KSUM 2026 — Categorical Course 2

Current Devices and Techniques of MR-US Fusion Prostate Biopsy

Organ-Based Tracking Elastic Fusion

Min Je Kim

Department of Radiology, U-Well Urology Clinic

Declaration of Conflicts of Interest

This lecture is sponsored by KOELIS (Meylan, France). The speaker has received research support from KOELIS for the study presented herein.

1. Introduction

Multiparametric MRI (mpMRI) has transformed prostate cancer diagnosis by enabling visualization of suspicious lesions before biopsy. The PRECISION trial (Kasivisvanathan et al., NEJM 2018) established the superiority of MRI-targeted biopsy over standard TRUS-guided biopsy, detecting clinically significant cancer in 38% versus 26% of men (p=0.005) while reducing the diagnosis of clinically insignificant cancer.

However, once a target is identified on MRI, the physician must accurately translate this information to the biopsy needle at the time of the procedure. As Cornud et al. (Abdom Imaging 2013) stated, an accurate TRUS–MRI image registration requires taking into account prostate deformation and motion inherent to TRUS probe insertion and prostate scanning, which have strong implications in the accuracy of the registration process. The precision of this fusion directly determines the cancer detection rate.

This lecture examines the technical principles and clinical evidence for Organ-Based Tracking (OBT) elastic fusion, and explains how it differs from other fusion approaches at a fundamental level.

2. Classification of MRI-US Fusion Methods

MRI-US fusion systems differ along two independent axes: the **registration algorithm** (rigid vs. elastic) and the **tracking method** (probe-based vs. organ-based). It is critical to recognize that these are separate concepts: **elastic registration ≠ organ-based tracking.** A system may employ elastic registration while still relying on probe-based tracking, leaving it vulnerable to real-time organ motion during the procedure.

2.1. Cognitive Fusion

Cognitive fusion relies on the operator mentally overlaying MRI findings onto the real-time ultrasound image. As Cornud et al. (2013) noted, differences in slice orientation between strictly axial MRI slices and the oblique scanning plane of end-fire TRUS probes make it inherently challenging to match the needle tract with the target. Its accuracy depends entirely on the operator's spatial reasoning, and several studies have produced discrepant results. While cognitive fusion may add value for anterior lesions in large-volume glands, its overall reproducibility remains limited.

2.2. Sensor-Based Fusion with Rigid Registration

Sensor-based systems perform rigid geometric registration after paired landmarks are selected on both TRUS and MRI. A navigation device (typically electromagnetic) computes the spatial coordinates of the US probe via a transmitter placed near the patient and a receiver on the TRUS probe. Once TRUS–MRI overlay is deemed acceptable, biopsies are performed toward the registered image, *assuming that no patient movement and no displacement or deformation of the prostate by the TRUS probe occur* (Cornud et al. 2013).

The critical limitations are well established. First, the prostate shape on TRUS and MRI is inherently different; MRI images are simply superimposed onto US images and the prostate contour is not deformed during registration. Second, sensor-based systems only track the TRUS probe, not the prostate itself. They do not account for anterior displacement of the gland during TRUS scanning, leading to loss of overlay. When registration has to be repeated, it is subject to the same errors as the initial attempt. As a result, the topographic precision of rigid registration **may not exceed 5–10 mm** (Cornud et al. 2013).

2.3. Sensor-Based Fusion with Elastic Registration

Several systems incorporate elastic registration algorithms while still using probe-based tracking. These include UroNav (Philips, EM probe tracking), ARTEMIS (Eigen/Hitachi, semi-robotic mechanical arm with position-encoded joints), BiopSee (MedCom, mechanical stepper or EM), and BioJet (D&K Technologies/BK Medical, mechanical stepper). All support elastic or semi-elastic registration to compensate for shape differences between MRI and ultrasound at the time of initial alignment.

However, a fundamental limitation remains: these systems track the **probe**, not the **organ**. As Cornud et al. (2013) explained regarding the ARTEMIS system, surface-based registration *requires total patient immobility to achieve a reliable registration*. Furthermore, the probe only performs an initial 3D acquisition during biopsy, and the 2D scanning during the tracking phase cannot be registered in real time to the reference volume. This means that elastic registration compensates for shape differences at the *moment of initial alignment*, but does not continuously update to reflect real-time organ motion during the biopsy session.

