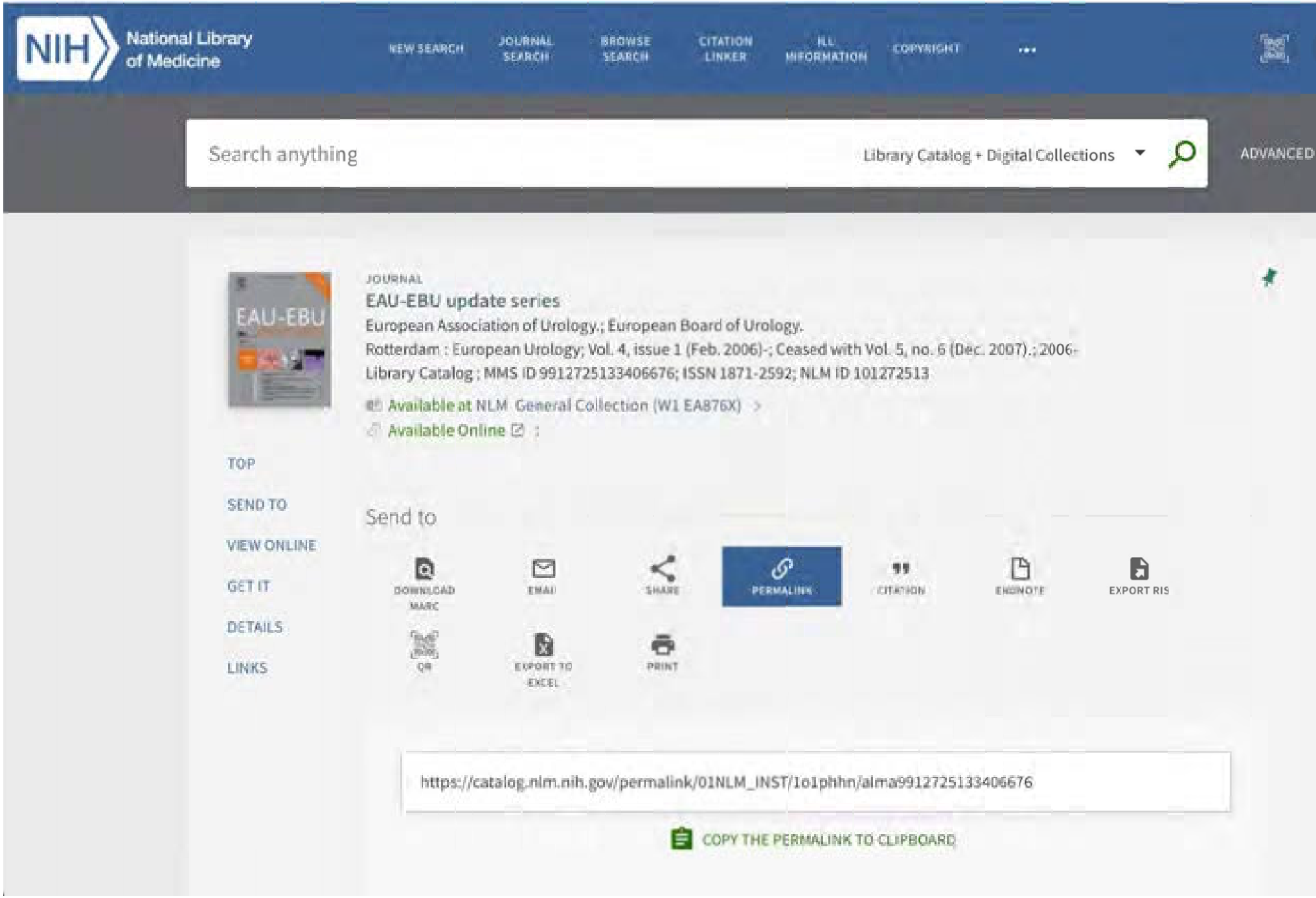
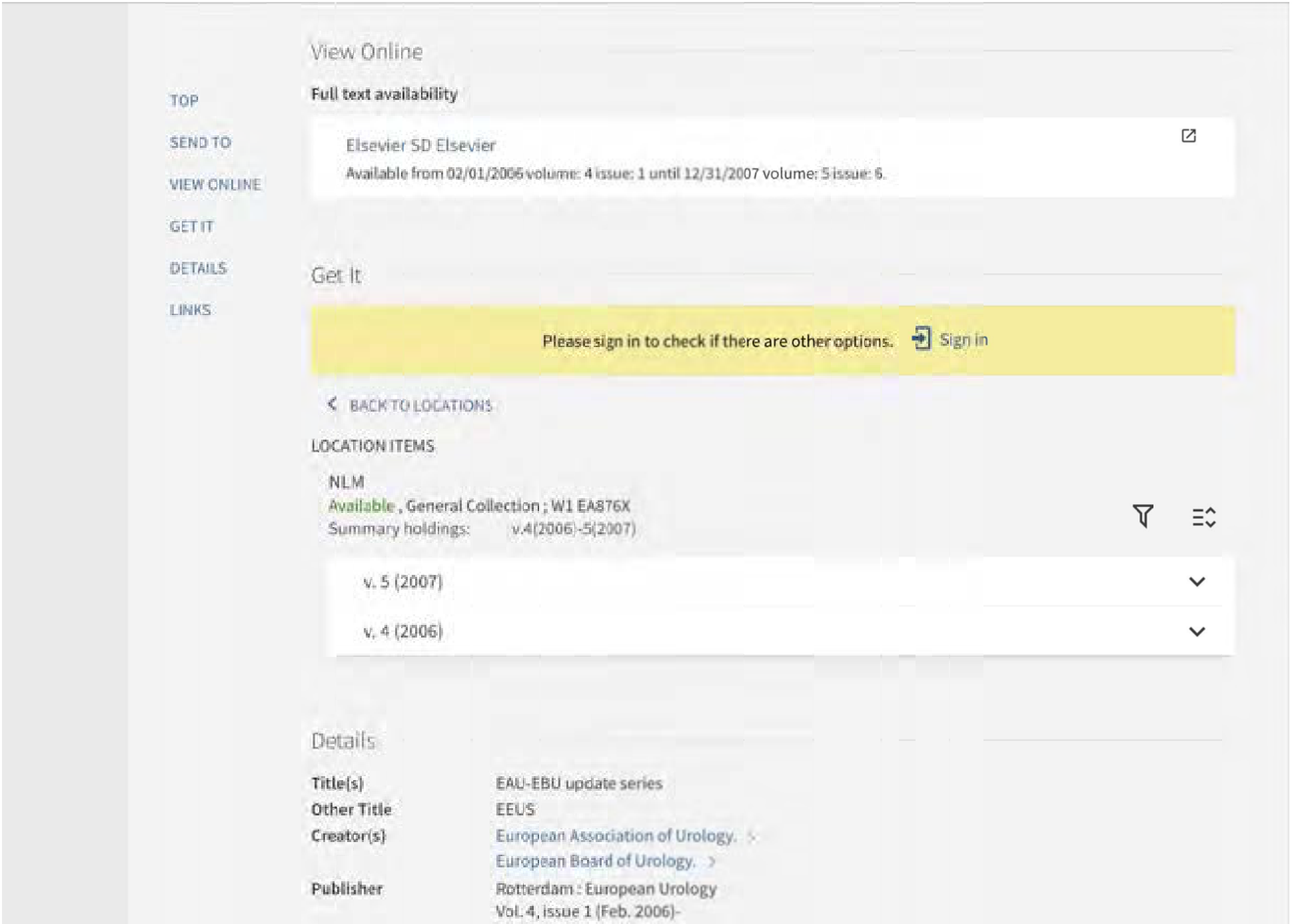

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APPENDIX 1008C

Appendix 1008C
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Galfano, A., Novara, G., Iafrate, M., Cosentino, M., Cavalleri, S., Artibani, W., & Ficarra, V. (2007). Prostate biopsy: the transperineal approach. *EAU-EBU update series*, *5*(6), 241-249.

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EXHIBIT 1009

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Endosonic Probe

User Guide

Type 1850



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Endosonic Probe Type 1850

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Introduction

This is the user guide for Endosonic Probe Type 1850 and must be used together with *Transducer Care, Cleaning & Safety* which contains important safety information.

1850 is a mechanical (single-element) transducer for anorectal and transurethral examinations.

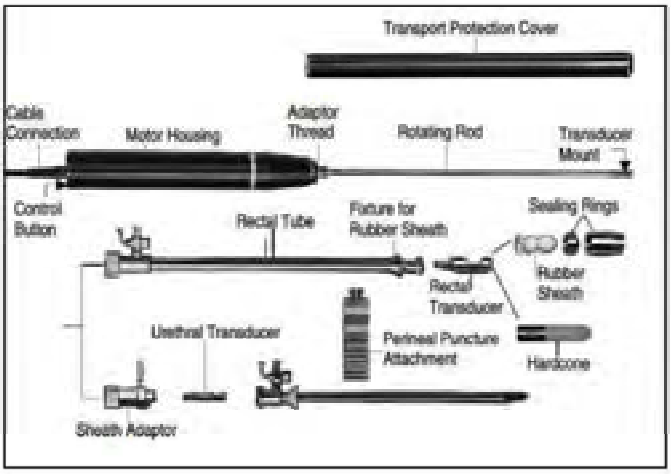


Fig. 1. Endosonic Probe Type 1850 with accessories

FDA WARNING for the United States of America
Type 1850 should **not** be used for fetal examinations.

Scanning Plane

The endosonic probe has three transducer attachments. See Fig. 2. for details.

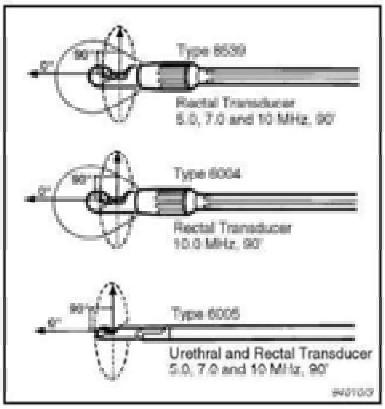


Fig. 2. Transducers for Type 1850

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General Information

Product specifications for this transducer can be found in the Product Data sheet that accompanies this user guide.

Acoustic output data and data about EMC (electromagnetic compatibility) for this transducer are on the Technical Data CD that accompanies this user guide. A full explanation of acoustic output is given in your scanner user guide.

WARNING
If at any time the scanner malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the scanner is not functioning correctly:

- *Remove all transducers from contact with the patient.*
- *Turn off the scanner. Unplug the scanner from the wall and make sure it cannot be used until it has been checked.*
- *Do not remove the scanner cover.*
- *Contact your B-K Medical representative or hospital technician.*

WARNING
Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Caring for the Transducer

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface. It should also be checked thoroughly once a month following the procedure in *Transducer Care, Cleaning & Safety*.

Cleaning and Disinfection

To ensure the best results when using B-K Medical equipment, it is important to maintain a strict regular cleaning routine.

Full details of cleaning and disinfection procedures can be found in *Transducer Care, Cleaning & Safety* that accompanies this user guide. A list of disinfectants and disinfection methods that the transducer can withstand are listed in the Product Data sheet.

Sterile covers are available. See the Product Data sheet for more details.

WARNING
Users of this equipment have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies for personnel and equipment established for your office, department or hospital.

Caution
Keep all plugs and sockets absolutely dry at all times.

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Starting Scanning

All equipment must be cleaned and disinfected before use.

Connecting the Transducer

WARNING
Keep all plugs and sockets absolutely dry at all times.

Unscrew the connector plug cover on the transducer (if attached). On the connector plug, make sure that the red arrow is aligned with the red dot on the transducer socket. Pull back the outer locking mechanism and insert the plug in the socket. Release the locking mechanism to secure in place.

When connected the transducer complies with Type B requirements of EN60601-1 (IEC 60601-1).

Using a Transducer Cover

The transducer should be enclosed in a transducer cover or a standard condom. See the Product Data sheet for a list of available transducer covers.

Note: Sterile, disposable sheaths are recommended for intraoperative use. In the United States of America, it is recommended that probe sheaths have been market-cleared. In Canada, use only licensed probe sheaths.

WARNING
Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.

Note: For Intraoperative Applications
Apply sterile gel to the tip of the transducer or fill the cover with 1 to 2ml of sterile water. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer.

WARNING
Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover material.

Using the Transducer Control Button

The transducer has a control button that you can press to **Start** or **Stop** scanning (freeze frame). Press the button for more than one second to make a copy of the image.

Each time the button is pressed, a "beep" is emitted.

Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable scanner user guide for instructions.

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Assembling Type 1850 for Transurethral Use

Type 1850 can use a Storz 24Fr. resectoscope, which is shown in Fig. 3. The resectoscope is attached to the probe using the appropriate adaptor.

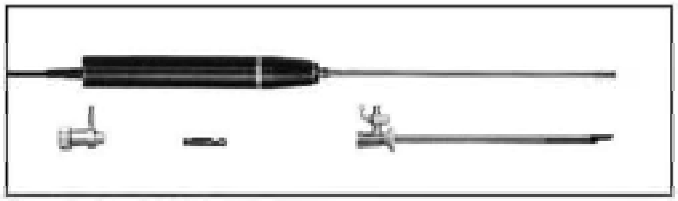


Fig. 3. Storz 24Fr. resectoscope

Slide the appropriate resectoscope adaptor over the probe's rotating rod as shown in Fig. 4. Align the slot inside the adaptor with the small nodule on the probe. Push firmly into position and tighten by turning the adaptor's ridged neck until it closes tightly against the probe's handle.

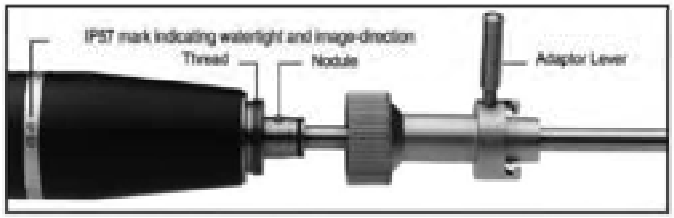


Fig. 4. Fitting Type 1850 with the resectoscope adaptor

Select the urethral transducer, locate the small nodule on the transducer, align it with the slot at the end of the probe's rotating rod and push the transducer firmly into place (see Fig. 5.). When correctly connected, the transducer and the rod will form a flat surface.

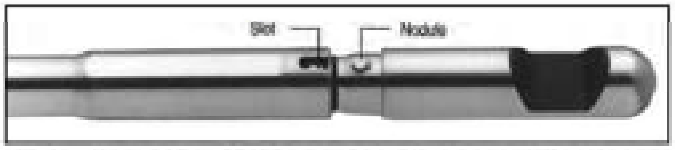


Fig. 5. Fitting Type 1850's rotating rod with one of the transurethral transducers

The 12 o'clock position on the displayed image will be in the direction of the midline between the P and the 5 (part of the IP57 watertight symbol) on the probe's handle.

The arrow shows the alignment position ↓ .

The watertight symbol (IP57) should usually point in the ventral direction of the patient as shown in Fig. 4.

Assembling Type 1850 for Transrectal Use

To assemble the probe for transrectal scanning, remove the sealing rings from the appropriate rectal tube and slide it over the probe's rotating rod (see Fig. 6.). Align the slot inside the

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threaded collar of the rectal tube with the nodule on the probe and push firmly into position. Turn the collar on the rectal tube until it closes tightly against the probe's handle.

