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High-Intensity Focused Ultrasound (HIFU) and Pain Management

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Conflicts of Interest

Speaker for:

-Abbott

-Promedica Europe


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Outline

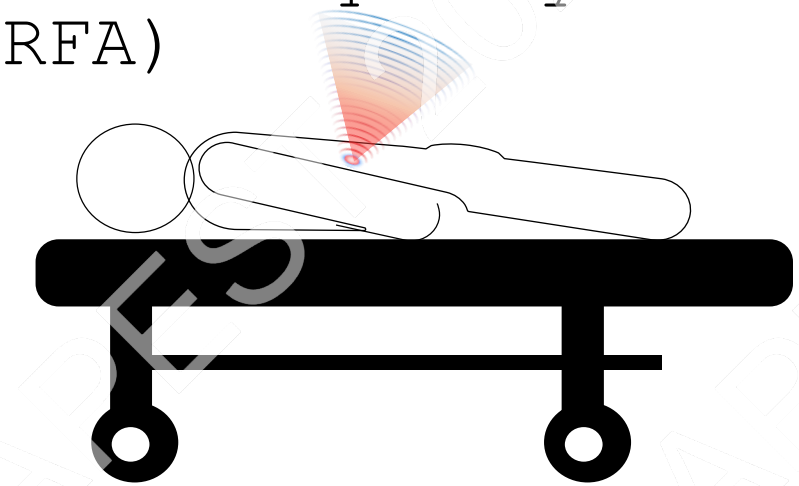
1. Introduction to HIFU
2. Mechanism of action
3. Evidence from preclinical and clinical studies
4. My clinical experience in Italy
5. Advantages and limitations
6. Future directions

What is HI-FU?

- Non-invasive, image-guided thermal ablation
- Focused ultrasound converges at a precise target → thermal necrosis
- No skin incision, no needle
- Image guidance: fluoroscopy or MRI

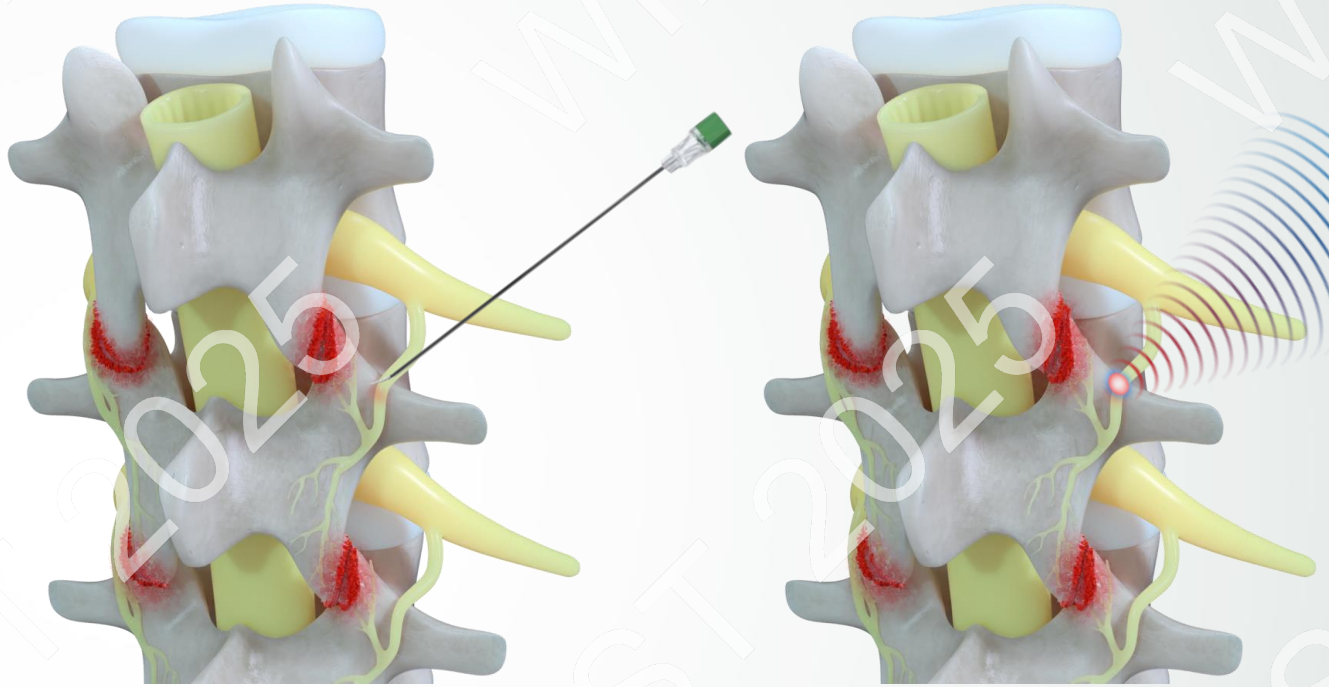
Mechanism in Pain Management

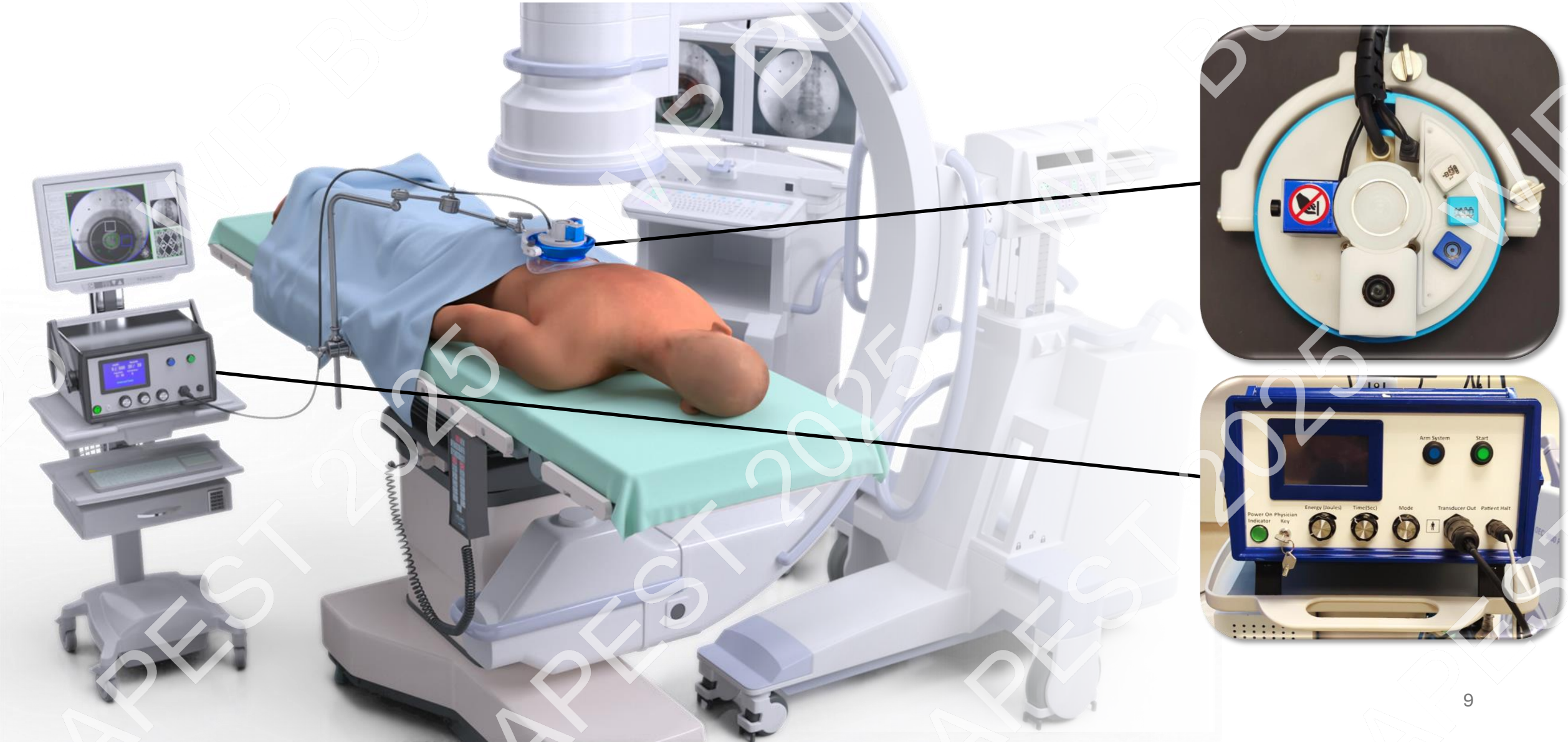
- Targets sensory nerves or periosteal innervation
- Bone absorbs ultrasound energy efficiently
- Denervation at bone–nerve interface
- Comparable goal to radiofrequency ablation (RFA)