2.4. Organ-Based Tracking (OBT) with Elastic Registration

OBT fusion, uniquely implemented by KOELIS in the Trinity® system, represents a fundamentally different paradigm. As Cornud et al. (2013) described, the principle differs from sensor-based registration because the computer tracks the organ itself, not the TRUS probe. No electromagnetic field generator, mechanical arm, or stepper device is required. Only image information is used to determine the position of the prostate.

OBT applies organ deformation in both the planning and guiding phases of the biopsy. Moreover, after each biopsy core, a new 3D TRUS volume is acquired and re-registered to the reference, continuously updating the spatial model. The detailed technical process is described in Section 3.

Table 1. Comparison of MRI-US Fusion Systems by Registration and Tracking Method

System	Registration	Tracking Method	OBT	External Sensor
KOELIS Trinity®	**Elastic only**	**3D US image-based organ tracking**	**Yes**	**Not required**
UroNav (Philips)	Rigid + Elastic	EM probe tracking	No	EM field generator
ARTEMIS (Eigen)	Rigid + Elastic	Mechanical robotic arm	No	Encoded arm joints
BiopSee (MedCom)	Rigid + Elastic	Mechanical stepper / EM	No	Stepper or EM
BioJet (D&K/BK)	Elastic + Rigid	Mechanical stepper	No	Encoded stepper

EM = Electromagnetic; OBT = Organ-Based Tracking

3. Technical Principles of OBT Elastic Fusion

The OBT fusion process consists of two major phases: the Planning Phase (MRI–TRUS geometric registration) and the Guiding Phase (TRUS–TRUS monomodal registration). Each phase employs a progressive, multi-step approach that transitions from rigid to elastic registration, incrementally improving accuracy at each step. The following description is based on the detailed technical account by Cornud et al. (Abdom Imaging 2013).

3.1. Planning Phase: MRI–TRUS Geometric Registration

The planning phase combines three sequential steps to achieve the final overlay of 3D-TRUS (reference volume) and MRI volumes. The 3D TRUS acquisition is performed with a motorized probe; the acquisition is automatic and does not require manual sweeping, thereby avoiding organ displacement during image capture.

Step 1: Landmark-Based Rigid Registration

Three anatomical landmarks (typically apex, base, and posterior surface) are placed on both the MRI and TRUS volumes. This is comparable to the initial step performed in sensor-based systems. The mismatch at this stage is approximately 3.6 ± 2.2 mm (Brolis et al., data presented in Cornud et al. 2013, n=49, 112 landmark pairs). Like sensor-based registration, this step is sensitive to landmark identification errors.

Step 2: Multiple Point-Based Rigid Registration (Surface-Based)

This step, which is **absent in sensor-based systems**, utilizes a shape-statistics-based semi-automatic prostate surface delineation. The operator selects 10–20 points on the prostate contour. A statistical shape model then interpolates these points to generate a **prostate mesh of approximately 3,000 surface points** defining the 3D prostate shape on each imaging modality. Rigid registration is then performed using all 3,000 point pairs, substantially increasing accuracy and reproducibility compared to the 3-point approach. After this step, the mismatch decreases to 2.1 ± 1.0 mm.

Step 3: Elastic 3D Organ-Based Registration

The 3,000-point surface-based registration still does not compensate for prostate deformation caused by rectal probe insertion or prostate displacement during scanning. To address this, an elastic deformation algorithm minimizes the distance between each corresponding point of the MRI and TRUS meshes. Critically, this deformation is applied **both at the surface and in the inner volume of the shape and its corresponding structures**. After elastic registration, the mismatch decreases further to **1.7 ± 0.7 mm**. In the worst 10% of cases, the initial error of 7.7 ± 2.8 mm was reduced to 3.5 ± 1.7 mm. The single worst case with an initial error of 15.1 mm was reduced to 2.6 mm — dividing the initial error by approximately six.

3.2. Guiding Phase: TRUS–TRUS Monomodal Registration

Once the planning phase is complete, the MRI target has been mapped onto the TRUS reference volume. During the actual biopsy, the system must now track the prostate in real time as it moves and deforms. This is achieved through **TRUS–TRUS monomodal voxel-based (iconic) registration** — a fundamentally different approach from the geometric MRI–TRUS registration of the planning phase. Before each biopsy core, a new 3D TRUS volume is acquired and automatically registered to the reference TRUS volume from the planning phase.

Step A: Plausible Position Estimation

A computational model estimates the plausible position of the prostate within the newly acquired 3D TRUS volume. This initial estimate provides a rough alignment with the reference volume.