WARNING

It is essential for patient safety that the correct rectal tube is used together with the appropriate transducer head.

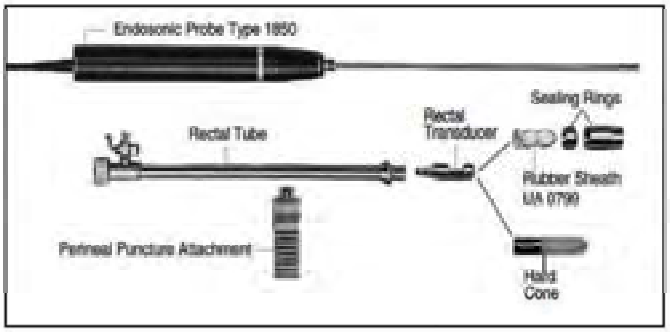


Fig. 6. Type 1850 with accessories for transrectal scanning and perineal puncture

Locate the nodule on the transducer. Align it with the slot at the end of the probe's rotating rod and push the transducer firmly into position (see Fig. 5.). Check the transducer is secure by rotating it. When correctly connected, the transducer and the rod will form a flat surface.

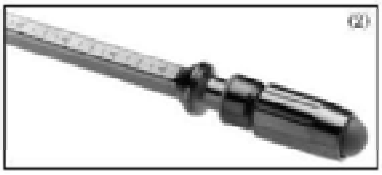
When the probe is assembled for transrectal scanning, check the rotation of the transducer and the probe's rod before the rubber sheath is fitted. To start the rotation, press the built-in control button on the base of the probe's handle. To stop rotation, press the button again.

Fitting a Rubber Sheath

Slide a rubber sheath (UA0799) over the transducer and, as far as possible, over the rectal tube (picture 1).

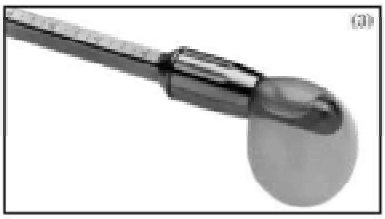


Slide the sealing rings over the sheath (picture 2).



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Pull the rubber sheath out gently at the exposed end and screw the sealing rings tight to the rectal tube (picture 3).



Fill the rubber sheath with approximately 50ml of degassed (lukewarm boiled) water through the valve on the rectal tube.

Note: Do not use sterile water.

Air bubbles may appear in the rubber sheath. As air bubbles will disrupt the path of the ultrasound beam and cause image artifacts, they must be removed.

To remove all the air from the rubber sheath, hold the probe with the rubber sheath pointing downwards (see Fig. 7.) and draw off as much air as possible using the syringe. Refill the rubber sheath with degassed water. Repeat this procedure until there is no air left in either the sheath or the water outlet. Then draw all the water out of the rubber sheath.



Fig. 7. Removal of air bubbles from the rectal tube and rubber sheath

Fitting the Plastic Hood WA0543 or EA4020

Slide a plastic hood over the transducer and screw it reasonably tight to the rectal tube.

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Fill the plastic hood with approximately 10-20ml of degassed (lukewarm boiled) water through the valve on the rectal tube.

Note: Do not use sterile water.

Air bubbles may appear in the plastic hood. As air bubbles will disrupt the path of the ultrasound beam and cause image artifacts, they must be removed.

To remove all the air from the plastic hood, hold the probe with the plastic hood pointing upwards and slowly inject more water using a syringe. Continue this procedure until there is no air left in either the plastic hood or the water outlet. Make sure that the 0.15mm air vent hole in the distal end of the plastic hood is not blocked.

The 12 o'clock position on the displayed image will be in the direction of the midline between the P and the 5 (part of the IP57 watertight symbol) on the probe's handle.

The arrow shows the alignment position .

The watertight symbol (IP57) should usually point in the ventral direction of the patient as shown in Fig. 4.

EA4020 can be autoclaved or disinfected by immersion in a suitable solution. Do not exceed 20 cycles. WA0543 can be disinfected by immersion in a suitable solution.

Single-Use Rectosigmoidoscope UA0681

The single-use rectosigmoidoscope UA0681 is designed to be used with Type 1850 to examine the rectum. Prepare the equipment as described earlier. See "Assembling Type 1850 for Transrectal Use" on page 4.

The single-use rectosigmoidoscope, obturator and grip (UA0681) are ETO-sterilized in the package and ready to use. The reusable light source cable adaptor UA0682 is delivered non-sterile, but it can be sterilized in a steam autoclave.

To use the light source cable adapter UA0682, insert the closed end into the hollow handle of the black grip (Fig. 8.). Use the appropriate adaptor ring to connect a light cable.



Fig. 8. The single-use rectosigmoidoscope UA0681

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The two small fins on the right of the black grip (Fig. 9.) are designed to anchor the rectosigmoidoscope to the transducer.



Fig. 9. The black grip

The numbers printed in italics on the rectosigmoidoscope tell you how far the image plane is from the anal verge (see Fig. 10.). Note that the actual end of the transducer is approximately 1 cm deeper into the rectum.



Fig. 10. The rectosigmoidoscope

Transurethral Scanning with Type 1850

All equipment must be cleaned and disinfected before use.

WARNING

Transurethral scanning with Type 1850 implies no greater risk of perforating the bladder wall than does normal cystoscopy. However, care must be taken to ensure that the bladder is not damaged by the tip of the transducer which protrudes 10 to 12mm in front of the origin of the ultrasound beam (i.e. in front of the scan center as seen on the screen).

To check the rotation of the transducer and the probe's rod, press the round button on the base of the probe's handle. To stop rotation, press the button again.

Note: There should be no rotation when the probe is being introduced into and removed from the patient.

Prepare the patient in the usual way for ordinary cystoscopy.

Perform an ordinary cystoscopy to ensure the urethra is clear and the resectoscope sheath is in the bladder.

Insert the probe's rotating rod into the resectoscope sheath. Fasten the sheath onto the probe by turning the adaptor lever clockwise to the lock position. See Fig. 4.

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Ensure the bladder is kept well distended to avoid the transducer touching the wall.

WARNING
When scanning with the 1850, always ensure the transducer set-up on the monitor corresponds to the transducer head in use. If it does not, press the appropriate transducer select control on the console to change the set-up. If it is not possible to select the correct transducer from the menu, do NOT proceed with scanning and contact your local B-K Medical representative.

To start scanning, press the probe's built-in control button.

Transrectal Scanning with Type 1850

Prepare the equipment as described earlier. See "Assembling Type 1850 for Transrectal Use" on page 4.

All equipment must be cleaned and disinfected before use.

To check the rotation of the transducer and the probe's rod, press the round button on the base of the probe's handle. To stop rotation, press the button again.

Note: There should be no rotation when the probe is being introduced into and removed from the patient.

The patient is examined in the left lateral decubitus, the lithotomy position or the prone position. A rectal palpation is made to ensure that the lumen of the rectum is clear.

Lubricate the rectal tube and rubber sheath or hard cone with scanning gel or exploration cream. Cover the probe with an extra condom – this will ease cleaning later. Lubricate the outside of the condom with exploration gel and insert the probe in the usual way. Fill the rubber sheath with about 50 ml of degassed water or the hard cone with 10 – 20 ml of degassed water.

WARNING
Do not use excessive force during insertion. Do not make excessive lateral movements during or after insertion. Risk of injury or tissue damage to the patient could occur under certain circumstances. A digital palpation of the rectum may need to be carried out by a clinician prior to insertion or use of the probe as a precautionary measure.

To start scanning, press the built-in control button at the base of the probe's handle.

Ensure that there is always water around the transducer. Check this on the displayed image.

To complete the examination, scan the caudal region to make sure the anus has not ligated the passage. When you are sure the passage is free, press the button at the base of the probe's handle to stop scanning. Ensure the probe has stopped rotating. Empty the water from the rubber sheath, if used, using a syringe and withdraw the probe.

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Puncture Facilities

Puncture and biopsy are possible with Type 1850. The puncture attachment is illustrated in the following pages with a brief description of its uses and operating instructions.

For hygiene reasons, the transducer should be enclosed in a transducer cover or a standard condom. When sterile conditions are required, cover it with a sterile transducer cover.

WARNING
It is essential for the patient's safety that only the correct puncture attachment is used with Type 1850. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments.

Mounting the Perineal Puncture Attachment UA0650

Loosen the thumb screw on the puncture attachment UA0650. Fit the puncture attachment on the rectal tube at a suitable position. Tighten the thumb screw. See Fig. 11.

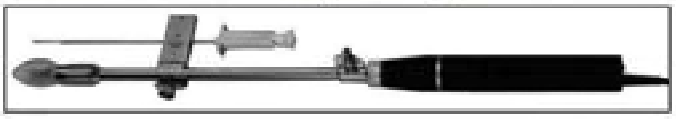


Fig. 11. Type 1850 assembled for transrectal scanning with puncture attachment UA0650

All parts of the puncture attachment can be autoclaved or disinfected by immersion in a suitable solution.

Performing Puncture and Biopsy

WARNING
It is essential for the patient's safety that only the correct puncture attachments, as described in this guide, are used. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers puncture attachments.

Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the puncture attachment match exactly those displayed on the scanner monitor.

WARNING
The row of puncture markers on the scan image is an indication of the expected needle path. However, the needle tip echo will not be seen before the tip actually is in the transaxial image plane.

Cover the transducer with a sterile transducer cover.

If the transducer cover is damaged when attaching the puncture attachment, replace it with a new cover.

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Note: Sterile, disposable sheaths are recommended for intraoperative use; and in the U.S.A. it is recommended that probe sheaths have been market-cleared. In Canada, use only licensed probe sheaths.

See the Product Data sheet for a list of available transducer covers.

Press the scanner **Puncture** or **Biopsy** control button to superimpose a row of puncture markers on the scan image.

Move the transducer until the row of puncture markers transects the target. Insert the needle. The needle tip echo will be seen as a bright dot on the screen.

WARNING
If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover.

To remove the row of puncture markers from the scan image, refer to the applicable scanner user guide for instructions.

WARNING
Remember that the endosonic probe must have stopped rotating before you attempt to remove it.

WARNING
When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

WARNING
If rotation of the shaft is obstructed by pushing hard on the transducer head or the shaft, the image orientation may be disturbed (rotated).

Do not perform punctures under these circumstances.

There is no problem if the overload protection is activated and stops the rotation of the shaft. Correct image orientation can be secured by stopping and restarting the transducer.

Transperineal Biopsy

For transperineal biopsy, place the patient in either the lithotomy or the left lateral decubitus position. The perineum is prepared for puncture and anesthetized.

Fit the perineal puncture attachment to the endosonic probe, insert the probe into the rectum. It is recommended that it is held fast on a fixation unit.

Press the scanner's **Puncture** control button to superimpose a row of puncture markers on the scan image. If there is more than one puncture guide available for the transducer, press the appropriate control button on the ultrasound scanner to select the required row of puncture markers.

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Refer to the applicable scanner user guide for the method of changing which row of puncture markers appears on the monitor.

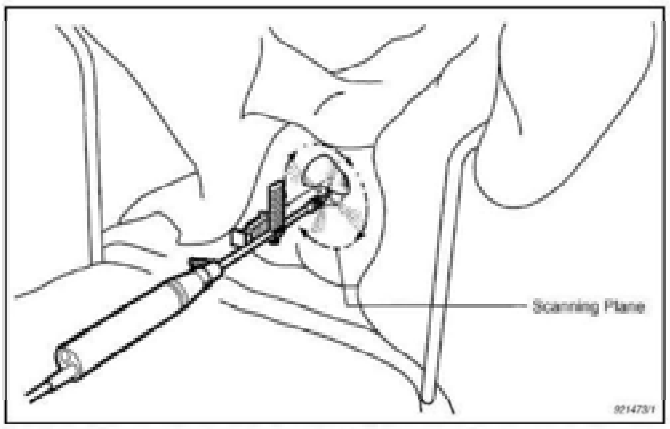


Fig. 12. The principle for perineal puncture. The scanning plane within the body is shown.

Move the transducer until one of the puncture markers transects the target. Insert the needle. The needle tip echo will be seen as a bright dot on the screen once it transects the image plane.

Take the biopsy in the usual way. If a fine needle is used, it may be helpful to use an additional needle guide.

Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer or puncture attachments, disinfection and sterilization processes may not be effective. Therefore, you must clean puncture attachments and transducers immediately after use.

Use a suitable brush to make sure that biological material and gel are removed from all needle guides and other channels and grooves. See *Transducer Care, Cleaning & Safety* for cleaning instructions.

3D Scanning with Type 1850

3D scanning with Type 1850 may be carried out in either of two ways:

- Freehand – where Type 1850 is combined with the appropriate 3D scanner software.
- Using mover support – where Type 1850 is combined with the appropriate 3D scanner software, the Pullback Mover UA0552 and the Variable Friction Arm UA0553.

3D Scanning using Mover Support

3D scanning with Type 1850 using Mover Support is carried out using:

- The appropriate 3D scanner software.
- The Pullback Mover UA0552.

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- The Variable Friction Arm UA0553.



Fig. 13. Type 1850 and Pullback Mover UA0552 mounted on Variable Friction Arm UA0553

Pullback Mover UA0552

Further information about the Pullback Mover UA0552 can be found in the user guide.

Variable Friction Support Arm UA0553

Maintenance

Periodically check that all screws on the Variable Friction Support Arm UA0553 are securely fastened and that all joints are adequately lubricated with standard lubricant oils or grease to ensure their continued performance.

Contact your B-K Medical representative if you believe the correct functioning of the Variable Friction Support Arm is impaired in any way.

Caution:

The Variable Friction Support Arm must not be immersed or autoclaved.

Assembly and Use of Mover Support

The Pullback Mover UA0552 is mounted on the examination bed using the Variable Friction Support Arm UA0553.

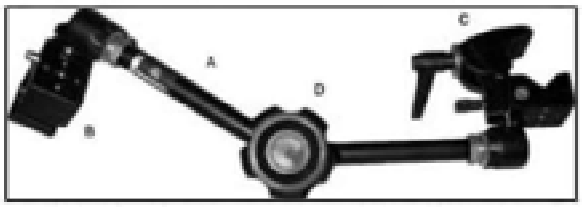


Fig. 14. Variable Friction Support Arm UA0553

The Variable Friction Support Arm UA0553 (see Fig. 14.) consists of:

- A Support Arm (A);
- Two identical fixation clamps (B and C);

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- A variable friction wheel (D).

One of the two fixation clamps (B or C) is used to secure the support arm to the examination table (the support clamp) with the other fixation clamp being used to secure the Pullback Mover to the Support Arm (the instrument clamp).

The Support Arm can be manipulated so that the Pullback Mover is optimally positioned with respect to the patient. It can also be locked into position, thus preventing accidental movement of the setup.

UA0553 fits onto the rail along the side of the examination bed or onto the bed itself. UA0553 should be positioned so that the Pullback Mover will easily reach the patient.

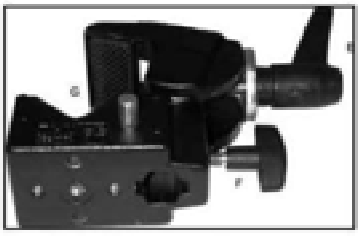


Fig. 15. Fixation Clamp

Attaching the Fixation Clamp to the Examination Bed

The fixation clamp is shown in Fig. 15. Turning the handle (E) in a clockwise direction tightens the jaws of the clamp to match the dimensions of the mounting rail or of the operating table itself.