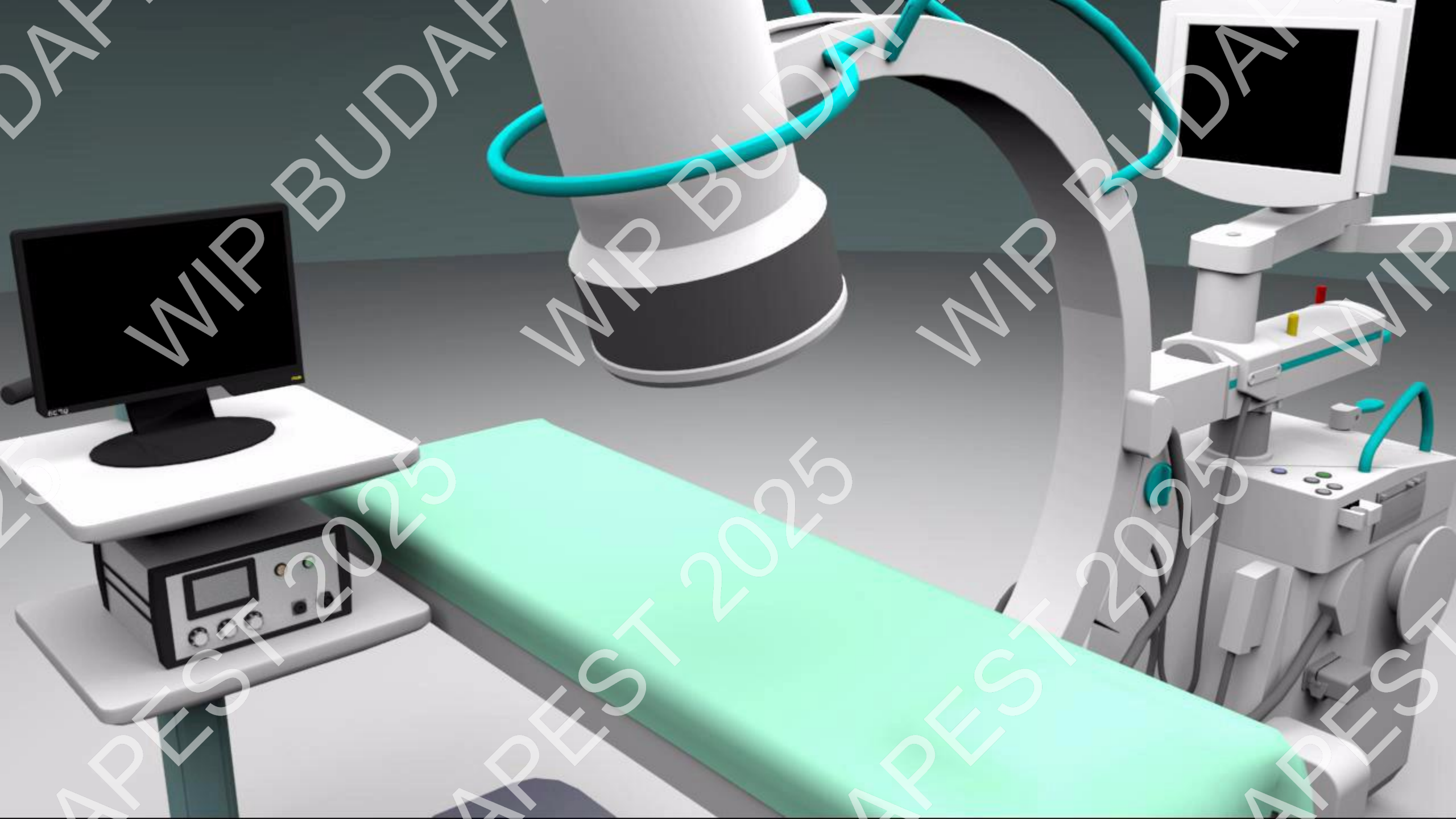


Fluoroscopy-Guided HIFU: Step-by-Step

- Patient positioning: prone, abdominal pillow to reduce lumbar lordosis
- Skin preparation and gel pad coupling
- Target identification via fluoroscopy
- Alignment of HIFU focal point with bone–nerve interface
- Energy delivery (single sonication per target)