Step B: 6-DOF Rigid Registration

A more general rigid registration model with six degrees of freedom (three translational + three rotational) refines the initial estimation, operating on the entire TRUS volume.

Step C: Voxel-Based Elastic Registration

In the final step, an elasticity constraint is applied to obtain **thousands of local displacements in the neighborhood of each voxel**. The algorithm computes a spatial transformation of one volume until maximal similarity with the other is achieved. This process takes approximately **4 seconds** after each acquisition — not real-time, but rapid enough to be clinically practical.

The accuracy of this automatic monomodal 3D-TRUS fusion was evaluated by Baumann et al. on 40 patients using 687 fiducials placed in small prostatic structures (calcifications, cysts). After the two rigid steps, targeting error decreased tenfold. Adding elastic deformation yielded a final accuracy of **0.8 ± 0.5 mm**. In the worst 10% of cases (mean initial error 17.9 mm), the process reduced the error to **2.0 mm (89% reduction)**.

3.3. Virtual Biopsy and Needle Verification

OBT provides a unique quality control mechanism during the biopsy procedure. If the MRI target is visible on TRUS, the biopsy is fired, the needle is left in place, a 3D TRUS scan is acquired, and TRUS–TRUS registration confirms whether the needle traversed the target — verifiable on both TRUS and MRI overlays.

If the target is **not visible on TRUS** (which is common for isoechoic lesions), a **virtual biopsy** is performed: the operator aims the needle at the presumed TRUS location of the target without firing the biopsy gun. After 3D TRUS acquisition and registration, the system displays whether the virtual trajectory passes through the target. If not, the operator adjusts the direction and

repeats the virtual biopsy until the trajectory is confirmed. Only then is the actual biopsy fired. This is particularly valuable for small lesions (<1 cm) where a few millimeters of error would mean missing the target entirely.

3.4. Clinical Significance of Submillimeter Accuracy

van de Ven et al. (Eur Radiol 2012) demonstrated that a spatial alignment of **1.9 mm** was necessary for correct grading of 95% of tumors when targeting high-grade cancer components. The guiding phase accuracy of OBT (0.8 ± 0.5 mm) comfortably meets this threshold. By contrast, sensor-based rigid registration precision of 5–10 mm significantly exceeds it, implying that targeting errors with probe-based systems may compromise histological grading accuracy.

As Cornud et al. (2013) concluded: organ-based registration may be preferred to sensor-based registration as the former has the advantage of being robust with respect to patient movements. Because organ-based registration applies an organ deformation in both the planning and the guiding phase of the biopsy, this technology represents currently the state of the art of TRUS–MRI image registration.

4. Clinical Evidence for OBT Elastic Fusion

4.1. Precision: Cognitive vs. Elastic Fusion

Cornud et al. (Radiology 2018) prospectively compared cognitive and OBT elastic fusion targeting accuracy in 88 patients. To quantify precision, they measured the distance from the center of each biopsy core to the center of the MRI target (dCC — the “miss distance”), and the distance from the core to the target surface (dCS — whether the core landed inside or outside the lesion; a negative dCS indicates the core is within the target).

Elastic fusion achieved a mean dCC of 2.8 mm versus 7.1 mm for cognitive fusion ($p<0.0001$). At the prostate base, cognitive fusion showed a dCC of 8.4 mm versus 3.6 mm for elastic fusion. On-target cores detected cancer 46.5% of the time versus 17.6% for off-target cores ($p=0.03$). At the per-patient level, elastic fusion detected cancer in 90.9% of cancer-positive patients versus 70.5% with cognitive fusion ($p=0.03$). Approximately 1 in 5 cancers missed by cognitive fusion were successfully sampled by elastic fusion.

4.2. Multicenter Real-World Detection Rates

Oderda et al. (Int J Urol 2018) reported a multicenter study of 2,115 patients across 15 institutions in four European countries using KOELIS elastic fusion. The cancer detection rate was 58% for all cancers and 43% for clinically significant prostate cancer. PI-RADS-stratified detection rates were 31%, 66%, and 89% for PI-RADS 3, 4, and 5, respectively. Additional random cores improved detection by 13% for all cancers and 9% for clinically significant cancer ($p<0.001$ for both).

