User's Voice

Transperineal MRI-TRUS fusion guided prostate biopsy under local anaesthesia without an antibiotic prophylaxis

Development and implementation of a new technique.

Dr. Karsten Günzel

Passionate Urologist

Department of Urology, Vivantes Klinikum
Am Urban, Berlin

Speciality: Transperineal MRI/US fusion biopsies, Laser enucleations, Focal therapy

Biopsies per year: > 800

Biopsy device: KOELIS Trinity®

Interview

Q. Do you need a fusion system in your modern urology practice?

Dr. Günzel: The implementation of multiparametric MRI in the diagnosis of prostate carcinoma was a paradigm shift. Since then, prostate carcinoma can be visualised. Furthermore, MRI/ultrasound fusion biopsies improve the detection of prostate cancer. Therefore, an accurate primary diagnosis with a robust fusion system is the prerequisite for individualised treatment planning (active surveillance, focal therapy, radiotherapy, and prostatectomy).

Q. What are your requirements/expectations of a fusion system?

Dr. Günzel: The most important requirement for a fusion system is an accurate fusion of MRI and ultrasound sequences. Two types of fusion (sensor-based or organ-based) are available for this purpose. For sensor-based fusion, the movement of the ultrasound probe is tracked mechanically or in an electromagnetic field and is transmitted to the MRI. For organ-based fusion, the prostate motion tracking is based on the full TRUS image of the prostate. During a biopsy, the fusion must be resistant to patient movement. In addition, a fusion system should be as mobile and flexible as possible. Needle tracking is also crucial to create clear and reproducible biopsy protocols. Finally, after a biopsy, documentation is essential.

Q. What are the advantages of KOELIS Trinity®?

Dr. Günzel: The KOELIS Trinity® system combines the features mentioned above. It is a flexible all-in-one system (ultrasound + fusion), which uses an accurate 3D probe and a unique organ-based fusion (OBT fusion®). The organ-based fusion for transrectal and transperineal biopsies ensures high accuracy and is not influenced by patient movement. In addition, needle tracking allows the mapping of the prostate with well-structured biopsy protocols.

What is prostate Cartography?

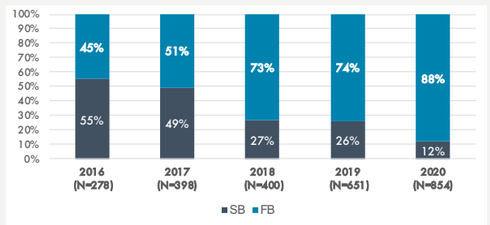
Needle Tracking documents the biopsies in a 3D model of the prostate where all cores are recorded. The biopsies can be represented in different MRI sequences (DWI, T2), and the location of the biopsies can be accurately verified during the biopsy procedure. Furthermore, the histological findings can be included in the biopsy protocol, and the cancer cores are marked in colour. This creates a 3D map of the prostate, including the areas where carcinoma has been found. This mapping helps to visualise the location of the tumour and simplifies a re-biopsy (2nd Look™) and the planning of further treatment.

The evolution of transperineal MRI-TRUS fusion guided prostate biopsy under local anaesthesia without antibiotic prophylaxis

In the beginning...

We all started with systematic biopsies (SB). Over the years, mpMRI has increasingly become part of our daily work. I began with cognitive fusion biopsies. After that, I used an ultrasound system with a sensor-based image fusion. Finding the same slices at the same angle in MRI and ultrasound continued to be a cognitive task with some imprecision. Nevertheless, MRI-TRUS fusion-guided prostate biopsy (MRI/TRUS FB) has become increasingly common.

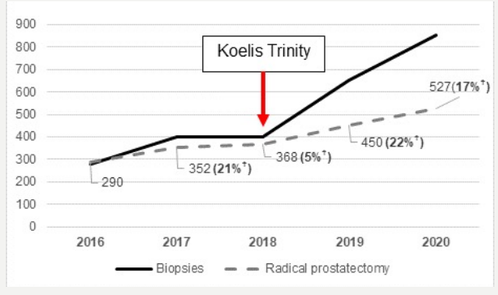
Development of SB vs. MRI/TRUS FB



After innovation...

In order to meet the increasing performance requirements of a FB, the new fusion system (KOELIS Trinity®) was implemented in our hospital in late 2018. Thanks to the marketing activities relating to the new system and the optimisation of the biopsy and patient protocols through needle tracking, we were again able to significantly increase the number of cases. So naturally, with the increase in biopsy cases, the number of radical prostatectomy cases has increased also.