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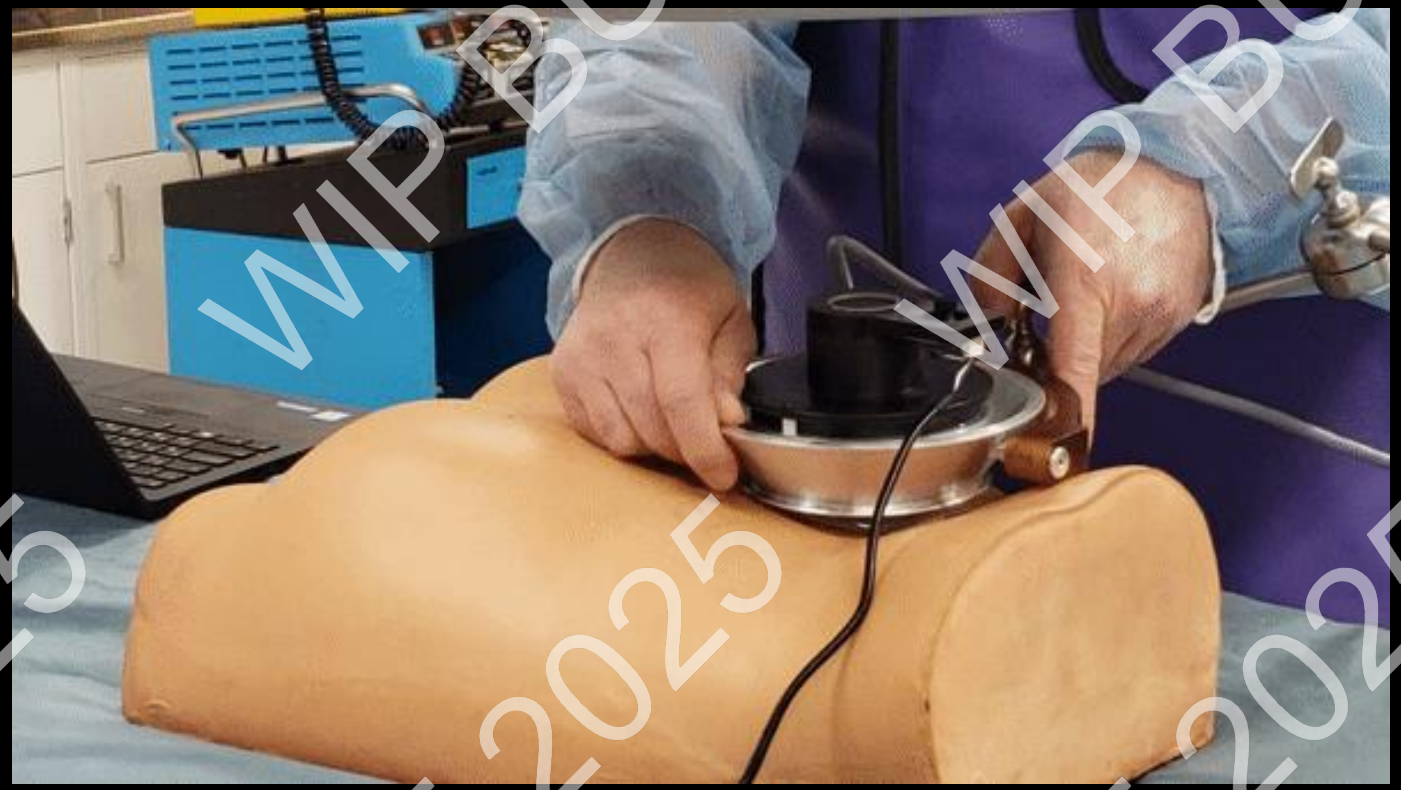
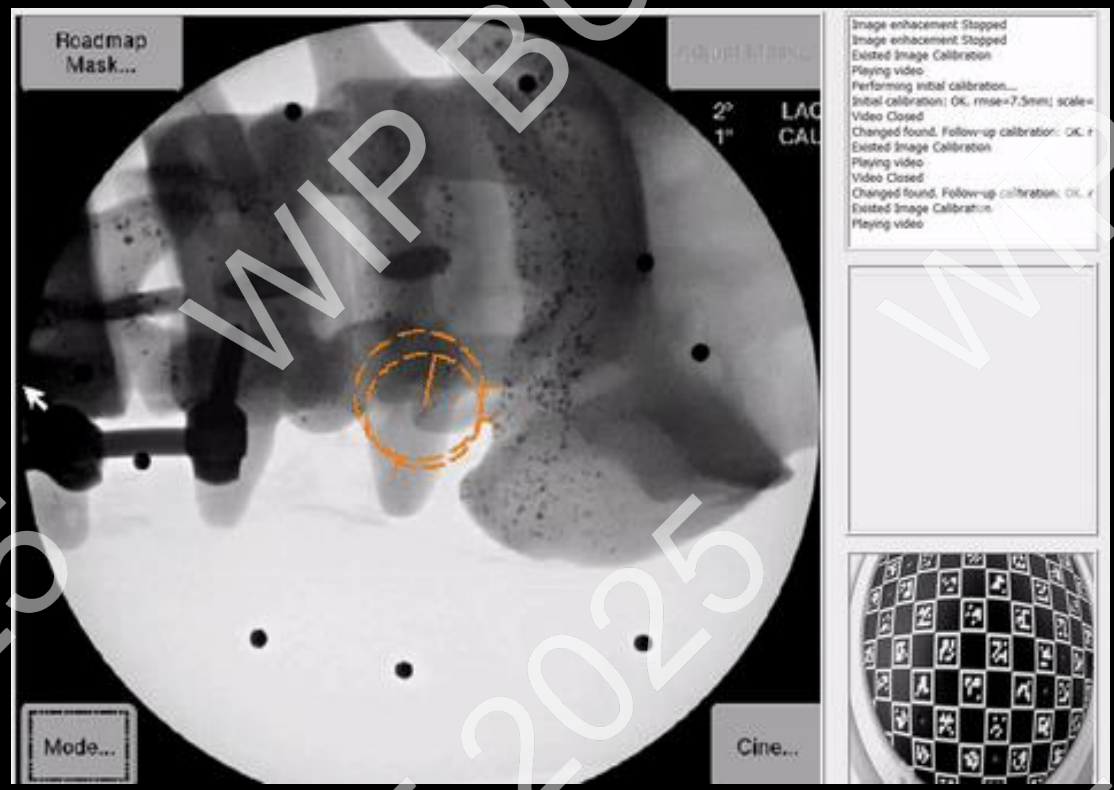
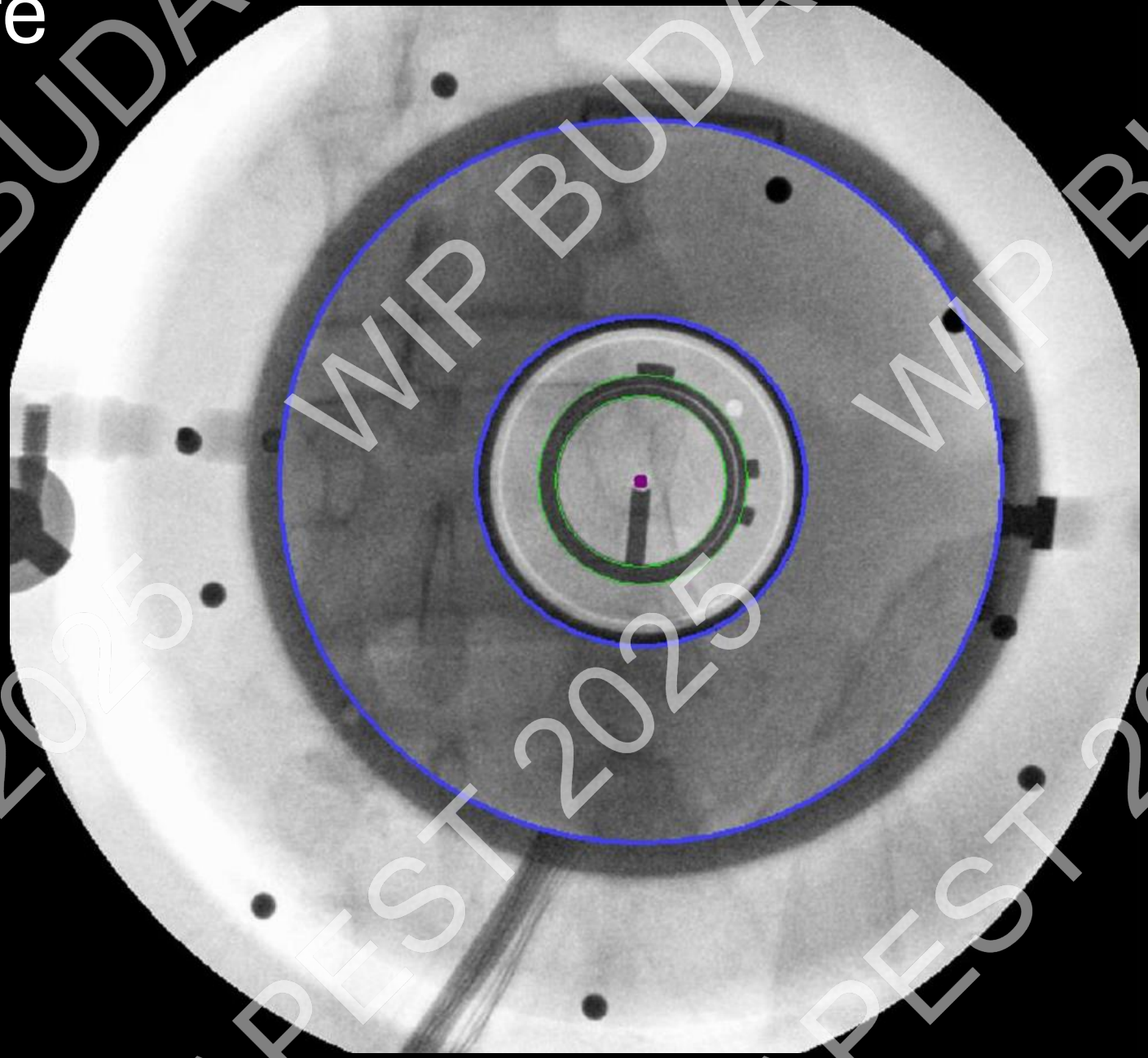
Procedure

