts held

- Trustee of the Japanese Urological Association
- Delegate of the West Japan Urological Association
- Trustee of the Japan Society of Endourology

Qualifications

- Japanese Board Certified Urologist
- Japanese Board Certified Instructor by JUA
- Board Certified Endocrinologist by JES
- Certified in Cancer Treatment by the Japanese Board of Cancer Therapy
- Endoscopic Surgical Skill Qualification System in Urological Laparoscopy
- Technical Certification in Urological Endoscopy by the Japan Society for Endoscopic Surgery
- Proctor Qualification System for Urological Robotic Surgery

Memberships

- Japanese Urological Association,
- Japanese Cancer Association,
- Japan Society of Clinical Oncology,
- Japanese Society of Endourology,
- Japan Society for Endoscopic Surgery,
- Japanese Society of Female Pelvic Floor Medicine,
- Japan Association of Endocrine Surgery,
- Japan Society of Urologic Oncology,
- Japan Endocrine Society,
- Japanese Society for Sexual Medicine, Japanese Society on Urolithiasis Research,
- Japanese Continence Society,
- West Japan Urological Association,
- Japanese Society of Renal Cancer,
- American Urological Association (AUA),
- Endourological Society