Attaching the Fixation Clamp to the Support Arm

The clamp has a hand-screw (F) and a security pin (G) on the upper jaw, which control the attachment of the Support Arm.

At each end of the support arm are universal ball joint brackets (H), which rotate 360° (see Fig. 16.). To attach the bracket to the support clamp:

- Loosen the hand-screw (F) by turning counterclockwise
- Insert the distal end of the bracket into the socket on the top of the support clamp while depressing the security pin (G).

To remove, reverse the procedure.

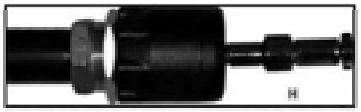


Fig. 16. Universal Ball Joint Bracket at the end of the Support Arm

With the joint inserted into the socket on the support clamp, the arm is secured by tightening the handscrew (F) in a clockwise direction.

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Attaching the Instrument Clamp to the Support Arm

The clamp has a hand-screw (F) and a security pin (G) on the upper jaw, which control the attachment of the Support Arm (see Fig. 15.).

At each end of the support arm are universal ball joint brackets (H), which rotate 360° (see Fig. 16.).

The joint is attached to the support clamp by loosening the hand-screw (F) by turning counterclockwise and inserting the distal end of joint into the socket on the top of the support clamp while depressing the security pin (G).

To remove, reverse the procedure.

Maneuvering the Support Arm

The support arm has a universal ball joint midway along its shaft. The Variable Friction Wheel (D) is used to fix the precise position and the setting of the arm. Tightening the wheel by turning in a clockwise direction secures the settings of all of the universal ball joints in the arm – in the mid-point and at both ends.

The setup can now be moved over into the patient area.

Caution:
All hand wheels and screws should be locked before any interventional procedure, thus preventing accidental movement of the setup.

Disposal

When the transducer is scrapped at the end of its life, national rules for the relevant material in each individual land must be followed. Within the EU, when you discard the transducer, you must send it to appropriate facilities for recovery and recycling. See the applicable scanner user guide for further details.

WARNING
For contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department or hospital.

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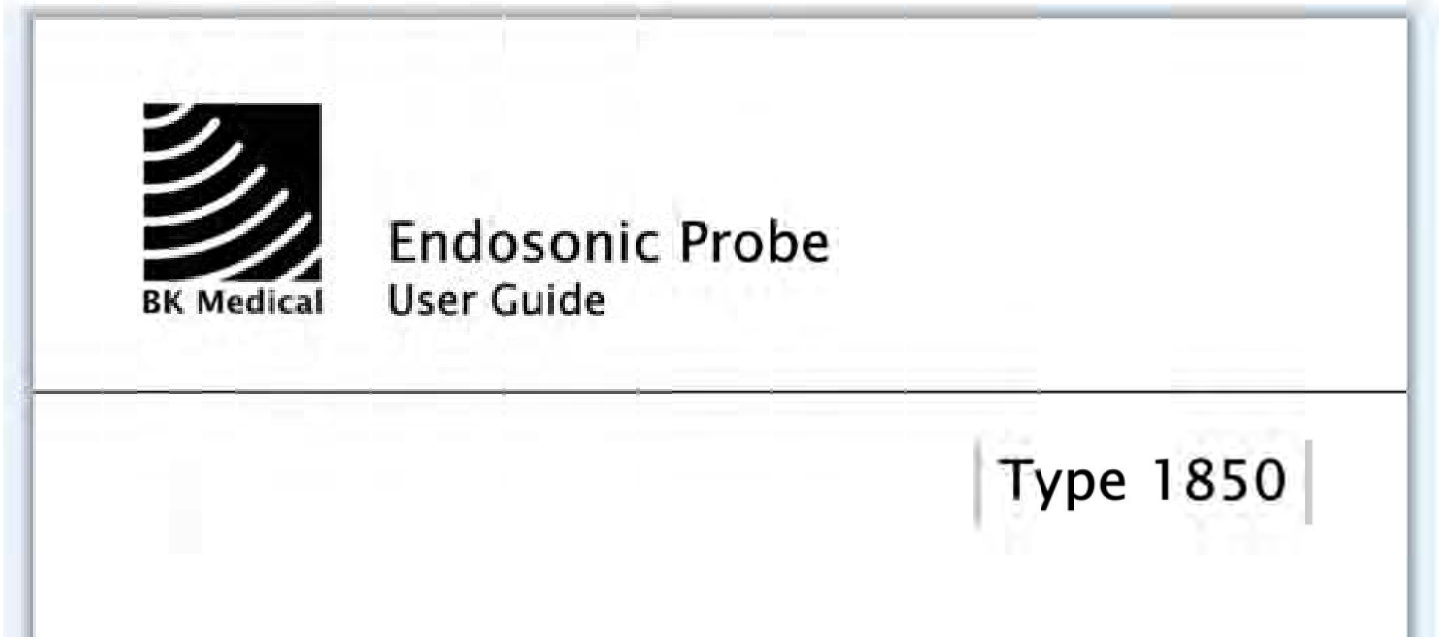
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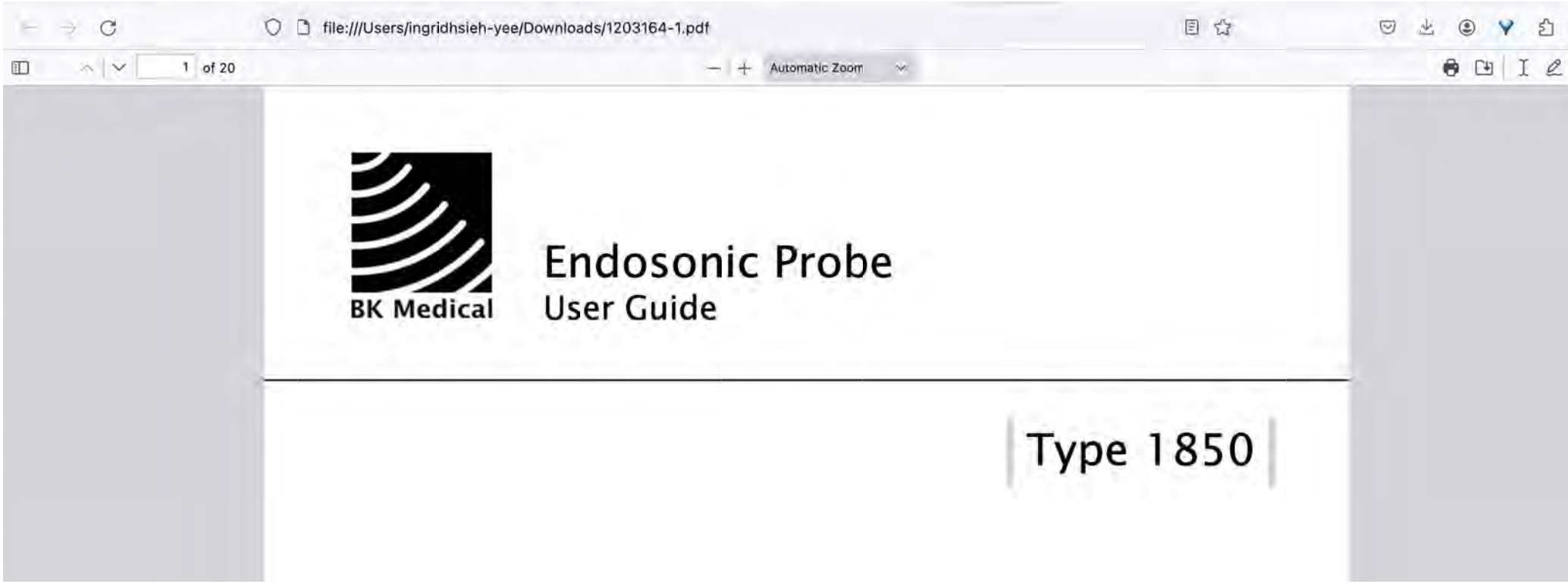
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	8848 A resolution revolution in image guided prostate therapy. Resolute, clear and detailed images of the prostate, for accurate volume studies and source dose planning.	Prostate brachytherapy Transrectal scanning Transperineal puncture Transvaginal scanning Prostate cryotherapy Spectral and CFM Doppler Contrast imaging*

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Urology	Transducer	Applications
	8848 A resolution revolution in image guided prostate therapy. Resolute, clear and detailed images of the prostate, for accurate volume studies and source dose planning.	Prostate brachytherapy Transrectal scanning Transperineal puncture Transvaginal scanning Prostate cryotherapy Spectral and CFM Doppler Contrast imaging*
	8666 The most advanced laparoscopic ultrasound transducer on the market. Rigid and 4-way laparoscopic scanning in one. A versatile built in biopsy guide for staging.	Laparoscopic ultrasound Intraoperative ultrasound Ultrasound guided: Radiofrequency tumor ablation (RFA) Biopsy Drainage
	8667 Endfire prostate imaging. A wide endfire image plane enables you to locate a lesion and then rotate the plane around a central axis.	Endorectal scanning Interventional procedures Spectral, CFM and Power Doppler Tissue harmonic imaging
	8670 Small part, musculoskeletal and vascular scanning. Its excellent Doppler makes it a great choice for penile Doppler and testis scanning.	Small part Breast scanning Testis scanning Penile Doppler Musculoskeletal Peripheral vascular Interventional procedures Contrast Imaging*
	8808 Simultaneous biplane imaging of the prostate. The 8808 uses two convex arrays, one for transverse scanning and one for sagittal scanning.	Transrectal scanning Transrectal puncture Transperineal puncture Spectral and CFM Doppler Tissue harmonic imaging
	8808e Orient yourself for biopsy with simultaneous biplane. The 8808e gives you real-time images of the sagittal and transverse planes which are invaluable for orientation.	Transrectal scanning Transrectal puncture Transperineal puncture Spectral and CFM Doppler Tissue harmonic imaging
	8811 A broadband linear array transducer with high frequencies unprecedented for scanning equipment of its class. Your benefit: excellent high-resolution imaging with good penetration during near-field small part scanning at a reasonable price.	Small part scanning Musculoskeletal scanning Peripheral vascular scanning Pediatric scanning Tissue harmonic imaging
	8818 Triplane imaging - all prostate zones with one transducer. The 8818 gives you unsurpassed image quality in three visionary planes that open up the entire prostate.	Transrectal prostate scanning Transrectal puncture and biopsy Transperineal puncture and biopsy Transvaginal scanning Spectral and CFM Doppler Tissue harmonic imaging Contrast imaging*

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Urology	Transducer	Applications
	8820e Comfort and quality in abdominal ultrasound. Broadband scanning and excellent image quality with a new, ergonomic design. The 8820e delivers the depth and sharpness you need from ultrasound images.	Liver Pancreas Bladder General abdominal Obstetric scanning Interventional procedures
	8823 Easy access to kidney diagnostics. The convenient 8823 renal transducer provides superior image quality for anatomical details while minimizing patient discomfort during intercostal scanning.	Kidney Bladder Pediatric Difficult to access areas
Surgery		
	8862 Craniotomy Transducer Premium performance neuroimaging, unmatched transducer function and design, convenient, sterile needle guides, STERRAD NX & 100NX compatible	Neurosurgical scanning Intraoperative scanning Pediatric scanning Interventional procedures Spectral and CFM Doppler examinations
	8863 Burr Hole Transducer Premium performance neuroimaging, unmatched transducer function and design, convenient, sterile needle guides, STERRAD NX & 100NX compatible	Neurosurgical scanning Intraoperative scanning Interventional procedures Spectral and CFM Doppler
	8809 Uniquely optimized for intraoperative vascular scanning, general intraoperative scanning and musculoskeletal applications. Its small flexible tip easily reaches difficult to access areas, and its very high frequency provides unsurpassed resolution in the extreme near field.	Intraoperative vascular General intraoperative Musculoskeletal scanning Small part scanning Interventional procedures
	8814 The ultimate tool for ultrasound-guided needle placement. A breakthrough in surgical imaging for precise needle guidance: simultaneous live biplane imaging.	Intraoperative Ultrasound guided: Tumor Ablation (RF, Microwave) Biopsy RF Ablation Drainage
	8815 Designed especially for interventional ultrasound during surgery. I-shaped intraoperative transducer guided intraoperative biopsy with a variety of angles and positions.	Intraoperative Ultrasound guided biopsy and RF ablation Pediatric scanning Spectral and CFM Doppler
	8816 A small, T-shaped transducer designed primarily for hepatic surgery. Excellent image quality and a wide near field view.	Intraoperative Abdominal scanning Spectral and CFM Doppler Coded excitation Contrast imaging* Harmonic Imaging
	8824 A small T-shaped intraoperative transducer. Choose between the I, T or simultaneous imaging. Combined I and T array for improved orientation Flexibility to take free hand biopsies from the front, back, left, or right.	Intraoperative scanning Vascular scanning Contrast imaging Tissue harmonic imaging Optimized for liver scanning 3D freehand
	8666 The most advanced laparoscopic ultrasound transducer on the market. Rigid and 4-way laparoscopic scanning in one. A versatile built in biopsy guide for staging.	Laparoscopic Intraoperative Ultrasound guided: RFA Biopsy Drainage
Colorectal		
	1850 The clearest view of rectal anatomy. One of the world's most versatile probes for transrectal examinations.	Investigating the anal sphincter Investigating the rectal wall Preoperative staging Intraoperative capabilities

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Urology	Transducer	Applications
	2050 An anorectal transducer from BK Medical is the world's first with a built-in 3D mover. The transducer offers superb 360° image quality, with a frequency range from 6-16 MHz. There are no moving parts in contact with the patient, providing easy, fast and convenient examinations.	Anorectal scanning Transvaginal
	2052 Detailed, high-resolution images and easy to use 3D.	Anorectal Endovaginal
Pelvic Floor		
	2052 3D imaging with no external moving parts. Clear, undisturbed images with the world's only 360° endocavitary transducer with built-in 3D mover.	Anorectal Transvaginal
	8802 Excellent image penetration and depth. Visualize the dynamics and function of pelvic floor dysfunction.	Pelvic Floor Abdominal Obstetric Pediatric Interventional procedures Tissue harmonic imaging
	8848 A resolution revolution in ultrasound imaging. Unsurpassed endovaginal imaging for dynamic urethral function and posterior compartment evaluation.	Prostate brachytherapy Transrectal Transperineal puncture Transvaginal Prostate cryotherapy Spectral and CFM Doppler Contrast imaging*
Anesthesia		
	8670 Small part, musculoskeletal and vascular scanning. Its excellent Doppler makes it a great choice for penile Doppler and testis scanning.	Small part Breast scanning Testis scanning Penile Doppler Musculoskeletal Peripheral vascular Interventional procedures Contrast Imaging*
	8809 Uniquely optimized for intraoperative vascular scanning, general intraoperative scanning and musculoskeletal applications. Its small flexible tip easily reaches difficult to access areas, and its very high frequency provides unsurpassed resolution in the extreme near field.	Intraoperative vascular General intraoperative Musculoskeletal scanning Small part scanning Interventional procedures
	8811 A broadband linear array transducer with high frequencies unprecedented for scanning equipment of its class. Your benefit: excellent high-resolution imaging with good penetration during near-field small part scanning at a reasonable price.	Small part scanning Musculoskeletal scanning Peripheral vascular scanning Pediatric scanning Tissue harmonic imaging
	8823 Easy access to kidney diagnostics. The convenient 8823 renal transducer provides superior image quality for anatomical details while minimizing patient discomfort during intercostal scanning.	Kidney Bladder Pediatric Difficult to access areas
	8827 Phased array technology fulfills basic cardiac ultrasound needs. It provides a wide scanning angle and a high frame rate, for all of the cardiac information you need.	Cardiac Transcranial