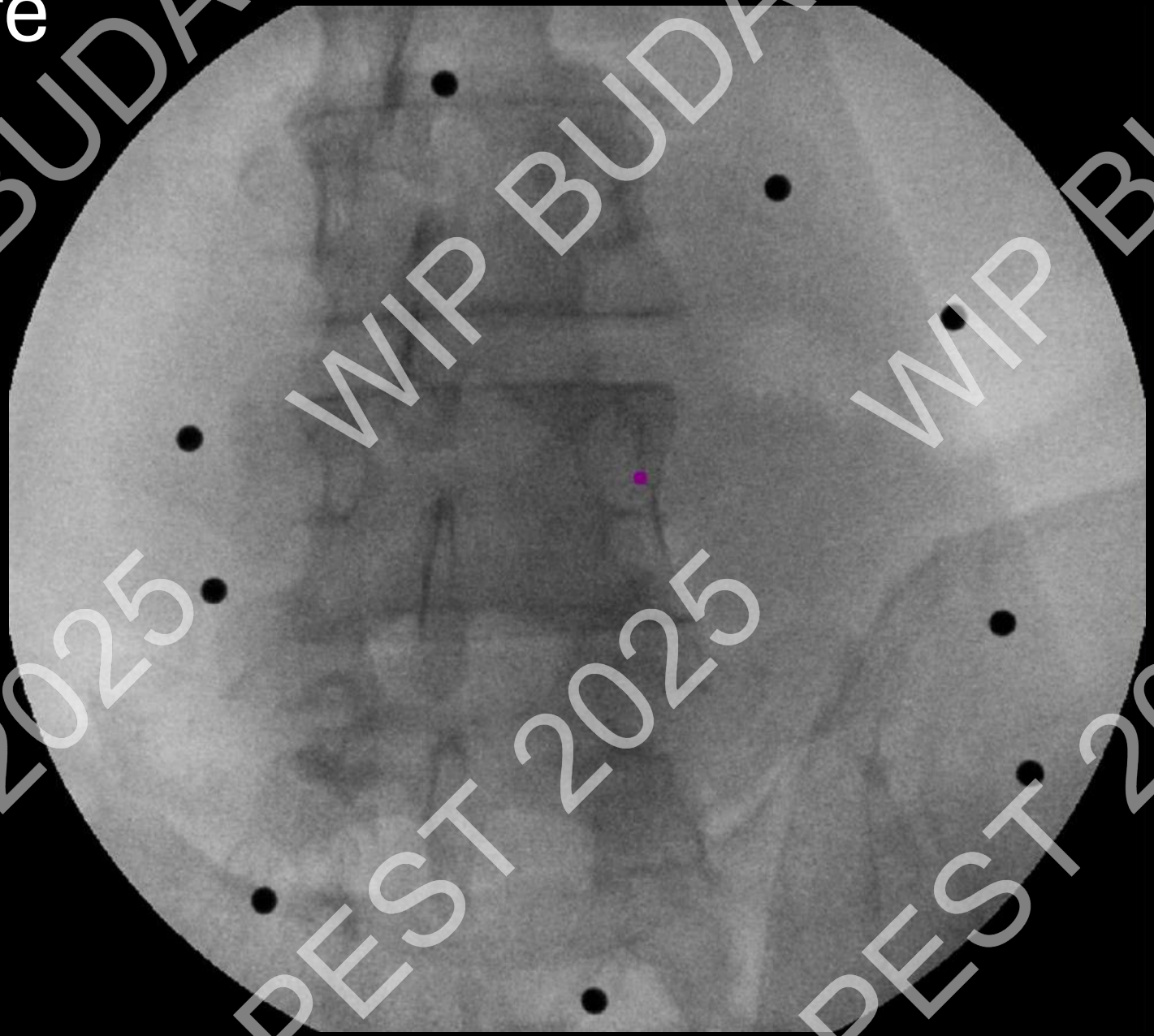




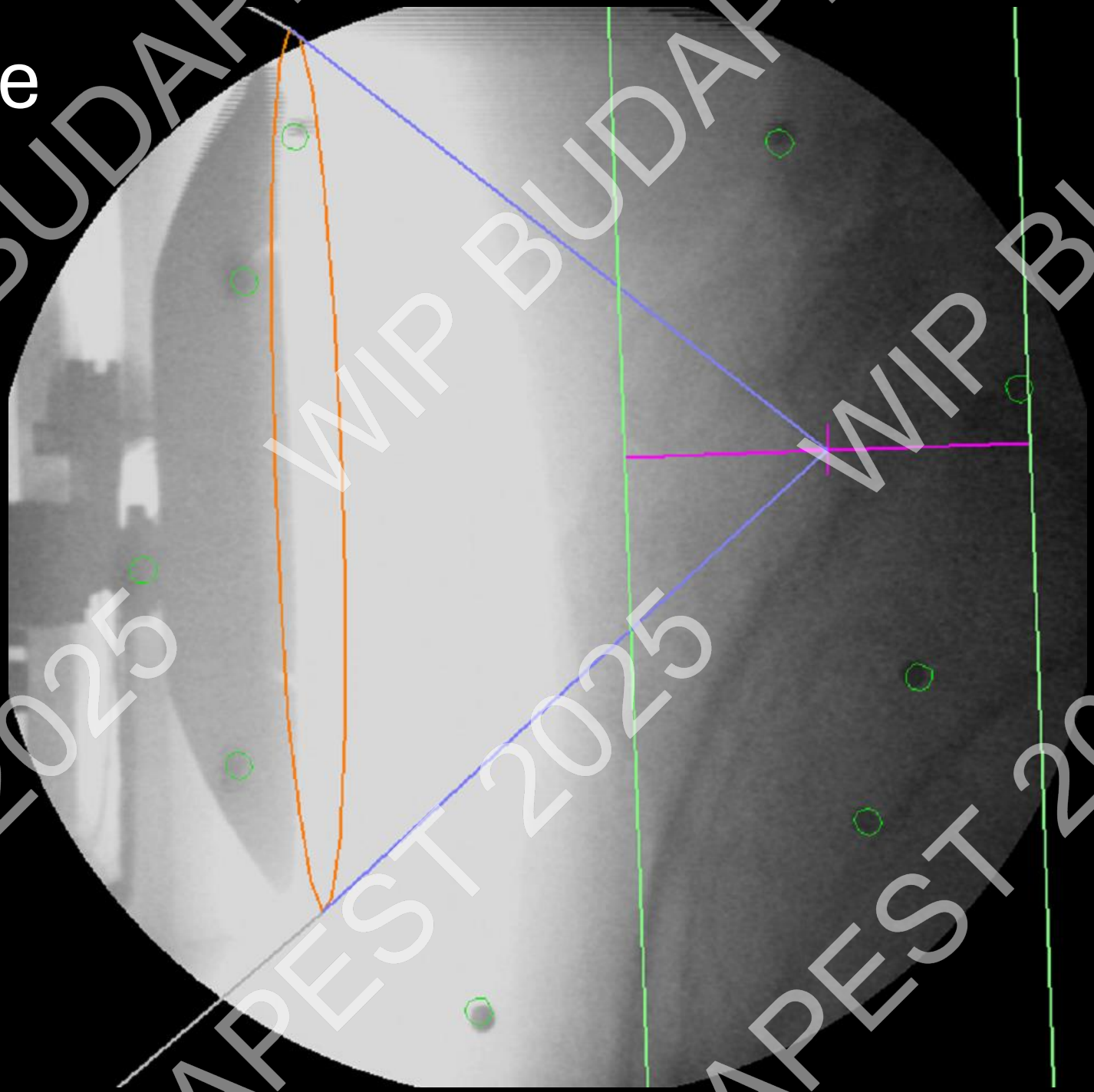
Procedure



Procedure



Procedure



Preclinical Evidence

- **Porcine model – Medial branch nerves:**
- HIFU ablation rates: 71–96% (1000–2000 J)
- Higher than RFA (50%)
- No significant adverse events

Original research

OPEN ACCESS

Fluoroscopy-guided high-intensity focused ultrasound ablation of the lumbar medial branch nerves: dose escalation study and comparison with radiofrequency ablation in a porcine model

Michael Gofeld ,[1] Thomas Tiennot,[2] Eric Miller,[3] Niv Rebhun,[3] Stephen Mobley,[3] Suzanne Leblang,[4] Ron Aginsky,[5] Arik Hananel,[3] Jean-Francois Aubry[6]

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/rapm-2024-105417).

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ABSTRACT

Background Radiofrequency ablation (RFA) is a common method for alleviating chronic back pain by targeting and ablating of facet joint sensory nerves. High-intensity focused ultrasound (HIFU) is an emerging, non-invasive, image-guided technology capable of providing thermal tissue ablation. While HIFU shows promise as a potentially superior option for ablating sensory nerves, its efficacy needs validation and comparison with existing methods.

Methods Nine adult pigs underwent fluoroscopy-guided HIFU ablation of eight lumbar medial branch nerves, with varying acoustic energy levels: 1000 (N=3), 1500 (N=3), or 2000 (N=3) joules (J). An additional three animals underwent standard RFA (two 90 s long lesions at 80°C) of the same eight nerves. Following 2 days of neurobehavioral observation, all 12 animals were sacrificed. The targeted tissue was excised and subjected to macropathology and micropathology, with a primary focus on the medial branch nerves.

Results The percentage of ablated nerves with HIFU was 71%, 86%, and 96% for 1000 J, 1500 J, and 2000 J, respectively. In contrast, RFA achieved a 50% ablation rate. No significant adverse events occurred during the procedure or follow-up period.

Conclusions These findings suggest that HIFU may be more effective than RFA in inducing thermal necrosis of the nerve.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ High-intensity focused ultrasound (HIFU) can be used in lieu of the radiofrequency ablation (RFA) method to ablate tissue. However, a direct in vivo comparison between these two methods has never been attempted.

WHAT THIS STUDY ADDS