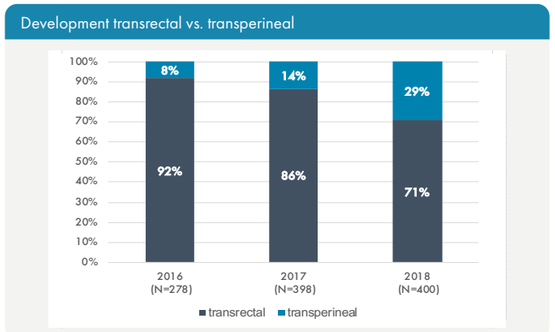
Development of prostate biopsy cases



Transrectal vs Transperineal?

With the KOELIS Trinity®, transrectal and transperineal biopsies are possible. I started with transrectal biopsies. However, due to the increasing resistance of intestinal bacteria, the difficult choice of perioperative antibiotic prophylaxis, and a postoperative infection rate of 4% (N=460), the perineal approach became paramount.

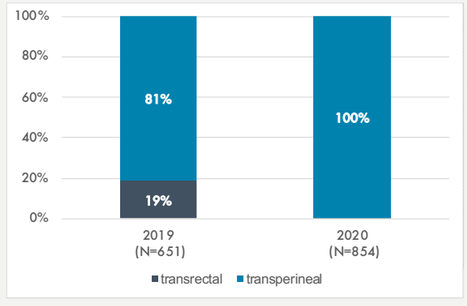
Development transrectal vs. transperineal



Local anaesthesia vs. General anaesthesia?

Performing transperineal biopsies under general anaesthesia reduced the possibility of broad utilization. Therefore, only with the implementation of local anaesthesia for transperineal biopsies was TREXIT made possible in April 2019. Since then, no transrectal biopsies have been performed in our hospital. With a median pain level of 2 (pain scale 0-10, N=1002), transperineal biopsy under local anaesthesia is well tolerated.

Development transrectal vs. transperineal

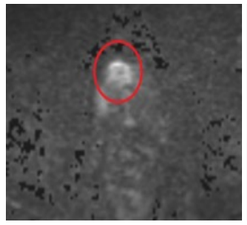
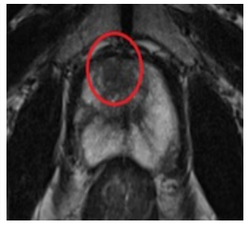


Antibiotic vs. No Antibiotic?

According to EAU guidelines, antibiotic prophylaxis is recommended for performing transperineal biopsies. However, as part of a prospective study, we avoided standard antibiotic prophylaxis for transperineal biopsies. As a result, only 98 of 879 patients received antibiotic prophylaxis due to urine suspected of infection or their co-morbidities. Nevertheless, we reduced our postoperative infection rate to 0.7% (6/879). A prospective, randomised-controlled, single-blind clinical trial is currently underway for further evaluation of antibiotic prophylaxis through transperineal biopsy.

The transperineal MRI-TRUS fusion-guided prostate biopsy under local anaesthesia without antibiotic prophylaxis is feasible, safe, effective, and well-tolerated.

My way of doing the biopsy – step by step

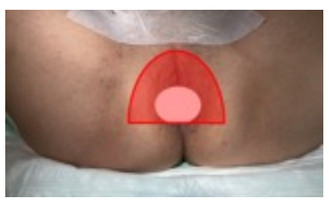
Patient:
- 68 years old
- PSA: 13.3ng/ml
- Prostate-volume: 35ml
- MRI: PI-RADS 5 ventral apex to mid

26.10.2020 (one day before the biopsy)

Pre-biopsy preparation of the patient:
- Documentation of the anamnesis
- Review of the biopsy indication
- Urine and blood tests
- Informed consent for biopsy
- Import of the MRI sequences (axial T2, DWI) and marking of the suspicious lesions


27.10.2020 (day of biopsy, outpatient case)

Room setting, equipment, and staff
- KOELIS Trinity®
- Steady Pro™
- Side-fire probe
- linear grid
- Staff: doctor + assistant



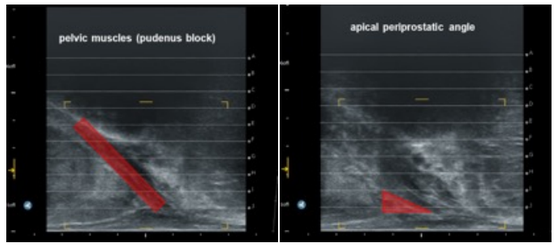
8.00 am
- the awake patient is placed in the lithotomy position
- disinfection of the perineal skin with Octenisept®