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Urology	Transducer	Applications
	8830 The 8830 is the ideal ultrasound tool for abdominal, urological and OB/GYN scanning. It gives you sharp images and clear details at all depths.	Abdominal Urology OB/GYN
	8870 Beautiful images just below the surface. The 8870 transducer gives you clear, sharp and detailed images at 18 MHz.	Musculoskeletal scanning Peripheral vascular scanning Small part scanning Interventional procedures Doppler examinations
General		
	8870 Beautiful images just below the surface. The 8870 transducer gives you clear, sharp and detailed images at 18 MHz.	Musculoskeletal scanning Peripheral vascular scanning Small part scanning Interventional procedures Doppler examinations
	8670 Quality, versatility and convenience in one transducer. With its large bandwidth and high maximum scanning frequency, the 8670 gives you both superb image detail in the near field and excellent penetration for deeper views.	Small part Breast Testis Penile Doppler Musculoskeletal Peripheral vascular Interventional Contrast Imaging*
	8802 For more detailed exaiminations and obstetrics, the 8802 with its smaller footprint and excellent resolution meets your needs.	Pelvic Floor Abdominal Obstetric Pediatric Interventional Tissue harmonic imaging
	8809 Uniquely optimized for intraoperative vascular scanning, general intraoperative scanning and musculoskeletal applications. Its small flexible tip easily reaches difficult to access areas, and its very high frequency provides unsurpassed resolution in the extreme near field.	Intraoperative vascular General intraoperative Musculoskeletal Small part Interventional
	8811 A broadband linear array transducer with high frequencies unprecedented for scanning equipment of its class. Your benefit: excellent high-resolution imaging with good penetration during near-field small part scanning at a reasonable price.	Small part Musculoskeletal Peripheral vascular Pediatric Tissue harmonic imaging
	8819 This endovaginal transducer is the ideal all-round ultrasound tool for routine gyneclogical investigations. Because the 8819 can provide detailed images at different depths, it is well-suited for a variety of situations and patient types.	Endovaginal Spectral and CFM Doppler
	8827 Phased array technology fulfills basic cardiac ultrasound needs. It provides a wide scanning angle and a high frame rate, for all of the cardiac information you need.	Cardiac Transcranial
	8830 The 8830 is the ideal ultrasound tool for abdominal, urological and OB/GYN scanning. It gives you sharp images and clear details at all depths. Note: * In the USA, contrast-enhanced ultrasound has not been market cleared by the FDA, with the exception of only select cardiac imaging applications.	Abdominal Urology OB/GYN
	8822 The 8822 vascular transducer gives superb imaging at all depths. Excellent color and spectral Doppler sensitivity, optimized for for all depths. Deep	Vascular

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Urology	Transducer	Applications
	penetration.	

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Full 360° Transverse Image

- Complete, transverse view without having to move the handle.

Interchangeable Transducer Tips to Suit all Examinations

- Frequency range from 4.0 - 10.0 MHz.
- Multifrequency for improved resolution

1850 Applications

1850 Specifications	
Frequency Range	4-10 MHz
Focal range (typical)	10-60 mm
Sector angle	360°

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Full 360° Transverse Image

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Interchangeable Transducer Tips to Suit all Examinations

- Frequency range from 4.0 - 10.0 MHz.
- Multifrequency for improved resolution

1850 Applications

- Investigating the anal sphincter
- Investigating the rectal wall
- Preoperative staging for treatment planning
- Intraoperative capabilities for the urethra and bladder

1850 Specifications

Frequency Range	4-10 MHz
Focal range (typical)	10-60 mm
Sector angle	360º
Disinfection	Immersion
Physical data	Length: 590 mm (approx)
Weight (approx.)	600 g
Transducer tips	8539: 4.0 MHz,diameter 13 mm 6004: 10.0 MHz,diameter 13 mm 6005: 5.0, 7.0, 10.0 MHz, diameter 13 mm

Clinical Solutions
Colorectal

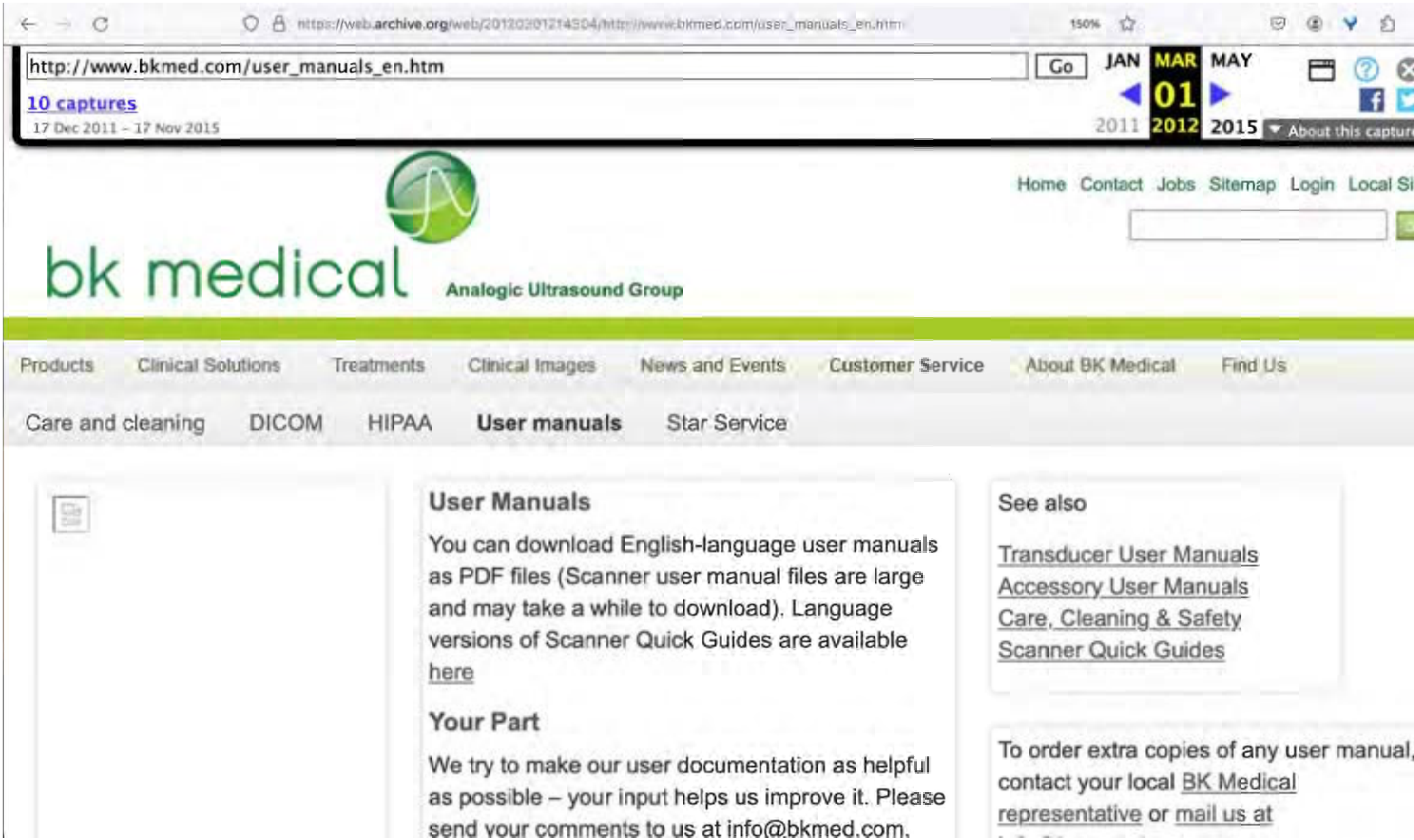
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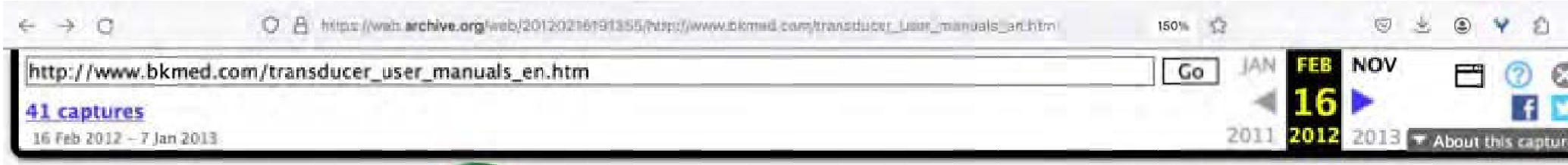
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Transducer User Manual

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MR-guided transgluteal biopsies with an open low-field system in patients with clinically suspected prostate cancer: technique and preliminary results

Stephan Zangos, Katrin Eichler, Kerstin Engelmann, Mukhtiar Ahmed, Sebastian Dettmer, Christopher Herzog, Wasilios Pegios, A. Wetter, Thomas Lehnert, Martin G. Mack & Thomas J. Vogl

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MR-guided transgluteal biopsies with an open low-field system in patients with clinically suspected prostate cancer: technique and preliminary results

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Abstract The purpose of this study was to examine the feasibility and safety of MR-guided biopsies with a transgluteal approach in patients with uncertain or suspicious prostate lesions. Twenty-five patients with uncertain or suspicious focal prostate lesions detected by high-field MR imaging of the prostate gland using endorectal coil imaging were biopsied with a transgluteal approach in a low-field MRI system (0.2 T, Concerto, Siemens). The procedures were guided using T1-weighted FLASH sequences. The prostate gland was biopsied repeatedly with a coaxial technique through a 15-gauge pencil tip with a 16-gauge biopsy handy (median 3.8 samples per patient). Complications and biopsy findings were documented retrospectively. Using T1-weighted sequences biopsy procedures were performed successfully with MR guidance in all cases without any side effects or complications. The median intervention time was 11.3 min. Pathological findings revealed ten cases of hyperplasia or atrophy, three cases of prostatitis, ten cases of carcinoma and two cases of normal tissue. The clinical follow-up showed that in two patients prostate cancer was missed at MR-guided biopsy. Transgluteal MR-guided biopsy of the prostate gland is a safe and promising approach for histological clarification of uncertain or suspicious lesions.

Keywords Prostate MR · Prostatic neoplasm · Interventional procedures · MR-guided biopsy

Introduction

Prostate cancer is the most common malignancy in the Western hemisphere in men aged 50 years and older, and the incidence of prostate carcinoma has been declining since 1992 after a period of marked increase [1, 2]. Early detection programs for prostate cancer with prostate-specific antigen (PSA) level testing and an annual digital rectal examination (DRE) should be performed in men aged 50 years or older. The serum concentration of PSA is considered to be an important indicator in the early detection of prostate cancer [2]. In patients with a PSA level higher than 4 ng/ml, a transrectal ultrasonography (US) has often been performed [3] for the detection of possible tumors. Likewise, magnetic resonance imaging (MRI) is an accepted and promising diagnostic option for prostate examinations. Recent studies showed that MR imaging with the use of an endorectal coil improved results in the detection of tumor foci in patients who had elevated PSA levels [4, 5] and described cancer detection rates between 37 and 87% for T2-weighted endorectal MR imaging [5–10]. Particularly, the detection of lesions smaller than 5 mm in diameter is poor [11]. Likewise, less differentiated prostate cancer showed only a

poor T2-contrast [12]. With better detection of prostate tumors, an increasing number of patients need a precise histological tumor clarification before the planning of further treatment. The gold standard of histological confirmation of prostate cancer in patients with elevated PSA levels is at the moment systematic sextant biopsy of the prostate, involving the apex, middle and base of both sides of the prostate gland [13]. However, a large number of patients with elevated PSA levels have negative biopsy results with US guidance, so that repeated biopsies are necessary for a sufficient diagnosis of prostate cancer [14]. For these reasons alternative image-guiding modalities like CT and MRI have been evaluated for specific indications [15–17].

MRI examinations of the prostate gland for the detection of prostate cancer are a promising imaging modality and this technique may also be useful for the guidance of prostate biopsies. The purpose of this study was to examine the feasibility and safety of a transgluteal approach for MR-guided biopsies in patients with uncertain or suspicious prostate lesions in endorectal high-field MRI.

Materials and methods

Patients

In an 18-month period 25 patients ranging in age from 48 to 74 years (median 61.9 years) were examined with endorectal body-phase array coil followed by MRI-guided biopsies of the prostate gland if MRI showed uncertain or suspicious prostate lesions for histological clarification. The median PSA level was 11.8 ng/ml in all patients ranging from 4.8 to 28.0 ng/ml.

Fifteen of these patients had been referred to us by their urologists; ten came without referral by a urologist because they had heard something about our new biopsy technique. In 17 patients prior transrectal US-guided quadrant or sextant biopsy results were negative. The other patients refused prior US-guided biopsies. Informed consent was obtained from all patients. The patients included in the study had a PSA level higher than 4 ng/ml and/or uncertain or suspicious MR imaging results. Patient exclusion criteria were contraindications to MR imaging and to biopsies.

High-field MR imaging technique

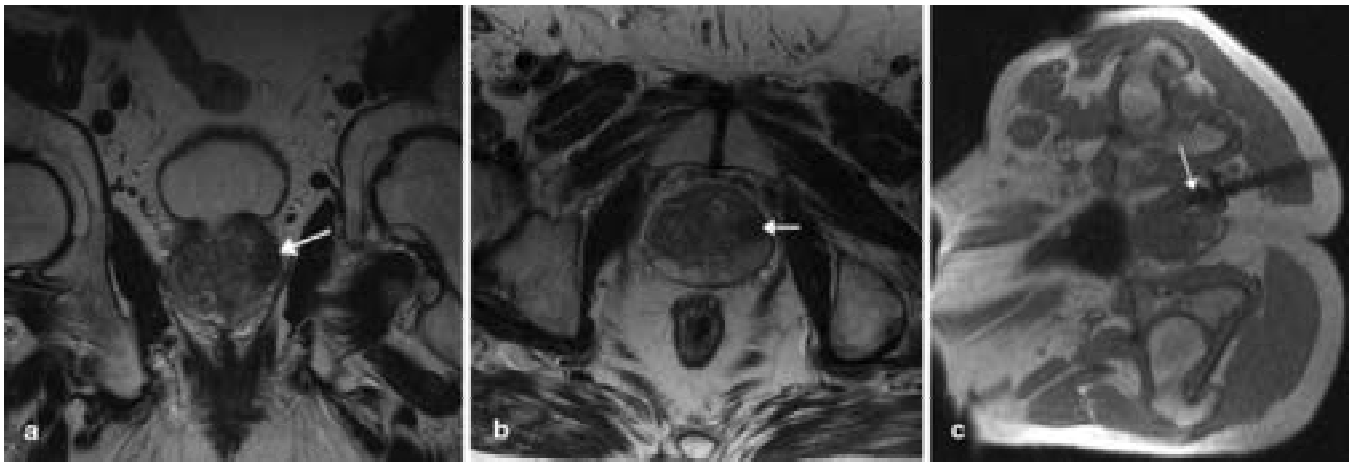
Before the biopsies, we performed endorectal MR imaging using a 1.5-T unit (Magnetom Symphony; Siemens, Erlangen, Germany) and an endorectal surface coil (Medrad; Indianola, USA) coupled to an anterior body-phase array coil. The examination was performed with a routine imaging protocol. After the coil position had been checked using a gradient-echo localizer sequence, fast T2-weighted turbo spin-echo sequences were acquired (TR/TE=3,500/100; 4-mm section thickness, 0.8-mm intersec-tion gap, 512×256 matrix) at angulated transverse-section and coronal-section orientations by using 16×16-cm field of view. Supplementary angulated transverse T1-weighted spin-echo images (TR/TE=500/10; 4-mm section thickness, 0.8-mm intersection gap, 512×256 matrix; 16×16-cm field of view) were acquired. During the examination no medications for suppression of peristaltic artifacts were applied. One patient refused the introduction of the endorectal coil (Fig. 1).