⇒ This animal study evaluated the macroanatomy and microanatomy of HIFU and RFA lesions and confirmed that HIFU produced a more reliable medial branch neurotomy in a porcine model.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results suggest that further HIFU clinical research is anatomically justified, and the method may eventually replace RFA in interventional pain practice.

INTRODUCTION

Back pain is the second-leading symptom prompting all physician visits in the USA.[1] The etiology is often multifactorial and may be linked to musculoskeletal, neurological, and behavioral causes, fitting the biopsychosocial concept of chronic pain. However, discrete pain generators, such as the lumbar facet joints, can be addressed by therapeutic interventions based on a proper selection of candidates. The cited prevalence of lumbar facet joint pain ranges from as low as 4.8% in the multicenter national low back pain survey to over 50% in systemic reviews.[2] A conservative clinically sound estimation of the prevalence of painful degenerative spondyloarthropathy (figure 1A) is hovering at about 15%.[3 4]

Radiofrequency ablation (RFA) of the medial branch nerves of the dorsal primary rami is an effective minimally invasive therapeutic option providing long-lasting pain relief and functional improvement.[2] However, RFA may be associated with an aggravation of pain, injury to the spinal cord or nerve roots, and bleeding.[2 4] Although, the infection rate was not specifically addressed in the published surveys, theoretically, any invasive procedure has a risk of contamination. Special considerations for patients with implanted electrical devices and adjacent metallic hardware are required.[2 5] In addition, the withholding heparin and heparinoids before invasive spine procedures such as RFA has been strongly recommended,[6] and a shared decision model was recommended for other anticoagulants and antiaggregants.[2]

High-intensity focused ultrasound (HIFU) is a novel, non-invasive, image-guided thermal ablation technology[7 8] that has been introduced as an alternative to achieve the same goal as RFA.[9–11] Using an extracorporeal transducer, ultrasound energy is focused on a target location, much like a magnifying glass converges light to a single point to ignite a fire. The concentration of energy generates coagulative necrosis precisely in the targeted volume while sparing near-field and far-field tissue.[12]

Therefore, HIFU can be used as another method for thermal neurotomy[13–15] and potentially be more

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Clinical Evidence – Pilot Study

- 10 patients, lumbar facet pain
- Clinical success:
- 90% at 1 month
- 60% at 6 months
- No significant adverse events