8.03 am

Starting with the local anaesthesia

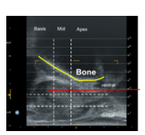
...of the perineal skin
- 20ml 0,5% Lidocaine
- 27G subcutaneous needle

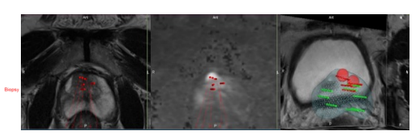
...of the deep perineal tissue
- 20ml 1% Lidocaine
- 22G spinal needle (17.8cm)
- Infiltration of the pelvic muscles and the apical periprostatic angle on both sides



8.06 am
- Preparing the fusion of TRUS and MRI
- 3D ultrasound (US) imaging and contouring of the prostate
- Comparison of the volume of the 3D model in the MRI and the US (difference < 5 ml indicates a high accuracy)
- Elastic fusion of MRI and US

8.11 am
- At first, performing targeted biopsies (2-4 per lesion)
- Afterwards, systematic biopsies (omitting region of targeted biopsies)





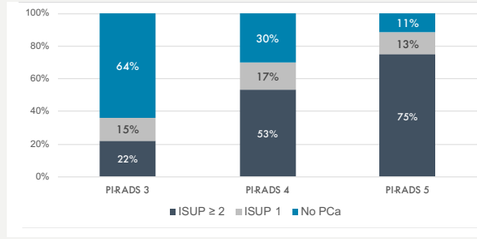
8.20 am End of procedure
- Intervention-time: 20min
- Results: PCa in 4 of 12 biopsies, Gleason score: 3+4
- Median pain-sensation (0-10) during biopsy: 2

Scientific achievements

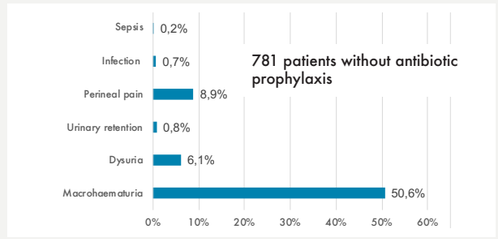
- Günzel K, Heinrich S, Schlegel J, Ri C, Schostak M, Magheli A, Shahin O, Hinz S. **Initial results of perineal MRI/ultrasound fusion biopsies under local anesthesia without standard perioperative antibiotic prophylaxis.** Urologe A. 2020 Oct;59(10):1225-1230. doi: 10.1007/s00120-020-01164-2.
- Jacewicz M, Günzel K, Rud E, Mæhre Lauritzen P,Flor Galtung K, Hinz S, Magheli A, Baco E. **Multicenter transperineal MRI-TRUS fusion guided outpatient clinic prostate biopsies under local anesthesia.** Urol Oncol. 2020 Nov 27;S1078-1439(20)30578-0. doi: 10.1016/j.urolonc.2020.11.009.
- K. Günzel, A. Magheli, E. Baco, H. Cash, S. Heinrich, H. Neubert, J. Schlegel, M. Schostak, T. Henkel, P. Asbach, S. Hinz. **Infection rate and complications after 621 transperineal MRI-TRUS fusion biopsies in local anesthesia without standard antibiotic prophylaxis.** World J Urol. 2021 Apr 18. doi: 10.1007/s00345-021-03699-1.

Results after 879 MRI/TRUS TPBX in LA

Overall Cancer Detection Rate dependent on PI-RADS



Postoperative complications



Quotes

Prof. A. Magheli (urological surgeon, more than 250 open and robot-assisted prostatectomies per year)

"The fusion-biopsy technique with KOELIS® not only makes diagnosis more accurate and safer for the patient, it also helps me in the operation room to perform better nerve-sparing surgeries, which directly translates to a superior health-related quality of life for patients suffering from prostate cancer."

PD S. Hinz (urological surgeon, more than 200 open and robot-assisted prostatectomies per year)

"For prostate cancer, precise diagnostics are essential for individualized therapy planning. 3D mapping of the prostate in combination with MRI sequences and needle tracking is particularly helpful."

Dr. T. Henkel (outpatient urologist, expert for brachytherapy and focal therapy)

"The KOELIS Trinity® offers a precise 3-D protocol of the biopsied PIRADS-suspect regions of the prostate, which helps me, as a performer of brachytherapy and focal therapy, to plan my procedure and at the same time explain clearly to the patient what needs to be done."

Stephane P. (patient and urologist)

"With this biopsy technique and procedure, I, as a patient, was able to track exactly where the suspicious lesions were on the MRI and how they were precisely biopsied. Precise localisation of the prostate carcinoma makes precise surgical treatment possible."