The MR imaging findings of the high-field system were analyzed by two readers (S.Z.; T.V.). Diffuse and inhomogeneous hypointense areas of the peripheral zone in T2-weighted images were classified as uncertain findings. The presence of cancer or suspicious areas, identified as areas of low signal intensity within the peripheral zone in T2-weighted images, was estimated on a four-point rating scale: 1, normal tissue; 2, probably normal tissue; 3, possible cancer; 4, definite cancer. In patients with findings rated three or four we performed MRI-guided biopsies for histological differentiation of these lesions.

MRI-guided biopsies

Two to 16 days (median 6 days) after high-field MR imaging of the prostate gland with suspicious MRI results, MRI-guided biopsies were performed in 25 patients by one radiologist and one technical assistant with the MR imaging findings taken into account. The biopsies were performed after elimination of all contraindications, detailed information of the patient and a written

Fig. 1 Coronal (**a**) and transversal (**b**) view of T2-weighted FSE (TR/TE=3,500/100) images with a 1.5-T system obtained from a 69-year-old patient with a PSA level of 18 ng/dl and negative US-guided biopsy result. The images show a small hypointense tumor in the left peripheral zone (*arrow*). **c** Transversal T1-weighted FLASH sequence (TR/TE=100/9) in a 0.2-T system during the biopsy (**c**): the needle tip (*arrow*) was placed in the left peripheral zone. Pathological result of the sample was prostatic adenocarcinoma



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Fig. 2 Typical positioning of the patient in lateral decubitus during the biopsy of the prostate gland for an optimal biopsy approach. MR compatible in-room components of the interventional MRI (Magnetom Concerto: 0.2 T): a lamp (*1*) for optimal lighting of the insertion, a flexible surface coil (*2*), an in-room console with mouse (*3*) and a seat (*4*) for an easy performance of the biopsy

consent. All patients had to stop eating 6 h before the biopsy. Fluids and necessary medications could be consumed until 2 h before the intervention.

For the guidance of the biopsies an open 0.2-T MR imaging device (Magnetom Concerto, Siemens; Erlangen, Germany) with a vertical field-axis was used because it provides the performing physician with a wide lateral access to the patient. The receiver was a flexible, standard, multi-purpose coil (Siemens; Erlangen, Germany) with a diameter of 45 cm, and the coil was positioned at the patients' greater trochanter. Constant monitoring and evaluation of the path of the biopsy instruments as well as the imaging management was done with a standard in-room workstation (Siemens; Erlangen, Germany). The setup for the biopsy is demonstrated in Fig. 2. The previously sampled MR images were recruited for the planning of the biopsy path and the positioning of the patients. The patients' position was chosen to allow a real-time MRI-guided biopsy and to facilitate access by the physician. We used a transgluteal approach for the biopsy of the prostate gland (Fig. 3). After choosing the path for the procedure the point of insertion was marked by taping a marker to the expected point of insertion or by using real-time imaging together with a finger as an external marker.

For the localization and the planning of the biopsy path, a FLASH (fast low angle shot) 2-D-GRE sequence (TR/TE=100/9; flip angle 70°, 8-mm section thickness, 96×256 matrix, acquisition time 18 s) and a modified FLASH 2-D-GRE sequence (TR/TE=100/7; flip angle 70°, 8-mm section thickness, 96×256 matrix; acquisition time 16 s) were used. We did not take T2-weighted images because the needle cannot be visualized as well as in T1-weight images during the biopsy.

Monitoring during the procedure was performed using the FLASH 2-D-GRE sequence (TR/TE=100/9; flip angle 70°, 8-mm section thickness, 96×256 matrix, acquisition time 18 s). After the biopsy FLASH 2-D-GRE sequences (TR/TE=100/9; flip angle 70°, 8-mm section thickness, 96×256 matrix, acquisition time 18 s) were used to rule out further complications.

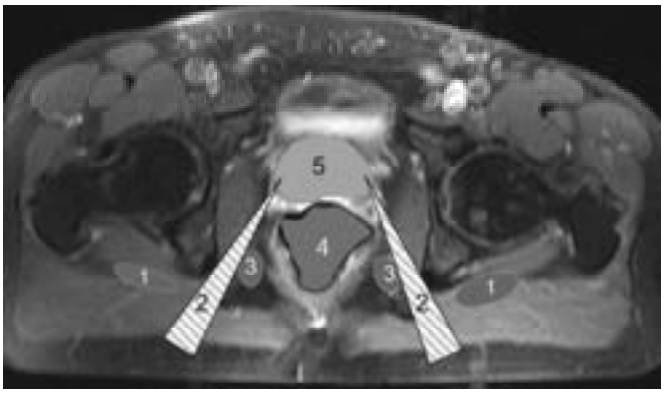


Fig. 3 Exposure of the vital structures of the male pelvis, which might be marked during the biopsy of the prostate gland (*5*) with a transgluteal access (*2*): rectum (*4*), internal pudendal artery and vein/pudic nerve (*3*), gluteal artery and vein/ischiadic nerve (*1*)

After disinfection of the skin and local infiltration anesthesia [10–20 ml local anesthetic (Scandicain; AstraZeneca; Wedel, Germany)], a 15-gauge biopsy needle (Pencil Tip, Somatex, Berlin, Germany) was guided to the target lesion so that a true-cut MRI-compatible biopsy handy (Somatex; Berlin, Germany) of 16 gauge in size could be inserted into the suspicious areas. Multiple tissue samples of one lesion were withdrawn with this coaxial technique to ensure that enough histological material could be acquired for histological clarification. A total of 98 tissue samples were taken (median 3.8 per patient) from uncertain or suspicious lesions, and the trephine biopsy samples were fixed in 10% formaldehyde. The procedure time was recorded. The biopsies were performed in all patients as an outpatient treatment with observation for 2 h after the procedure. Side effects after the biopsies were evaluated by an interview of the patients in the following weeks.

Insufficient samples or diagnosed necroses in trephine biopsies were determined as false negative. The current or final diagnosis of patients with benign results was made by a clinical follow-up between 6 and 13 months (median time 9.7 months). The diagnostic accuracy was achieved by comparing the changes in the PSA level and the histopathological diagnosis. The indication for surgical treatment was made by the urologist and the patient based on our results and the patients' request. The diagnostic accuracy for the histology of the biopsy samples was reported as true positive, true negative, false positive or false negative, confirmed with surgery or clinical follow-up.

Results

The average size of the prostate gland was 38.8 cm^3 (range 27.1–83.2 cm^3). High-field MRI documented signal abnormalities in 14 patients in the left peripheral zone of the prostate gland and in 11 patients in the right peripheral zone. Mean size of the suspicious prostate lesion was 11 mm ranging from 8 to 15 mm.

The biopsies were performed technically successfully in all patients. The biopsies were performed in all patients using the FLASH sequences, and additionally in five patients using the modified FLASH sequences. The

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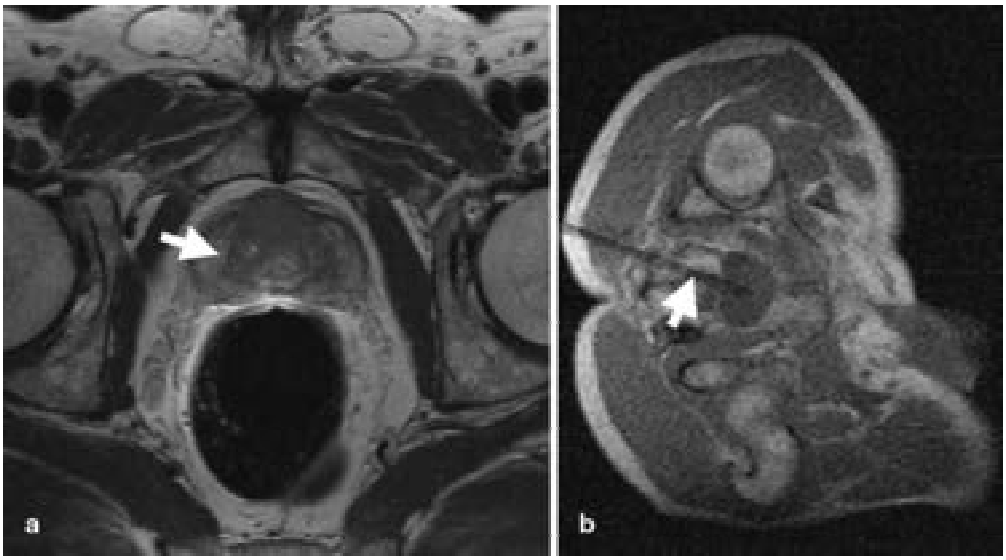


Fig. 4 **a** Transversal T2-weighted TSE image obtained with a 1.5-T system using an endorectal coil (TR/TE= 3,500/100) from a 64-year-old patient who showed a suspicious lesion in the central zone of the prostate gland (*arrow*), which was classified as a possible cancer. **b** T1-weighted FLASH (TR/TE=100/9) during biopsy of the central zone in the 0.2-T open field system. The images showed that a safe insertion of the biopsy needle (*arrow*) into central prostatic structures is possible. Histological tissue demonstrated a prostatic adenocarcinoma

mean number of image acquisitions used during the procedure was 13.7, ranging from 7 to 22.

In all cases the location of the area with the suspicious lesion leads to a safe approach by using MR guidance. The median needle artifact measured was 3.2 mm (range 1.9–5.6 mm). The position of the needle tip could be well visualized in all patients. The visualization of the soft tissue, the vessels and the biopsy needle was good or moderate in all patients, resulting in a safe guidance of the biopsy (Fig. 4).

The median operation time from entering to leaving the operating room was 19.4 min (maximum 35.3 min and minimum 13.5 min). The median puncture time from the insertion of the needle through the skin to needle retraction was 11.3 min (maximum 16.8 min and minimum 5.3 min). The median distance of the access path was 12.1 cm (ranging from 10.5 to 13.2 cm).

At the time of the biopsies all patients tolerated the treatment with minimal or no discomfort after local anesthesia. Only two patients (8% of all patients) showed hematuria after the biopsies. No rectal bleeding or other minor complications were observed during the procedure or the following days. Likewise, no major complications, defined as those requiring hospital admissions, were observed in any patients.

The trephine biopsy yielded a malignant diagnosis in ten patients, an infectious reaction in three patients, regressive tissue in one patient, a hyperplasia of the prostate gland in nine patients and non-pathological findings in two patients. Six-month clinical follow-up in two patients showed that the lesions were wrongly classified as negative. These must be seen as failed biopsies. The biopsy and the follow-up results are shown in Table 1.

None of the patients complained of fever at the time after the biopsy, although they did not receive any antibiotic prophylaxis. No complications were ascertained in a patient with an indwelling catheter, either.

Discussion

Early cancer detection programs seem to be the key to achieving an early detection of prostate cancer and may lead to an increase in the number of patients with curable diseases who can undergo curative radical prostatectomy or curative radiation therapy [18]. Thus, the mortality of this disease can be decreased. Tumor volume, TNM stage, Gleason score and PSA level are relevant prognostic factors of prostate carcinoma.

In patients with elevated PSA levels, transrectal ultrasonography (US) is routinely performed. Likewise, since 1989 endorectal MR imaging was been used increasingly to prove and to predict the extension of prostate cancer [2, 19–21]. In this regard MR imaging provides a high tissue contrast of the detailed structure of prostate gland and periprostatic tissue without the use of a contrast medium. However, non-cancerous tissue, such as prostatitis, dysplasia and prostatic hyperplasia, can show low-intensity areas similar to prostate cancer [5, 19, 22–24]. T2-weighted echo-planar imaging (EPI) has potential usefulness in the detection of impalpable PSA detected prostate cancer [25]. New developments in MR techniques such as the gadolinium-enhanced dynamic subtraction technique [26, 27] and spectroscopic imaging [8, 28, 29] may improve the results for prostate cancer detection in the future. However, because of largely overlapping enhancement pattern, cancer will probably not be depicted within adenoma by dynamic imaging, at least by using low temporal resolution [26].

For the assessment of indistinct prostate lesions, histological clarifications have mostly been performed. At

Table 1 Histological results after MR-guided biopsy and follow-up [prostatic specific antigen (PSA), Gleason score (GS)]

Patient	Age	Histology	GS	PSA	Follow-up
1	61.4	Fibromatous hyperplasia	–	9.4	PSA/clinic
2	58.6	Carcinoma with perineural infiltration, GS 6	6 (3+3)	11.2	PSA/clinic/surgery
3	55.2	Hyperplasia	–	8.6	PSA/clinic
4	63.4	Hyperplasia, lymphocytic infiltration	–	4.8	PSA/clinic
5	61.3	Chronic prostatitis	–	12.8	PSA/clinic/antibiosis
6	55.6	Adenomatous hyperplasia	–	13.5	PSA/clinic
7	62.8	No malignancy	–	6.4	PSA/clinic
8	69.0	Well-differentiated adenocarcinoma	6 (3+3)	9.7	Surgery
9	57.7	Hyperplasia	–	13.4	PSA/clinic
10	65.3	Regressive prostate tissue	–	10.9	PSA/clinic/surgery
11	60.9	Adenomatous hyperplasia	–	16.1	PSA/clinic/surgery
12	59.1	Fibromyomatous hyperplasia	–	10.1	PSA/clinic
13	74.1	Hyperplasia	–	17.2	PSA/clinic
14	65.7	Chronic prostatitis	–	10.9	PSA/clinic/antibiosis
15	59.4	No malignancy	–	7.4	PSA/clinic
16	48.7	Hyperplasia	–	5.2	PSA/clinic
17	68.6	Acinar adenocarcinoma	1–2	11.8	PSA/clinic
18	63.6	Adenocarcinoma	7 (3+4)	28.0	PSA/clinic/surgery
19	65.0	Azonal clear cell carcinoma	6 (3+3)	16.1	PSA/clinic/surgery
20	68.4	Acinar adenocarcinoma	7 (3+4)	15.2	PSA/clinic
21	66.0	Adenocarcinoma	6 (3+3)	14.9	PSA/clinic/surgery
22	69.2	PIN 1	–	8.4	PSA/clinic
23	68.5	Chronic prostatitis	–	16.3	PSA/clinic
24	66.0	Adenocarcinoma	6 (3+3)	21.6	PSA/clinic/surgery
25	64.6	Adenocarcinoma	7 (4+3)	12.7	PSA/clinic

the moment, transrectal ultrasound-guided systematic sextant biopsies as described by Hodge [30] have become a gold standard, and they are commonly performed on an outpatient basis. Nevertheless, it remains unclear how many biopsy cores are mandatory for optimizing tumor detection. So far, biopsies of 12 sites of the prostate have been described to increase the detection rate of prostate cancer and commonly have been applied [19, 31, 32].