4.3. 10-Year Longitudinal Experience

Lenfant et al. (World J Urol 2022) reported on 2,942 men over 10 years at Hôpital Pitié-Salpêtrière, Paris. Clinically significant cancer detection increased 2.5-fold from 23% to 58%. MRI-targeted biopsy patients had significantly higher detection rates for both overall cancer (67% vs 52%) and clinically significant cancer (40% vs 32%) compared to systematic biopsy alone ($p<0.001$). Clinically insignificant cancer decreased to below 20% after excluding negative

MRI patients from biopsy.

4.4. Transperineal Biopsy Under Local Anesthesia

Jacewicz et al. (Urol Oncol 2020) reported on 377 patients undergoing transperineal MRI-TRUS fusion biopsy under local anesthesia (Oslo and Berlin). Overall detection was 64% for any cancer and 52% for clinically significant cancer, with PI-RADS-stratified rates of 30%, 70%, and 94% for PI-RADS 3, 4, and 5. Median pain score was 2/10 and the infection rate was 0.5%.

Günzel et al. (World J Urol 2021) demonstrated feasibility without standard antibiotic prophylaxis in 621 patients (PI-RADS ≥3). Combined detection was 67% for any cancer and 52% for clinically significant cancer. Only 0.6% developed post-biopsy infection.

4.5. Resolving Discordant MRI-Biopsy Findings

Bajeot et al. (Eur Urol Onco 2021) reported that 23.7% of 558 patients had discordant findings between mpMRI and initial transrectal biopsy. Reassessment with OBT-guided transperineal targeted biopsy using fewer cores (7 vs 14, $p<0.0001$) yielded more cancer tissue (56 vs 42.5 mm, $p=0.0003$). As a result, 40% of patients initially recommended for follow-up and 49% for active surveillance were reclassified to surgery or radiation therapy.

4.6. Active Surveillance and Focal Therapy

The 3D mapping capability enables precise re-visiting of previously biopsied sites. Ukimura et al. (The Prostate 2015) demonstrated 86% per-lesion re-sampling accuracy using 3D-documented biopsy mapping during active surveillance. Fujihara et al. (BJUI Inter 2020) showed that PI-RADS ≥3 and PSA density on surveillance MRI were independent predictors of pathological progression.

For focal therapy, Peltier et al. (Eur Urol Open Sci 2020) reported feasibility of microwave ablation guided by OBT fusion in an ablate-and-resect pilot study, with well-delimited ablation zones on whole-mount histology. Crouzet et al. (FTI 2019) demonstrated successful targeted focal cryotherapy using the KOELIS Trinity® 3D cartography for planning, guidance, and monitoring.

5. Summary of Key Advantages of OBT Elastic Fusion

Organ tracking, not probe tracking: The system monitors the prostate itself through 3D image matching, making it inherently robust to patient movement, probe repositioning, and progressive organ deformation.

Two-phase elastic deformation: Elastic registration is applied in both the planning phase (MRI–TRUS) and guiding phase (TRUS–TRUS), addressing the full spectrum of shape differences and real-time motion.

Continuous re-registration: Unlike probe-based systems that perform a one-time alignment, OBT re-registers after every biopsy core, maintaining fusion accuracy throughout the entire session even as the prostate progressively deforms.

Submillimeter guiding accuracy: The TRUS–TRUS monomodal registration achieves 0.8 ± 0.5 mm accuracy (Baumann et al.), well within the 1.9 mm threshold required for correct tumor

grading (van de Ven et al.).

Virtual biopsy capability: Pre-fire trajectory verification ensures the needle will traverse the target before the biopsy gun is activated, particularly valuable for TRUS-invisible and small lesions.

No external tracking hardware: No EM field generator, mechanical arm, or stepper device is required, reducing setup complexity and eliminating susceptibility to electromagnetic interference.

Real-time 3D needle tracking: Every biopsy trajectory is recorded in a 3D prostate map, providing quality control, gap identification, and comprehensive documentation.

Multimodal fusion: Beyond MRI-US, the system supports PET/CT-US fusion (PSMA-PET, Choline-PET), expanding targeted biopsy options for MRI-invisible lesions.

Versatile approach: Both transrectal and transperineal biopsies are supported, including free-hand transperineal under local anesthesia.

Longitudinal tracking (2nd Look™): 86% per-lesion re-sampling accuracy enables precise serial monitoring during active surveillance (Ukimura et al. 2015).

Focal therapy guidance: The same 3D cartography platform extends to treatment planning, energy delivery guidance, and post-treatment follow-up.