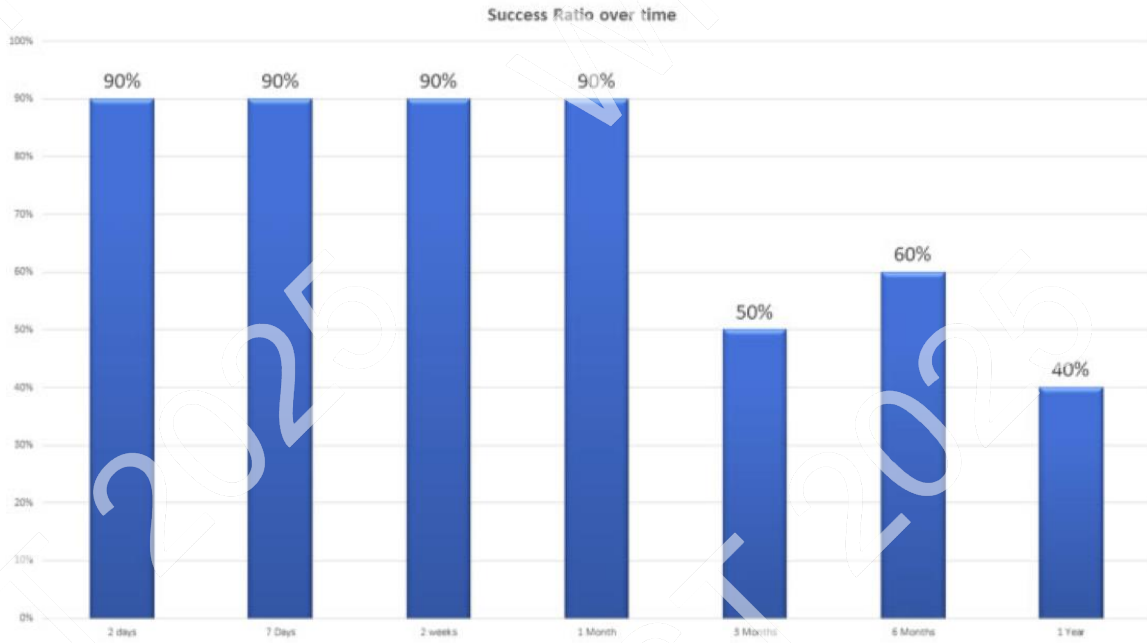

Figure 6. Clinical success ratio over time. Clinical success rates at the 1-, 3-, 6-, and 12-month follow-up periods were 90% (n = 10), 50% (n = 10), 60% (n = 10), and 40% (n = 10), respectively.

Clinical Evidence – Prospective Study

- 30 patients, zygapophyseal joint pain
- Responder rate:
- 82.6% at 6 months
- Mean NRS ↓ from 7.1 to 3.3 at 6 months
- No device/procedure-related serious adverse events

Original research

OPEN ACCESS

Fluoroscopy-guided high-intensity focused ultrasound neurotomy of the lumbar zygapophyseal joints: a prospective, open-label study

Michael Gofeld,[1] Kevin J Smith,[1] Anuj Bhatia,[2] Vladimir Djuric,[3] Suzanne Leblang,[4] Niv Rebhun,[5] Ron Aginsky,[6] Eric Miller,[5] Brian Skoglind,[5] Arik Hananei[5]

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/rapm-2024-105345).

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ABSTRACT

Objective The objective of this study is to investigate safety and effectiveness of a fluoroscopy-guided high-intensity focused ultrasound (HIFU) system for thermal ablation of the lumbar medial branch nerves.

Methods This dual center prospective cohort study enrolled 30 participants with lumbar zygapophyseal joint syndrome. Each participant previously had a positive response to either a single diagnostic analgesic block or radiofrequency ablation (RFA). The primary effectiveness outcome was individual responder rate, defined as a reduction of two points or more on the pain intensity numerical rating scale without an increase in opioid intake, or a reduction in opioid intake without an increase in pain at 6 months after the intervention. The primary safety outcome was procedure-related or device-related adverse events (AEs). Secondary outcome variables included MRI evidence of tissue ablation, Oswestry Disability Index, 12-Item Short Form Health Survey, Brief Pain Inventory, and Patient Global Impression of Change.

Results The individual responder rate was 89.7% at 2 days, 89.7% at 7 days, 72.4% at 14 days, 82.1% at 30 days, 59.3% at 90 days and 82.6% at 180 days. The average Numeric Rating Scale for pain severity decreased from 7.1 at baseline to 3.0 (N=29) after 2 days, 3.0 (N=29) after 7 days, 3.1 (N=29) after 14 days, 3.2 (N=28) after 30 days, 4.3 (N=27) after 90 days, and 3.3 (N=23) after 180 days. All participants tolerated the procedure well with no significant side effects or complications.

Conclusions Fluoroscopy-guided HIFU neurotomy achieved clinical responses comparable with RFA, and there were no significant device-related or procedure-related AEs.

Trial registration number NCT04129034.

WHAT IS ALREADY KNOWN ON THIS TOPIC
⇒ Initial preclinical and clinical evidence have confirmed the safety and preliminary effectiveness of using fluoroscopy-guided high-intensity focused ultrasound (HIFU) as a thermal neurotomy method of the lumbar medial branch nerves.

WHAT THIS STUDY ADDS
⇒ The current study adds further clinical and imaging evidence based on a pragmatic, real-life study design and conservative outcome goals.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY
⇒ This study strengthens the position of fluoroscopy-guided HIFU neurotomy of the lumbar medial branches as a safe, effective, and non-invasive method to alleviate low back pain.

INTRODUCTION

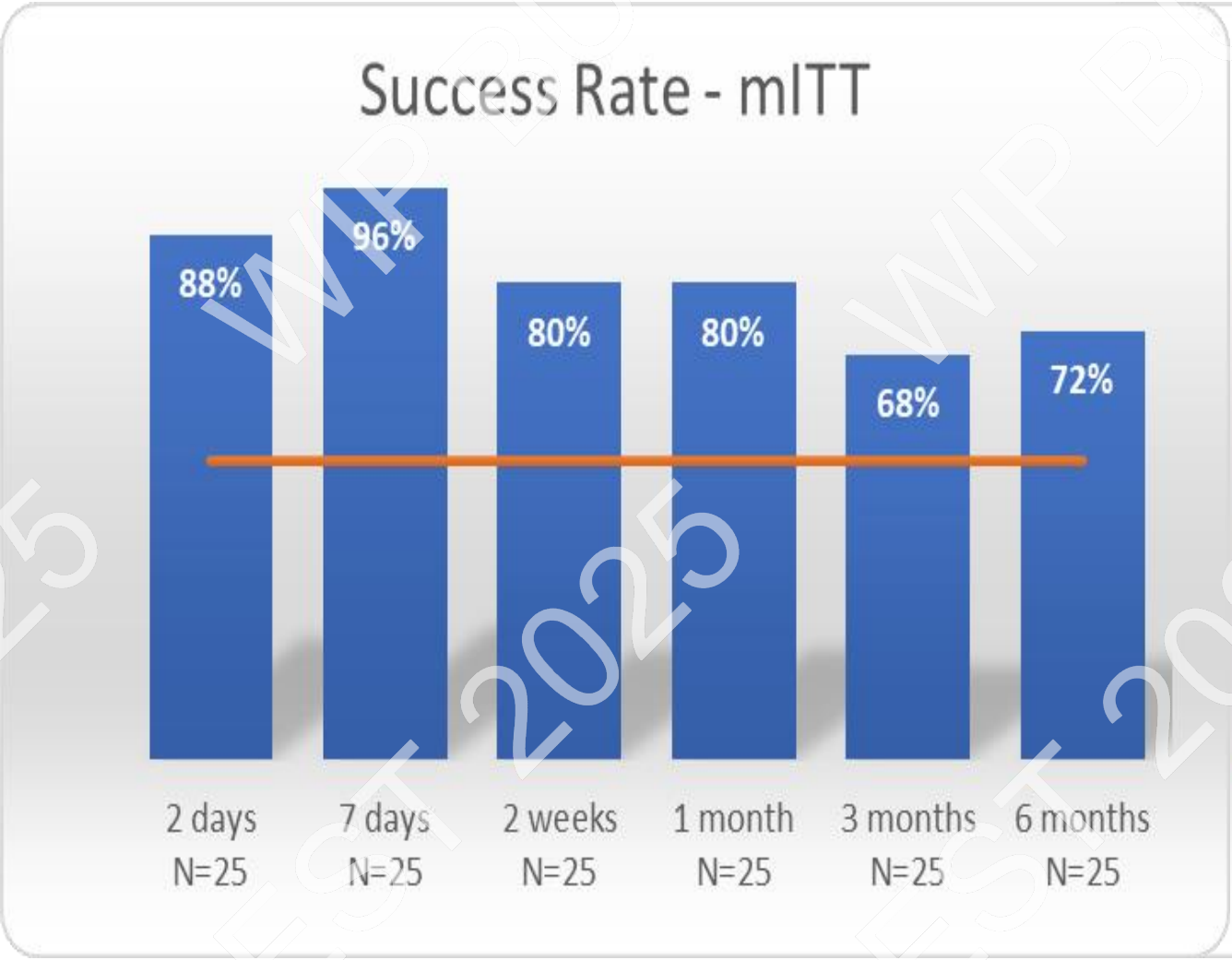
Lumbar zygapophyseal joint (z-joint) syndrome is a common diagnosis among patients with chronic low back pain.[1–4] Routine standard-of-care interventions to manage pain associated with z-joint syndrome include blockade of the medial branches of the z-joint nerves or blockade of the joint itself, often followed by radiofrequency ablation (RFA). Some studies have concluded that RFA is ineffective[5–7] while others report significantly positive results.[8–12] Patient selection, anatomical precision, and lesion size are cited as determinants of success for treating z-joint syndrome with RFA.[13–15] Despite its widespread clinical adoption, the main drawback of RFA is its invasiveness, which can cause periprocedural and postprocedural pain, bleeding, and spinal cord and nerve root damage.[16]