Frequently, a negative result after transrectal ultrasonography is achieved in patients with a highly suspicion index of prostate cancer. The detection of prostate cancer through a second US-guided biopsy is a rather common finding and was encountered in previous studies in 12–30% of patients with the results of the first biopsy being negative [14]. In contrast, cancer detection in the third and fourth biopsy is rare. Third and fourth biopsies should only be obtained in an exclusive group of patients with high suspicion of cancer [14].

The cancer detection with targeted biopsy of the prostate performed on the basis of high-frequency Doppler ultrasonography (US) showed no benefit for the biopsy results, and a substantial number of cancers detected with sextant biopsy findings will miss [33]. Possibly patient position caused flow asymmetry in patients who underwent biopsy resulting in these poor results [34].

Transrectal ultrasound-guided prostate needle biopsies are generally safe, although the incidence of complications after transrectal ultrasound-guided needle biopsies has been reported by different authors [14, 18, 31]. Fever or general signs of infections could be observed in 1.2% up to 53.3% and sepsis in up to 5.4% of the biopsied patients [18]. At least two deaths from anaerobic septicemia have been reported [35, 36]. Several studies have shown a decreased rate of infectious complications after application of antibiotic prophylaxis [18]. The literature indicates that hemorrhage with gross hematuria is the most common complication after transrectal ultrasound-guided biopsies. At least 50% of all patients have persistent hematuria 3–7 days after the biopsies [18].

The depiction of suspicious prostate areas with high-field MRI offers the possibility to use this imaging method also for the guidance of the needle to the prostate gland during biopsies in order to achieve better biopsy results. Localizing and targeting tumor foci with MR imaging before the prostate biopsy may increase the cancer detection rate [9, 37]. Vilanova et al. published that endorectal MR imaging may be helpful in patients with discrepancy of clinical status and biopsy or with PSA range of 10–20 ng/ml. Systematic biopsies should not be performed in patients with negative results after endorectal MR imaging [38]. Perotti et al. showed a high rate of tumor detection with transrectal US-guided biopsies of suspected tumor foci after the use of endorectal MR imaging findings [4]. Nevertheless, MR imaging-guided biopsy may improve accuracy because it can be performed directly, without matching MR imaging and transrectal US findings.

However, a problem in the initial years of MR imaging was the great amount of time that was necessary

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to take MR images, so that MR-guided interventions seemed unlikely. The speed of MR imaging has been drastically increased so that in 1988 the first interventions with an MRI device could be performed [39–41]. The increased interest in open systems is mostly due to the higher comfort level of the patients and the lower system and service costs. Even though open MRI devices were first described in 1987 [42, 43], it was not until 1995 that open MRI devices were established for routine clinical diagnostics and interventions with a wide spectrum of applications.

Papanicolaou et al. [15] reported about the safe use of a transgluteal approach for prostatic biopsies after proctocolectomy with CT guidance. In these patients, no complications were observed, and all patients tolerated the procedure well [15]. The transgluteal approach makes it possible to minimize the risk of injury to the bladder, bowel loops and external iliac vessels. The lateral access at the MRI improved the patient comfort, because a prone position as with CT-guidance is not necessary [44]. Other groups described their first experiences with a transperineal access for MR-guided biopsy of the prostate gland [16, 17]. This transperineal access was used by different groups for the MR-guided insertion of the therapy needles for cancer treatment [45, 46].

Also, the first robotic systems were used for a transperineal needle placement into the prostate and showed a positive potential in a variety of other percutaneous clinical applications [47]. However, these systems were not regularly applied in human bodies and could therefore not be used in a magnetic field. Hata et al. [17] preferred the direct way through the perineum for the biopsy of the prostate gland and expected an increasing sample volume in the peripheral zone. We believe that the use of the transgluteal approach provides comparable results for the biopsy of the peripheral zone and superior results for the biopsy of the apex. The puncture of lesions in the periphery of the prostate gland is probably easier to perform. However, no comparison of the access routes was implemented.

For a successful biopsy, two parameters are of importance. First, tracing the instrument path and position for secure positioning into the lesion. Second, the monitoring process for control and presentation of the performed biopsy. It is possible to monitor functional information such as blood flow, temperature dispersion, organ perfusion and diffusion, which makes MRI superior to other monitoring devices. While using other imaging devices, compromises between the two points of interest listed above have to be made.

The cancer detection rate with transrectal US-guided biopsies was described to be from 10 to 50% in different studies [18, 48]. Although our sample size is small, it seems that the obtained results of MRI-guided biopsies are comparable or superior to US-guided biopsies in patients with previously negative US-guided biopsies. The falsely negative results might be caused by a multifocal appearance of the prostate cancer and the small volume of sampled biopsy specimens, which represents only a small part of the area assessed with MR imaging. The repeated collection of biopsy trephine with the coaxial access might improve the clinical results. Withdrawal of a specimen from different suspicious lesions of the prostate might improve the diagnostic accuracy.

In our study, we showed that percutaneous MRI-guided biopsies of the peripheral zone of the prostate gland with a transgluteal approach are feasible, safe and accurate. The long transgluteal needle passage is stabilized by the gluteal muscles so that accurate positioning of the needle is possible [44]. All patients were treated on an outpatient basis with no significant complications after the biopsy.

The transgluteal access used by us facilitated the biopsy of the peripheral zone of the prostate gland without the introduction of intestinal germs, as there was no contact with the intestine. Our first data show that a prophylactic antibiotic coverage seems unnecessary for the transgluteal biopsy approach of the peripheral zone of the prostate gland without increasing the number of prostate infections. Nevertheless, it is still possible that the bowel could be nicked or traversed using this access path to take histological samples from the medial parts of the prostate gland [44]. In those cases, and in patients with possible contact of the biopsy needle to the bowel during the intervention, antibiotics should be given to decrease the risk of septic shock [18]. Therefore, transgluteal MR-guided biopsies of the prostate are generally considered to cause no or minimal discomfort, and it has become common practice to perform them without general anesthesia.

A disadvantage of our study was the difference in the imaging technique for diagnostics and intervention. For the diagnostics of the prostate lesions we used a high-field MRI and the images were obtained in a supine position with the use of an endorectal coil. For the diagnosis high resolution T2-weighted images were used.

In contrast, the images used for biopsy-guidance were T1 weighted, obtained in a lateral decubitus position, with less resolution and without an endorectal coil. Neither the zonal anatomy of the prostate nor the suspicious lesions can be well differentiated in T1-weighted sequences. For these reasons the biopsied lesions cannot be directly visualized, so that the target lesions had to be extrapolated based on probable movement and deformation of the prostate relative to other structures in the pelvis.

At the moment the quality of the T2-weighted sequences is not satisfactorily for the guidance of the biopsy. A further problem with T2-weighted images is that the needle cannot be visualized as well as in T1-weighted images. However, better visualization of the zonal anatomy might be achieved with modified fast T2-

Table 2 Total results after MR-guided biopsies of the prostate gland

Patients	Positive biopsy	Negative biopsy	TM in follow-up after negative biopsy
25	10	13	2

weighted sequences for low-field MRI resulting in better biopsy results. In contrast to this the additional use of an endorectal coil at the low-field system provides better results in the detection of the target lesion resulting in a higher biopsy sensitivity for the detection of prostate cancer.

Possibly in the future the transgluteal access can be also used for the guidance of prostate biopsies in a high-field system. The shape of the new MRI systems might be a further step to the performance of biopsies in a high-field system. However, first the instrument producers have to transform their technical applications for a wide range of uses.

Despite these first positive results, further randomized studies have to follow to evaluate the clinical value of MR-guided biopsies of the prostate gland in comparison to US-guided biopsies to detect prostate cancer in patients with suspicious lesions.

It is not the intention of the MRI-guided biopsies to replace the more simple, effective, prevalent and economical transrectal US-guided biopsies. This biopsy technique is rather intended to provide an alternative to the prevalent US-guided biopsy in patients with high suspicion of prostate cancer, with persistent elevation of PSA level and indistinct results from endorectal coil MR imaging after prior negative routine systematic US-guided biopsies, which should be performed in specialized clinics. Since the costs of MR-guided biopsies are higher, the indication for this technique must be critically verified. However, a cost reduction of this expensive technique can be achieved by avoiding repeated unsuccessful TRUS.

In the future, it might be possible to reduce costs in patients with negative US biopsy findings with this expensive technique when repeated US-guided biopsies are expected over a long time (Table 2).

Conclusion

Transgluteal access to uncertain or suspicious prostate lesions by MR-guidance is a safe access with a low complication rate and could be used as an alternative method to transrectal US-guided biopsies.

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MR-guided transgluteal biopsies with an open low-field system in patients with clinically suspected prostate cancer: technique and preliminary results

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Abstract The purpose of this study was to examine the feasibility and safety of MR-guided biopsies with a transgluteal approach in patients with uncertain or suspicious prostate lesions. Twenty-five patients with uncertain or suspicious focal prostate lesions detected by high-field MR imaging of the prostate gland using endorectal coil imaging were biopsied with a transgluteal approach in a low-field MRI system (0.2 T, Concerto, Siemens). The procedures were guided using T1-weighted FLASH sequences. The prostate gland was biopsied repeatedly with a coaxial technique through a 15-gauge pencil tip with a 16-gauge biopsy handy (median 3.8 samples per patient). Complications and biopsy findings were documented retrospectively. Using T1-weighted sequences biopsy procedures were performed successfully with MR guidance in all cases without any side effects or complications. The median intervention time was 11.3 min. Pathological findings revealed ten cases of hyperplasia or atrophy, three cases of prostatitis, ten cases of carcinoma and two cases of normal tissue. The clinical follow-up showed that in two patients prostate cancer was missed at MR-guided biopsy. Transgluteal MR-guided biopsy of the prostate gland is a safe and promising approach for histological clarification of uncertain or suspicious lesions.

Keywords Prostate MR · Prostatic neoplasm · Interventional procedures · MR-guided biopsy

Introduction

Prostate cancer is the most common malignancy in the Western hemisphere in men aged 50 years and older, and the incidence of prostate carcinoma has been declining since 1992 after a period of marked increase [1, 2]. Early detection programs for prostate cancer with prostate-specific antigen (PSA) level testing and an annual digital rectal examination (DRE) should be performed in men aged 50 years or older. The serum concentration of PSA is considered to be an important indicator in the early detection of prostate cancer [2]. In patients with a PSA level higher than 4 ng/ml, a transrectal ultrasonography (US) has often been performed [3] for the detection of possible tumors. Likewise, magnetic resonance imaging (MRI) is an accepted and promising diagnostic option for prostate examinations. Recent studies showed that MR imaging with the use of an endorectal coil improved results in the detection of tumor foci in patients who had elevated PSA levels [4, 5] and described cancer detection rates between 37 and 87% for T2-weighted endorectal MR imaging [5–10]. Particularly, the detection of lesions smaller than 5 mm in diameter is poor [11]. Likewise, less differentiated prostate cancer showed only a

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poor T2-contrast [12]. With better detection of prostate tumors, an increasing number of patients need a precise histological tumor clarification before the planning of further treatment. The gold standard of histological confirmation of prostate cancer in patients with elevated PSA levels is at the moment systematic sextant biopsy of the prostate, involving the apex, middle and base of both sides of the prostate gland [13]. However, a large number of patients with elevated PSA levels have negative biopsy results with US guidance, so that repeated biopsies are necessary for a sufficient diagnosis of prostate cancer [14]. For these reasons alternative image-guiding modalities like CT and MRI have been evaluated for specific indications [15–17].

MRI examinations of the prostate gland for the detection of prostate cancer are a promising imaging modality and this technique may also be useful for the guidance of prostate biopsies. The purpose of this study was to examine the feasibility and safety of a transgluteal approach for MR-guided biopsies in patients with uncertain or suspicious prostate lesions in endorectal high-field MRI.

Materials and methods

Patients

In an 18-month period 25 patients ranging in age from 48 to 74 years (median 61.9 years) were examined with endorectal body-phase array coil followed by MRI-guided biopsies of the prostate gland if MRI showed uncertain or suspicious prostate lesions for histological clarification. The median PSA level was 11.8 ng/ml in all patients ranging from 4.8 to 28.0 ng/ml.

Fifteen of these patients had been referred to us by their urologists; ten came without referral by a urologist because they had heard something about our new biopsy technique. In 17 patients prior transrectal US-guided quadrant or sextant biopsy results were negative. The other patients refused prior US-guided biopsies. Informed consent was obtained from all patients. The patients included in the study had a PSA level higher than 4 ng/ml and/or uncertain or suspicious MR imaging results. Patient exclusion criteria were contraindications to MR imaging and to biopsies.

High-field MR imaging technique

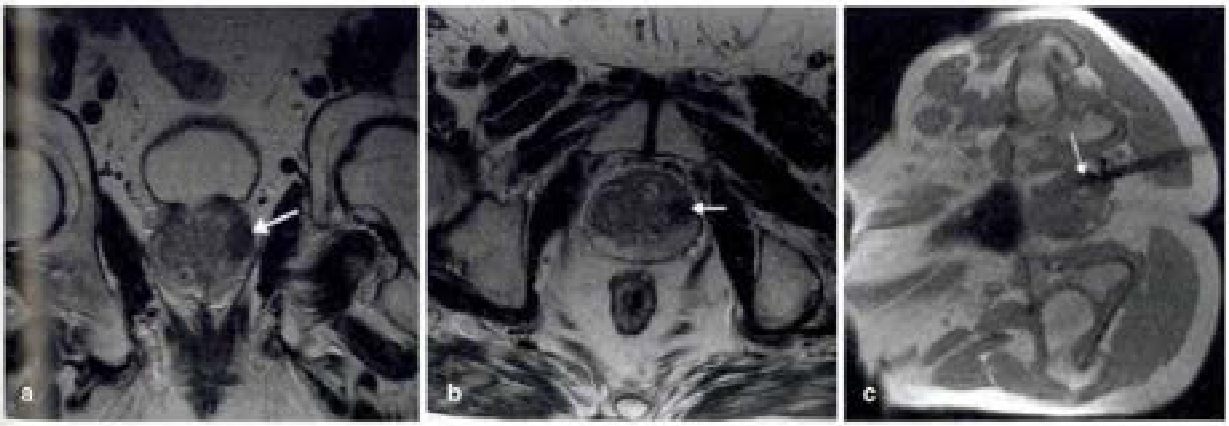
Before the biopsies, we performed endorectal MR imaging using a 1.5-T unit (Magnetom Symphony; Siemens, Erlangen, Germany) and an endorectal surface coil (Medrad; Indianola, USA) coupled to an anterior body-phase array coil. The examination was performed with a routine imaging protocol. After the coil position had been checked using a gradient-echo localizer sequence, fast T2-weighted turbo spin-echo sequences were acquired (TR/TE=3,500/100; 4-mm section thickness, 0.8-mm intersec-tion gap, 512×256 matrix) at angulated transverse-section and coronal-section orientations by using 16×16-cm field of view. Supplementary angulated transverse T1-weighted spin-echo images (TR/TE=500/10; 4-mm section thickness, 0.8-mm intersection gap, 512×256 matrix; 16×16-cm field of view) were acquired. During the examination no medications for suppression of peristaltic artifacts were applied. One patient refused the introduction of the endorectal coil (Fig. 1).

The MR imaging findings of the high-field system were analyzed by two readers (S.Z.; T.V.). Diffuse and inhomogeneous hypointense areas of the peripheral zone in T2-weighted images were classified as uncertain findings. The presence of cancer or suspicious areas, identified as areas of low signal intensity within the peripheral zone in T2-weighted images, was estimated on a four-point rating scale: 1, normal tissue; 2, probably normal tissue; 3, possible cancer; 4, definite cancer. In patients with findings rated three or four we performed MRI-guided biopsies for histological differentiation of these lesions.