6. Conclusion

A critical conceptual distinction must be recognized: **elastic registration and organ-based tracking are independent concepts.** Several commercially available systems offer elastic registration algorithms while still relying on probe-based tracking. These systems compensate for shape differences between MRI and ultrasound at the time of initial alignment, but do not continuously monitor or compensate for real-time organ motion during the procedure. Only OBT, as implemented in the KOELIS Trinity®, combines elastic deformable registration with continuous organ-based tracking to address the full spectrum of targeting error.

The technical architecture of OBT — a progressive multi-step pipeline from landmark-based rigid alignment through 3,000-point surface registration to elastic deformation in the planning phase, followed by voxel-based iconic tracking with elastic constraints in the guiding phase — achieves submillimeter spatial accuracy that meets the stringent requirements for correct tumor grading. This is supported by a robust body of clinical evidence spanning precision studies, large multicenter series, and 10-year longitudinal data.

Beyond initial diagnosis, the 3D mapping and documentation capabilities extend the platform’s utility into active surveillance monitoring and focal therapy guidance, making OBT elastic fusion a comprehensive tool for personalized prostate cancer management from diagnosis through treatment.

References

1. Kasivisvanathan V et al. MRI-targeted or standard biopsy for prostate-cancer diagnosis. NEJM 2018.

2. Cornud F et al. TRUS-MRI image registration: a paradigm shift in the diagnosis of significant prostate cancer. Abdom Imaging 2013.

3. Cornud F et al. Precision matters in MR imaging-targeted prostate biopsies: evidence from a prospective study of cognitive and elastic fusion registration transrectal biopsies. Radiology 2018.

4. Baumann M et al. Prostate biopsy tracking with deformation estimation. Med Image Anal 2012.

5. van de Ven WJ et al. Simulated required accuracy of image registration tools for targeting high-grade cancer components with prostate biopsies. Eur Radiol 2012.

6. Oderda M et al. Accuracy of elastic fusion biopsy in daily practice: results of a multicenter study of 2115 patients. Int J Urol 2018.

7. Rouvière O et al. Use of prostate systematic and targeted biopsy on the basis of multiparametric MRI in biopsy-naive patients (MRI-FIRST). Lancet Oncol 2018.

8. Lenfant L et al. Dynamic evaluation of MRI-targeted, systematic and combined biopsy for prostate cancer diagnosis through 10 years of practice in a single institution. World J Urol 2022.

9. Jacewicz M et al. Multicenter transperineal MRI-TRUS fusion guided outpatient clinic prostate biopsies under local anesthesia. Urol Oncol 2020.

10. Günzel K et al. Infection rate and complications after 621 transperineal MRI-TRUS fusion biopsies in local anesthesia without standard antibiotic prophylaxis. World J Urol 2021.

11. Bajeot A-N et al. Managing discordant findings between mpMRI and transrectal MRI-directed prostate biopsy — the key role of MRI-directed transperineal biopsy. Eur Urol Onco 2021.

12. Ukimura O et al. A novel technique using 3D documented biopsy mapping allows precise re-visiting of prostate cancer foci with serial surveillance of CCP gene panel. The Prostate 2015.

13. Fujihara A et al. Multiparametric MRI facilitates reclassification during active surveillance for prostate cancer. BJUI Inter 2020.

14. Peltier A et al. A novel focal therapy — microwave ablation under OBT fusion in patients with localized prostate cancer: preliminary results of FOSTINE 01b pilot study. Eur Urol Open Sci 2020.

15. Crouzet S et al. 3D targeted focal cryotherapy treatment: case report of the first procedure at our institution. Poster FTI 2019.

16. Mozer P et al. First round of targeted biopsies using MRI/US fusion compared with conventional TRUS-guided biopsies for the diagnosis of localised prostate cancer. BJUI 2014.

17. Baco E et al. A randomized controlled trial to assess and compare the outcomes of two-core prostate biopsy guided by fused MR and TRUS images and traditional 12-core systematic biopsy. Eur Urol 2016.

18. Kaneko M et al. Techniques and outcomes of MRI-TRUS fusion prostate biopsy. Current Urology Report 2021.

19. Ploussard G et al. Performance of systematic, MRI-targeted biopsies alone or in combination for the prediction of unfavourable disease in MRI-positive low-risk PCa patients eligible for active surveillance. World J Urol 2019.

20. Portalez D et al. Validation of the ESUR scoring system for prostate cancer diagnosis on multiparametric MRI in a cohort of repeat biopsy patients. Eur Urol 2012.