We previously conducted a pilot clinical trial with 10 participants to test a novel, non-invasive method for treating z-joint syndrome using high-intensity focused ultrasound (HIFU) and reported similar effectiveness as RFA and no adverse events (AEs).[17] The current clinical trial was designed as a larger, open-label, prospective clinical trial to provide further evidence for the efficacy of fluoroscopy-guided HIFU neurotomy of the lumbar medial branch nerves.

METHODS

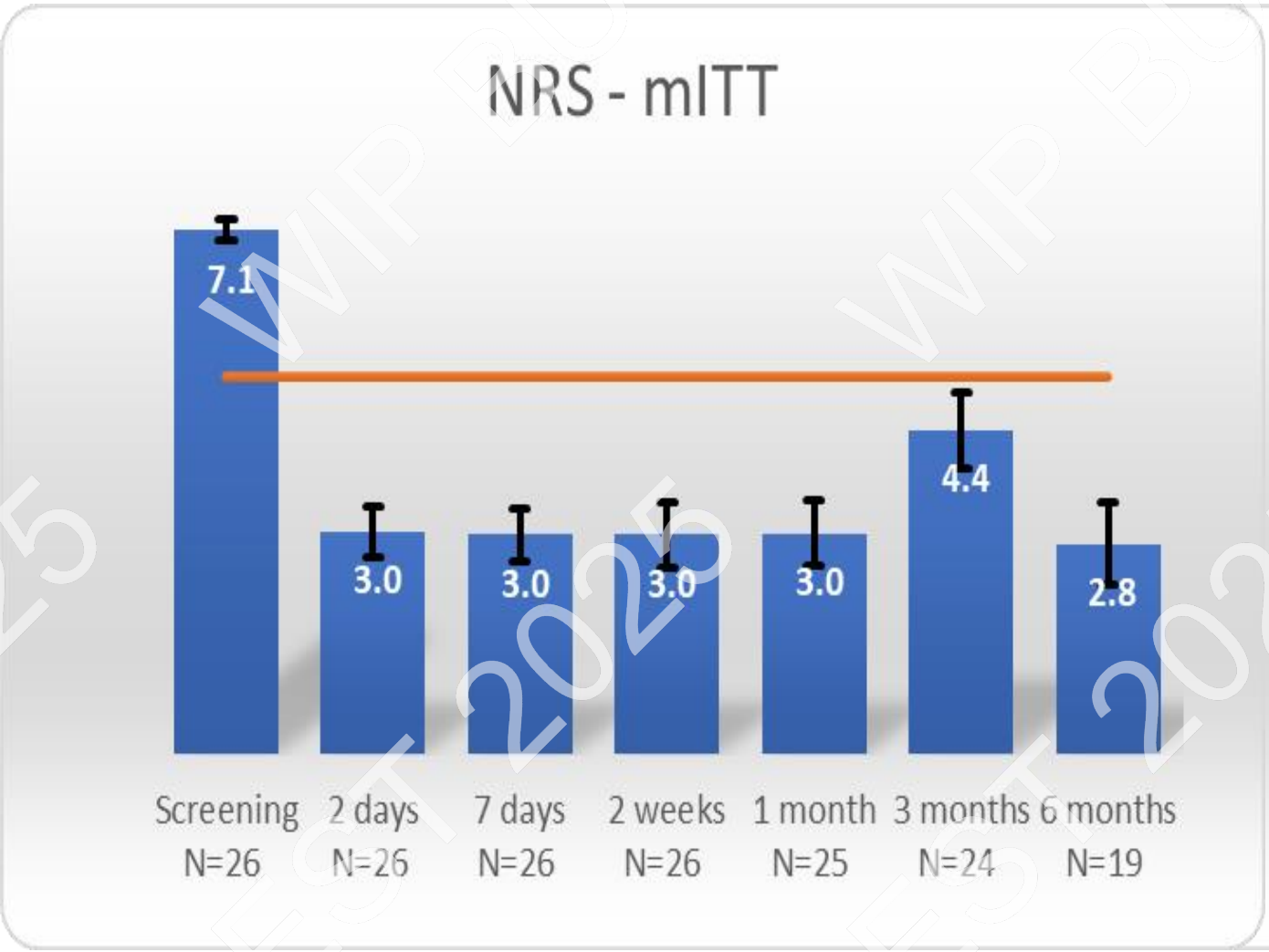
The study was registered on ClinicalTrials.gov (NCT04129034, September 24, 2019). 30 participants with z-joint syndrome were recruited between September 2019 and October 2022 at two enrolment sites (figure 1). The first patient was recruited on November 11, 2019. The COVID-19 pandemic led to a slower than planned recruitment. The investigational device (figure 2) was a 1-MHz