MRI-guided biopsies

Two to 16 days (median 6 days) after high-field MR imaging of the prostate gland with suspicious MRI results, MRI-guided biopsies were performed in 25 patients by one radiologist and one technical assistant with the MR imaging findings taken into account. The biopsies were performed after elimination of all contraindications, detailed information of the patient and a written

Fig. 1 Coronal (**a**) and transversal (**b**) view of T2-weighted FSE (TR/TE=3,500/100) images with a 1.5-T system obtained from a 69-year-old patient with a PSA level of 18 ng/dl and negative US-guided biopsy result. The images show a small hypointense tumor in the left peripheral zone (*arrow*). **c** Transversal T1-weighted FLASH sequence (TR/TE=100/9) in a 0.2-T system during the biopsy (cr. the needle tip (*arrow*) was placed in the left peripheral zone. Pathological result of the sample was prostatic adenocarcinoma



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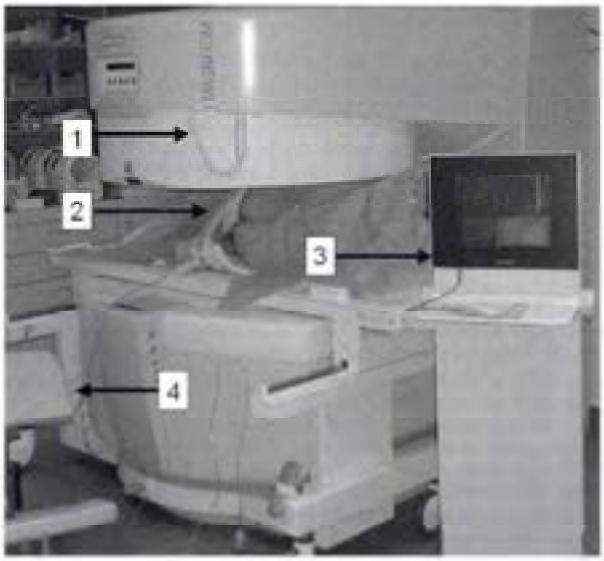


Fig. 2 Typical positioning of the patient in lateral decubitus during the biopsy of the prostate gland for an optimal biopsy approach. MR compatible in-room components of the interventional MRI (Magnetom Concerto; 0.2 T): a lamp (*1*) for optimal lighting of the insertion, a flexible surface coil (*2*), an in-room console with mouse (*3*) and a seat (*4*) for an easy performance of the biopsy

consent. All patients had to stop eating 6 h before the biopsy. Fluids and necessary medications could be consumed until 2 h before the intervention.

For the guidance of the biopsies an open 0.2-T MR imaging device (Magnetom Concerto, Siemens; Erlangen, Germany) with a vertical field-axis was used because it provides the performing physician with a wide lateral access to the patient. The receiver was a flexible, standard, multi-purpose coil (Siemens; Erlangen, Germany) with a diameter of 45 cm, and the coil was positioned at the patients' greater trochanter. Constant monitoring and evaluation of the path of the biopsy instruments as well as the imaging management was done with a standard in-room workstation (Siemens; Erlangen, Germany). The setup for the biopsy is demonstrated in Fig. 2. The previously sampled MR images were recruited for the planning of the biopsy path and the positioning of the patients. The patients' position was chosen to allow a real-time MRI-guided biopsy and to facilitate access by the physician. We used a transgluteal approach for the biopsy of the prostate gland (Fig. 3). After choosing the path for the procedure the point of insertion was marked by taping a marker to the expected point of insertion or by using real-time imaging together with a finger as an external marker.

For the localization and the planning of the biopsy path, a FLASH (fast low angle shot) 2-D-GRE sequence (TR/TE=100/9; flip angle 70°, 8-mm section thickness, 96×256 matrix, acquisition time 18 s) and a modified FLASH 2-D-GRE sequence (TR/TE=100/7; flip angle 70°, 8-mm section thickness, 96×256 matrix; acquisition time 16 s) were used. We did not take T2-weighted images because the needle cannot be visualized as well as in T1-weight images during the biopsy.

Monitoring during the procedure was performed using the FLASH 2-D-GRE sequence (TR/TE=100/9; flip angle 70°, 8-mm section thickness, 96×256 matrix, acquisition time 18 s). After the biopsy FLASH 2-D-GRE sequences (TR/TE=100/9; flip angle 70°, 8-mm section thickness, 96×256 matrix, acquisition time 18 s) were used to rule out further complications.

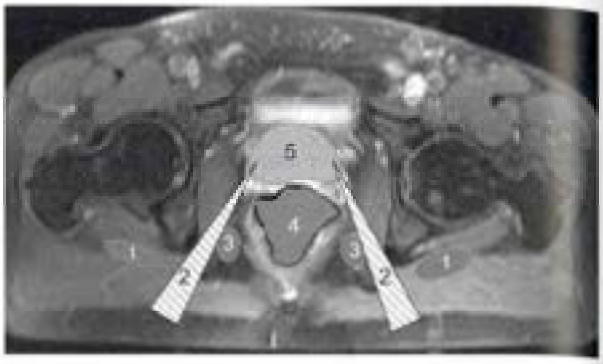


Fig. 3 Exposure of the vital structures of the male pelvis, which might be marked during the biopsy of the prostate gland (*5*) with a transgluteal access (*2*): rectum (*4*), internal pudendal artery and vein/pudic nerve (*3*), gluteal artery and vein/ischiadic nerve (*1*)

After disinfection of the skin and local infiltration anesthesia [10–20 ml local anesthetic (Scandicain; AstraZeneca; Wedel, Germany)], a 15-gauge biopsy needle (Pencil Tip, Somatex, Berlin, Germany) was guided to the target lesion so that a true-cut MRI-compatible biopsy handy (Somatex; Berlin, Germany) of 16 gauge in size could be inserted into the suspicious areas. Multiple tissue samples of one lesion were withdrawn with this coaxial technique to ensure that enough histological material could be acquired for histological clarification. A total of 98 tissue samples were taken (median 3.8 per patient) from uncertain or suspicious lesions, and the trephine biopsy samples were fixed in 10% formaldehyde. The procedure time was recorded. The biopsies were performed in all patients as an outpatient treatment with observation for 2 h after the procedure. Side effects after the biopsies were evaluated by an interview of the patients in the following weeks.

Insufficient samples or diagnosed necroses in trephine biopsies were determined as false negative. The current or final diagnosis of patients with benign results was made by a clinical follow-up between 6 and 13 months (median time 9.7 months). The diagnostic accuracy was achieved by comparing the changes in the PSA level and the histopathological diagnosis. The indication for surgical treatment was made by the urologist and the patient based on our results and the patients' request. The diagnostic accuracy for the histology of the biopsy samples was reported as true positive, true negative, false positive or false negative, confirmed with surgery or clinical follow-up.

Results

The average size of the prostate gland was 38.8 cm^3 (range 27.1–83.2 cm^3). High-field MRI documented signal abnormalities in 14 patients in the left peripheral zone of the prostate gland and in 11 patients in the right peripheral zone. Mean size of the suspicious prostate lesion was 11 mm ranging from 8 to 15 mm.

The biopsies were performed technically successfully in all patients. The biopsies were performed in all patients using the FLASH sequences, and additionally in five patients using the modified FLASH sequences. The

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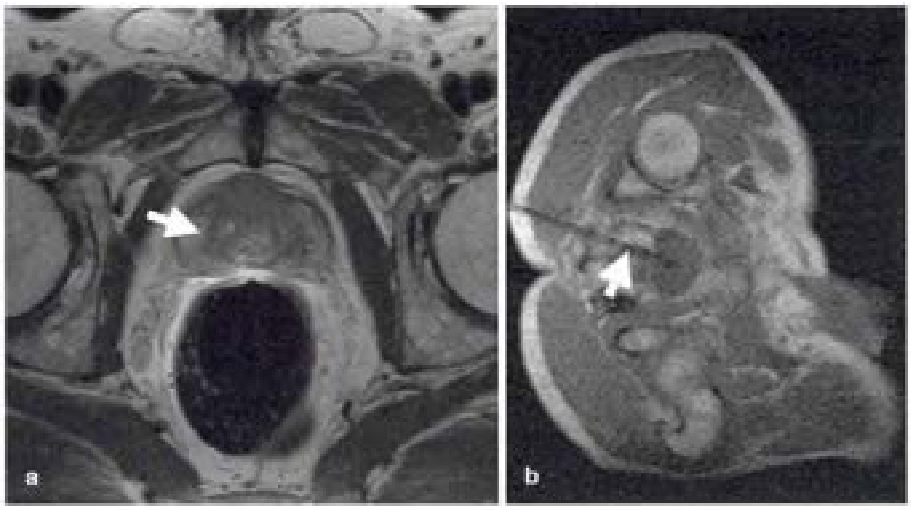


Fig. 4 **a** Transversal T2-weighted TSE image obtained with a 1.5-T system using an endorectal coil (TR/TE= 3,500/100) from a 64-year-old patient who showed a suspicious lesion in the central zone of the prostate gland (*arrow*), which was classified as a possible cancer. **b** T1-weighted FLASH (TR/TE=100/9) during biopsy of the central zone in the 0.2-T open field system. The images showed that a safe insertion of the biopsy needle (*arrow*) into central prostatic structures is possible. Histological tissue demonstrated a prostatic adenocarcinoma

mean number of image acquisitions used during the procedure was 13.7, ranging from 7 to 22.

In all cases the location of the area with the suspicious lesion leads to a safe approach by using MR guidance. The median needle artifact measured was 3.2 mm (range 1.9–5.6 mm). The position of the needle tip could be well visualized in all patients. The visualization of the soft tissue, the vessels and the biopsy needle was good or moderate in all patients, resulting in a safe guidance of the biopsy (Fig. 4).

The median operation time from entering to leaving the operating room was 19.4 min (maximum 35.3 min and minimum 13.5 min). The median puncture time from the insertion of the needle through the skin to needle retraction was 11.3 min (maximum 16.8 min and minimum 5.3 min). The median distance of the access path was 12.1 cm (ranging from 10.5 to 13.2 cm).

At the time of the biopsies all patients tolerated the treatment with minimal or no discomfort after local anesthesia. Only two patients (8% of all patients) showed hematuria after the biopsies. No rectal bleeding or other minor complications were observed during the procedure or the following days. Likewise, no major complications, defined as those requiring hospital admissions, were observed in any patients.

The trephine biopsy yielded a malignant diagnosis in ten patients, an infectious reaction in three patients, regressive tissue in one patient, a hyperplasia of the prostate gland in nine patients and non-pathological findings in two patients. Six-month clinical follow-up in two patients showed that the lesions were wrongly classified as negative. These must be seen as failed biopsies. The biopsy and the follow-up results are shown in Table 1.

None of the patients complained of fever at the time after the biopsy, although they did not receive any antibiotic prophylaxis. No complications were ascertained in a patient with an indwelling catheter, either.

Discussion

Early cancer detection programs seem to be the key to achieving an early detection of prostate cancer and may lead to an increase in the number of patients with curable diseases who can undergo curative radical prostatectomy or curative radiation therapy [18]. Thus, the mortality of this disease can be decreased. Tumor volume, TNM stage, Gleason score and PSA level are relevant prognostic factors of prostate carcinoma.

In patients with elevated PSA levels, transrectal ultrasonography (US) is routinely performed. Likewise, since 1989 endorectal MR imaging was been used increasingly to prove and to predict the extension of prostate cancer [2, 19–21]. In this regard MR imaging provides a high tissue contrast of the detailed structure of prostate gland and periprostatic tissue without the use of a contrast medium. However, non-cancerous tissue, such as prostatitis, dysplasia and prostatic hyperplasia, can show low-intensity areas similar to prostate cancer [5, 19, 22–24]. T2-weighted echo-planar imaging (EPI) has potential usefulness in the detection of impalpable PSA detected prostate cancer [25]. New developments in MR techniques such as the gadolinium-enhanced dynamic subtraction technique [26, 27] and spectroscopic imaging [8, 28, 29] may improve the results for prostate cancer detection in the future. However, because of largely overlapping enhancement pattern, cancer will probably not be depicted within adenoma by dynamic imaging, at least by using low temporal resolution [26].

For the assessment of indistinct prostate lesions, histological clarifications have mostly been performed. At

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Table 1 Histological results after MR-guided biopsy and follow-up [prostatic specific antigen (PSA), Gleason score (GS)]

Patient	Age	Histology	GS	PSA	Follow-up
1	61.4	Fibromatous hyperplasia	–	9.4	PSA/clinic
2	58.6	Carcinoma with perineural infiltration, GS 6	6 (3+3)	11.2	PSA/clinic/surgery
3	55.2	Hyperplasia	–	8.6	PSA/clinic
4	63.4	Hyperplasia, lymphocytic infiltration	–	4.8	PSA/clinic
5	61.3	Chronic prostatitis	–	12.8	PSA/clinic/antibiosis
6	55.6	Adenomatous hyperplasia	–	13.5	PSA/clinic
7	62.8	No malignancy	–	6.4	PSA/clinic
8	69.0	Well-differentiated adenocarcinoma	6 (3+3)	9.7	Surgery
9	57.7	Hyperplasia	–	13.4	PSA/clinic
10	65.3	Regressive prostate tissue	–	10.0	PSA/clinic/surgery
11	60.9	Adenomatous hyperplasia	–	16.1	PSA/clinic/surgery
12	59.1	Fibromyomatous hyperplasia	–	10.1	PSA/clinic
13	74.1	Hyperplasia	–	17.2	PSA/clinic
14	65.7	Chronic prostatitis	–	10.9	PSA/clinic/antibiosis
15	59.4	No malignancy	–	7.4	PSA/clinic
16	48.7	Hyperplasia	–	5.2	PSA/clinic
17	68.6	Acinar adenocarcinoma	1–2	11.8	PSA/clinic
18	63.6	Adenocarcinoma	7 (3+4)	28.0	PSA/clinic/surgery
19	65.0	Azonal clear cell carcinoma	6 (3+3)	16.1	PSA/clinic/surgery
20	68.4	Acinar adenocarcinoma	7 (3+4)	15.2	PSA/clinic
21	66.0	Adenocarcinoma	6 (3+3)	14.9	PSA/clinic/surgery
22	69.2	PIN 1	–	8.4	PSA/clinic
23	68.5	Chronic prostatitis	–	16.3	PSA/clinic
24	66.0	Adenocarcinoma	6 (3+3)	21.6	PSA/clinic/surgery
25	64.6	Adenocarcinoma	7 (4+3)	12.7	PSA/clinic

the moment, transrectal ultrasound-guided systematic sextant biopsies as described by Hodge [30] have become a gold standard, and they are commonly performed on an outpatient basis. Nevertheless, it remains unclear how many biopsy cores are mandatory for optimizing tumor detection. So far, biopsies of 12 sites of the prostate have been described to increase the detection rate of prostate cancer and commonly have been applied [19, 31, 32].

Frequently, a negative result after transrectal ultrasonography is achieved in patients with a highly suspicion index of prostate cancer. The detection of prostate cancer through a second US-guided biopsy is a rather common finding and was encountered in previous studies in 12–30% of patients with the results of the first biopsy being negative [14]. In contrast, cancer detection in the third and fourth biopsy is rare. Third and fourth biopsies should only be obtained in an exclusive group of patients with high suspicion of cancer [14].

The cancer detection with targeted biopsy of the prostate performed on the basis of high-frequency Doppler ultrasonography (US) showed no benefit for the biopsy results, and a substantial number of cancers detected with sextant biopsy findings will miss [33]. Possibly patient position caused flow asymmetry in patients who underwent biopsy resulting in these poor results [34].

Transrectal ultrasound-guided prostate needle biopsies are generally safe, although the incidence of complications after transrectal ultrasound-guided needle biopsies has been reported by different authors [14, 18, 31]. Fever or general signs of infections could be observed in 1.2% up to 53.3% and sepsis in up to 5.4% of the biopsied patients [18]. At least two deaths from anaerobic septicemia have been reported [35, 36]. Several studies have shown a decreased rate of infectious complications after application of antibiotic prophylaxis [18]. The literature indicates that hemorrhage with gross hematuria is the most common complication after transrectal ultrasound-guided biopsies. At least 50% of all patients have persistent hematuria 3–7 days after the biopsies [18].

The depiction of suspicious prostate areas with high-field MRI offers the possibility to use this imaging method also for the guidance of the needle to the prostate gland during biopsies in order to achieve better biopsy results. Localizing and targeting tumor foci with MR imaging before the prostate biopsy may increase the cancer detection rate [9, 37]. Vilanova et al. published that endorectal MR imaging may be helpful in patients with discrepancy of clinical status and biopsy or with PSA range of 10–20 ng/ml. Systematic biopsies should not be performed in patients with negative results after endorectal MR imaging [38]. Perotti et al. showed a high rate of tumor detection with transrectal US-guided biopsies of suspected tumor foci after the use of endorectal MR imaging findings [4]. Nevertheless, MR imaging-guided biopsy may improve accuracy because it can be performed directly, without matching MR imaging and transrectal US findings.

However, a problem in the initial years of MR imaging was the great amount of time that was necessary

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to take MR images, so that MR-guided interventions seemed unlikely. The speed of MR imaging has been drastically increased so that in 1988 the first interventions with an MRI device could be performed [39–41]. The increased interest in open systems is mostly due to the higher comfort level of the patients and the lower system and service costs. Even though open MRI devices were first described in 1987 [42, 43], it was not until 1995 that open MRI devices were established for routine clinical diagnostics and interventions with a wide spectrum of applications.

Papanicolaou et al. [15] reported about the safe use of a transgluteal approach for prostatic biopsies after proctocolectomy with CT guidance. In these patients, no complications were observed, and all patients tolerated the procedure well [15]. The transgluteal approach makes it possible to minimize the risk of injury to the bladder, bowel loops and external iliac vessels. The lateral access at the MRI improved the patient comfort, because a prone position as with CT-guidance is not necessary [44]. Other groups described their first experiences with a transperineal access for MR-guided biopsy of the prostate gland [16, 17]. This transperineal access was used by different groups for the MR-guided insertion of the therapy needles for cancer treatment [45, 46].

Also, the first robotic systems were used for a transperineal needle placement into the prostate and showed a positive potential in a variety of other percutaneous clinical applications [47]. However, these systems were not regularly applied in human bodies and could therefore not be used in a magnetic field. Hata et al. [17] preferred the direct way through the perineum for the biopsy of the prostate gland and expected an increasing sample volume in the peripheral zone. We believe that the use of the transgluteal approach provides comparable results for the biopsy of the peripheral zone and superior results for the biopsy of the apex. The puncture of lesions in the periphery of the prostate gland is probably easier to perform. However, no comparison of the access routes was implemented.

For a successful biopsy, two parameters are of importance. First, tracing the instrument path and position for secure positioning into the lesion. Second, the monitoring process for control and presentation of the performed biopsy. It is possible to monitor functional information such as blood flow, temperature dispersion, organ perfusion and diffusion, which makes MRI superior to other monitoring devices. While using other imaging devices, compromises between the two points of interest listed above have to be made.

The cancer detection rate with transrectal US-guided biopsies was described to be from 10 to 50% in different studies [18, 48]. Although our sample size is small, it seems that the obtained results of MRI-guided biopsies are comparable or superior to US-guided biopsies in patients with previously negative US-guided biopsies. The falsely negative results might be caused by a multifocal appearance of the prostate cancer and the small volume of sampled biopsy specimens, which represents only a small part of the area assessed with MR imaging. The repeated collection of biopsy trephine with the coaxial access might improve the clinical results. Withdrawal of a specimen from different suspicious lesions of the prostate might improve the diagnostic accuracy.

In our study, we showed that percutaneous MRI-guided biopsies of the peripheral zone of the prostate gland with a transgluteal approach are feasible, safe and accurate. The long transgluteal needle passage is stabilized by the gluteal muscles so that accurate positioning of the needle is possible [44]. All patients were treated on an outpatient basis with no significant complications after the biopsy.

The transgluteal access used by us facilitated the biopsy of the peripheral zone of the prostate gland without the introduction of intestinal germs, as there was no contact with the intestine. Our first data show that a prophylactic antibiotic coverage seems unnecessary for the transgluteal biopsy approach of the peripheral zone of the prostate gland without increasing the number of prostate infections. Nevertheless, it is still possible that the bowel could be nicked or traversed using this access path to take histological samples from the medial parts of the prostate gland [44]. In those cases, and in patients with possible contact of the biopsy needle to the bowel during the intervention, antibiotics should be given to decrease the risk of septic shock [18]. Therefore, transgluteal MR-guided biopsies of the prostate are generally considered to cause no or minimal discomfort, and it has become common practise to perform them without general anesthesia.

A disadvantage of our study was the difference in the imaging technique for diagnostics and intervention. For the diagnostics of the prostate lesions we used a high-field MRI and the images were obtained in a supine position with the use of an endorectal coil. For the diagnosis high resolution T2-weighted images were used.

In contrast, the images used for biopsy-guidance were T1 weighted, obtained in a lateral decubitus position, with less resolution and without an endorectal coil. Neither the zonal anatomy of the prostate nor the suspicious lesions can be well differentiated in T1-weighted sequences. For these reasons the biopsied lesions cannot be directly visualized, so that the target lesions had to be extrapolated based on probable movement and deformation of the prostate relative to other structures in the pelvis.

At the moment the quality of the T2-weighted sequences is not satisfactorily for the guidance of the biopsy. A further problem with T2-weighted images is that the needle cannot be visualized as well as in T1-weighted images. However, better visualization of the zonal anatomy might be achieved with modified fast T2-

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Table 2 Total results after MR-guided biopsies of the prostate gland

Patients	Positive biopsy	Negative biopsy	TM in follow-up after negative biopsy
25	10	13	2

weighted sequences for low-field MRI resulting in better biopsy results. In contrast to this the additional use of an endorectal coil at the low-field system provides better results in the detection of the target lesion resulting in a higher biopsy sensitivity for the detection of prostate cancer.

Possibly in the future the transgluteal access can be also used for the guidance of prostate biopsies in a high-field system. The shape of the new MRI systems might be a further step to the performance of biopsies in a high-field system. However, first the instrument producers have to transform their technical applications for a wide range of uses.

Despite these first positive results, further randomized studies have to follow to evaluate the clinical value of MR-guided biopsies of the prostate gland in comparison to US-guided biopsies to detect prostate cancer in patients with suspicious lesions.

It is not the intention of the MRI-guided biopsies to replace the more simple, effective, prevalent and economical transrectal US-guided biopsies. This biopsy technique is rather intended to provide an alternative to the prevalent US-guided biopsy in patients with high suspicion of prostate cancer, with persistent elevation of PSA level and indistinct results from endorectal coil MR imaging after prior negative routine systematic US-guided biopsies, which should be performed in specialized clinics. Since the costs of MR-guided biopsies are higher, the indication for this technique must be critically verified. However, a cost reduction of this expensive technique can be achieved by avoiding repeated unsuccessful TRUS.

In the future, it might be possible to reduce costs in patients with negative US biopsy findings with this expensive technique when repeated US-guided biopsies are expected over a long time (Table 2).

Conclusion

Transgluteal access to uncertain or suspicious prostate lesions by MR-guidance is a safe access with a low complication rate and could be used as an alternative method to transrectal US-guided biopsies.

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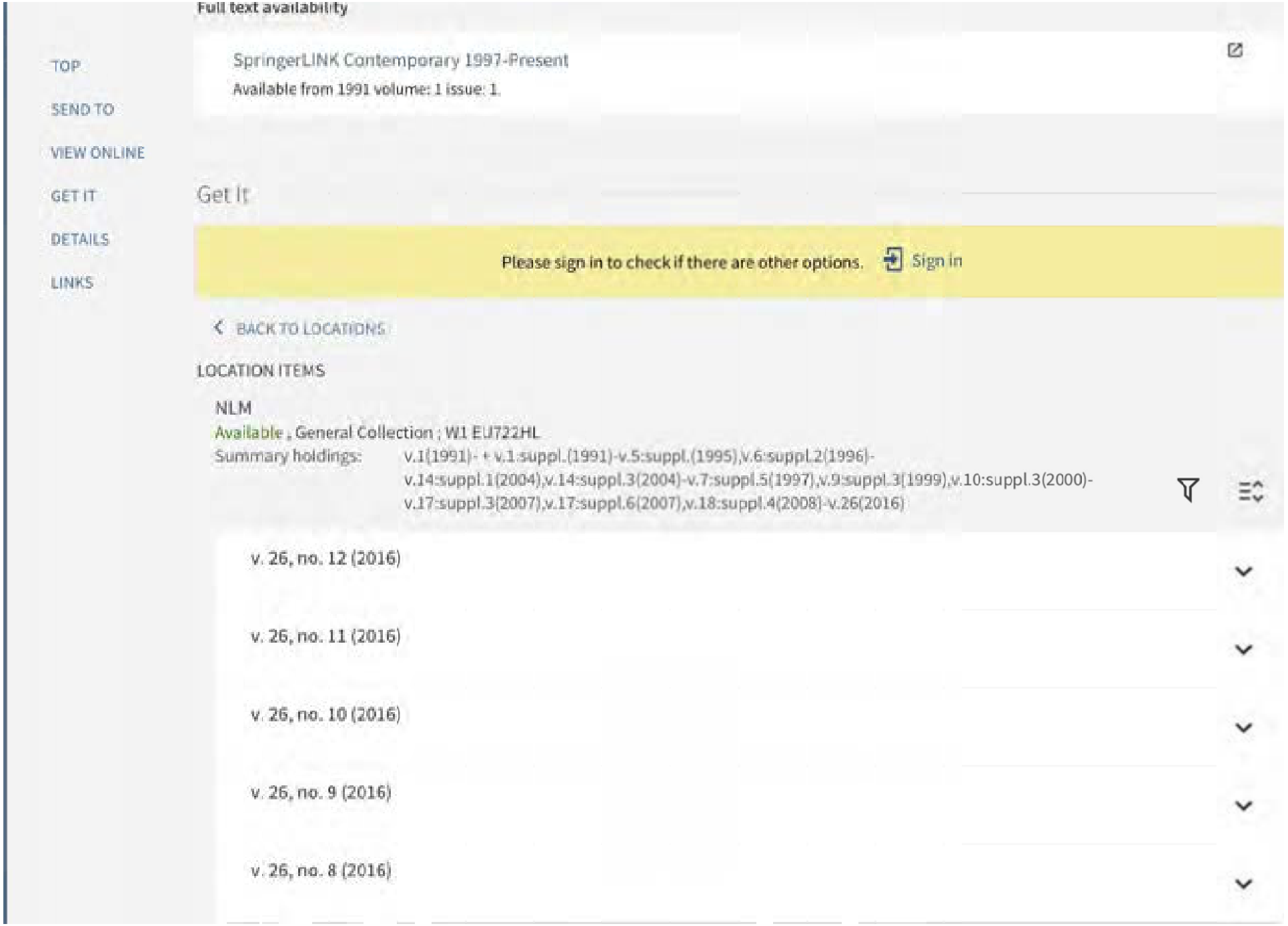
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MR-guided transgluteal biopsies with an open low-field system in patients with clinically suspected prostate cancer: technique and preliminary results

Stephan Zangos [1], Katrin Eichler, Kerstin Engelmann, Mukhtiar Ahmed, Sebastian Dettmer, Christopher Herzog, Wasilios Pegios, A Wetter, Thomas Lehnert, Martin G Mack, Thomas J Vogl

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Abstract

The purpose of this study was to examine the feasibility and safety of MR-guided biopsies with a transgluteal approach in patients with uncertain or suspicious prostate lesions. Twenty-five patients with uncertain or suspicious focal prostate lesions detected by high-field MR imaging of the prostate gland using endorectal coil imaging were biopsied with a transgluteal approach in a low-field MRI system (0.2 T, Concerto, Siemens). The procedures were guided using T1-weighted FLASH sequences. The prostate gland was biopsied repeatedly with a coaxial technique through a 15-gauge pencil tip with a 16-gauge biopsy handy (median 3.8 samples per patient). Complications and biopsy findings were documented retrospectively. Using T1-weighted sequences biopsy procedures were performed successfully with MR guidance in all cases without any side effects or complications. The median intervention time was 11.3 min. Pathological findings revealed ten cases of hyperplasia or atrophy, three cases of prostatitis, ten cases of carcinoma and two cases of normal tissue. The clinical follow-up showed that in two patients prostate cancer was missed at MR-guided biopsy. Transgluteal MR-guided biopsy of the prostate gland is a safe and promising approach for histological clarification of uncertain or suspicious lesions.

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PL - Germany
TA - Eur Radiol
JT - European radiology
JID - 9114774
SB - IM
MH - Aged
MH - Biopsy, Needle/*methods
MH - *Buttocks
MH - Feasibility Studies
MH - Humans
MH - *Magnetic Resonance Imaging
MH - Male
MH - Middle Aged
MH - Prostatic Neoplasms/*pathology
MH - Safety
EDAT- 2004/09/08 05:00
MHDA- 2005/05/13 09:00
CRDT- 2004/09/08 05:00
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PHST- 2004/07/16 00:00 [accepted]
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PHST- 2004/09/08 05:00 [pubmed]
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PHST- 2004/09/08 05:00 [entrez]
AID - 10.1007/s00330-004-2458-2 [doi]
PST - ppublish
SO - Eur Radiol. 2005 Jan;15(1):174-82. doi: 10.1007/s00330-004-2458-2. Epub 2004 Sep 4.

APPENDIX 1010D

Appendix 1010D
Early Citations to Zangos

Source Document

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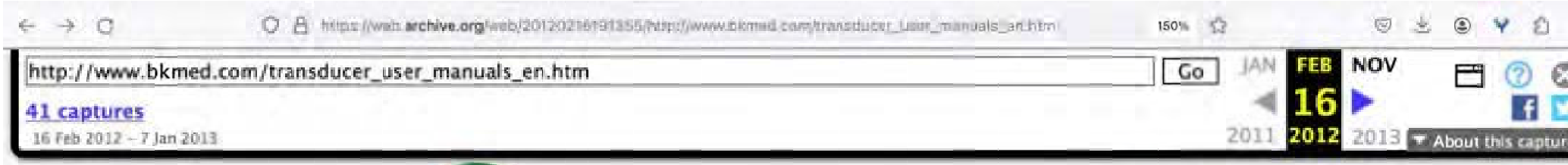
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EXHIBIT 1016



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8660	Linear Array Transducer	8820e	Curved Array Transducer
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