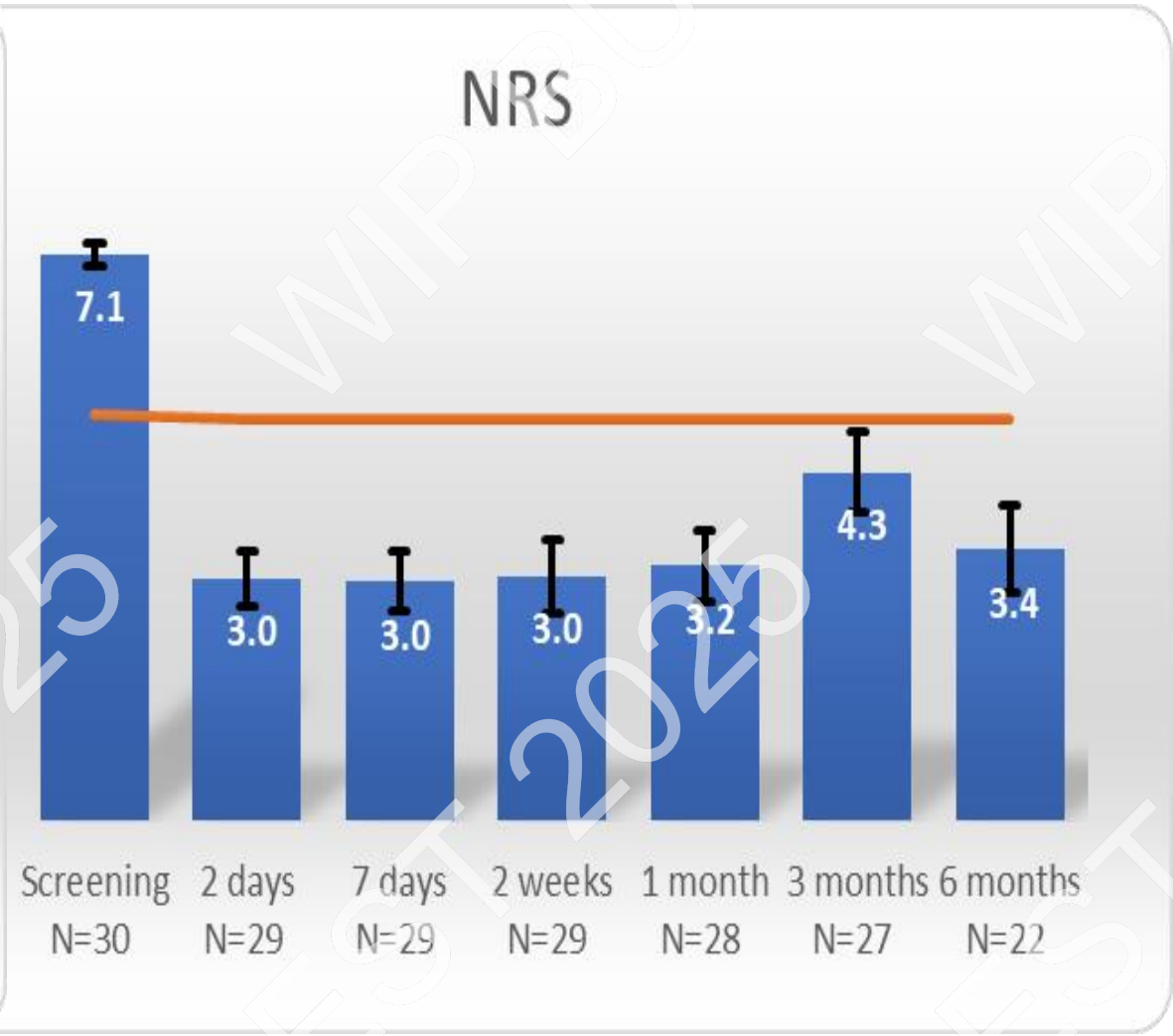
LBP-002 – Success Rate



Orange line represents 50% success rate which is the commonly known success rate for RFA

LBP-002 – Average NRS





Orange line represents 2 points drop

Clinical Studies (183 procedures to date)*

LBP-001 (Pilot - Canada): Completed (13/13)

- Multisite, Interventional, Prospective, Open label, Single Arm

LBP-021 (Pilot - Israel): Completed (10/10)

- Single Site, Interventional, Prospective, Open label, Single Arm

LBP-002 (Stage Pivotal OUS): Completed (30/30)

- Multisite, Interventional, Prospective, Open label, Single Arm, Last FU in April 2023

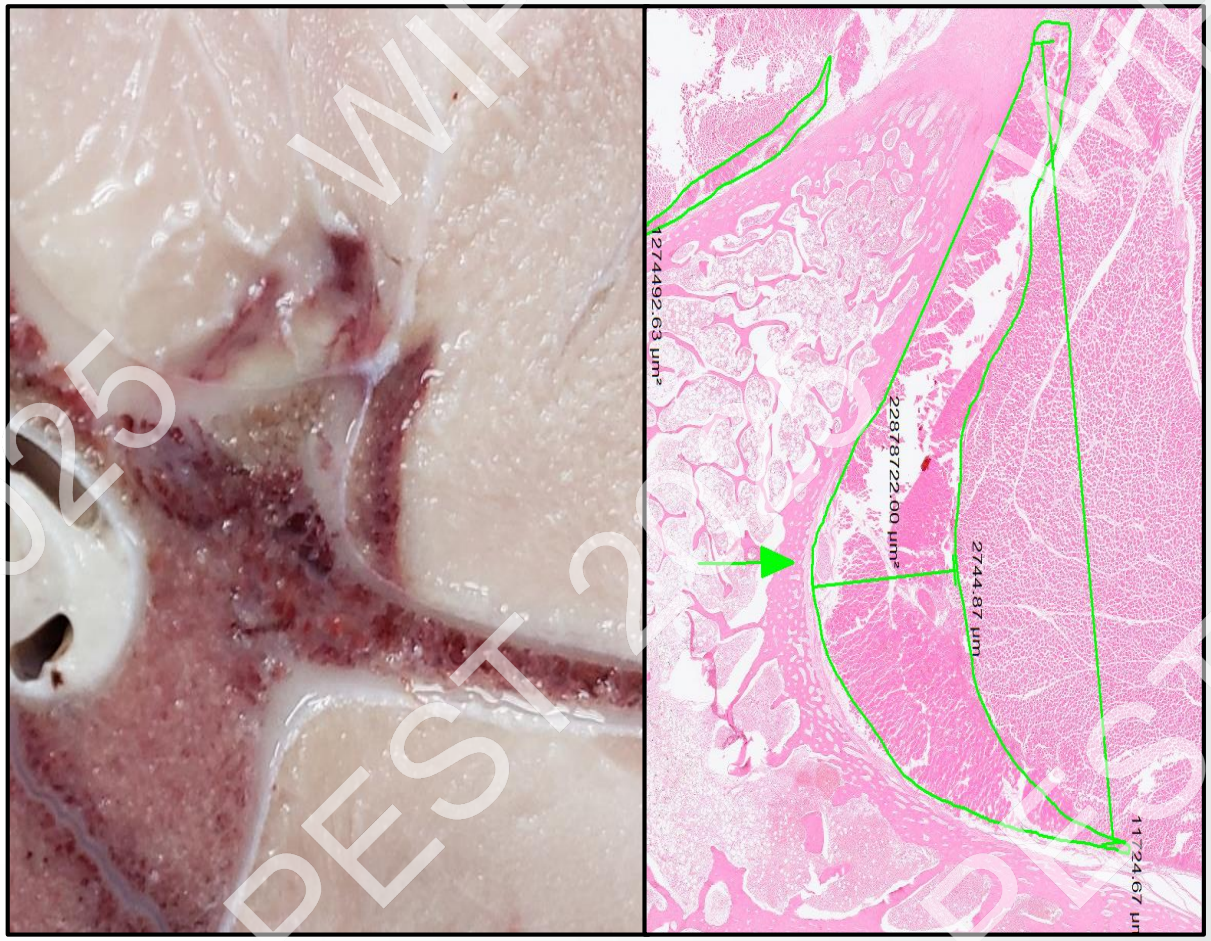
LBP-003 (FDA Pivotal): Finished Recruiting (90/90)+32 crossover

- Multisite, Interventional, Prospective, Double arm blinded with Sham control

SIJ (Pilot - Israel): Recruiting (8/10)

MRI & Histology Evidence

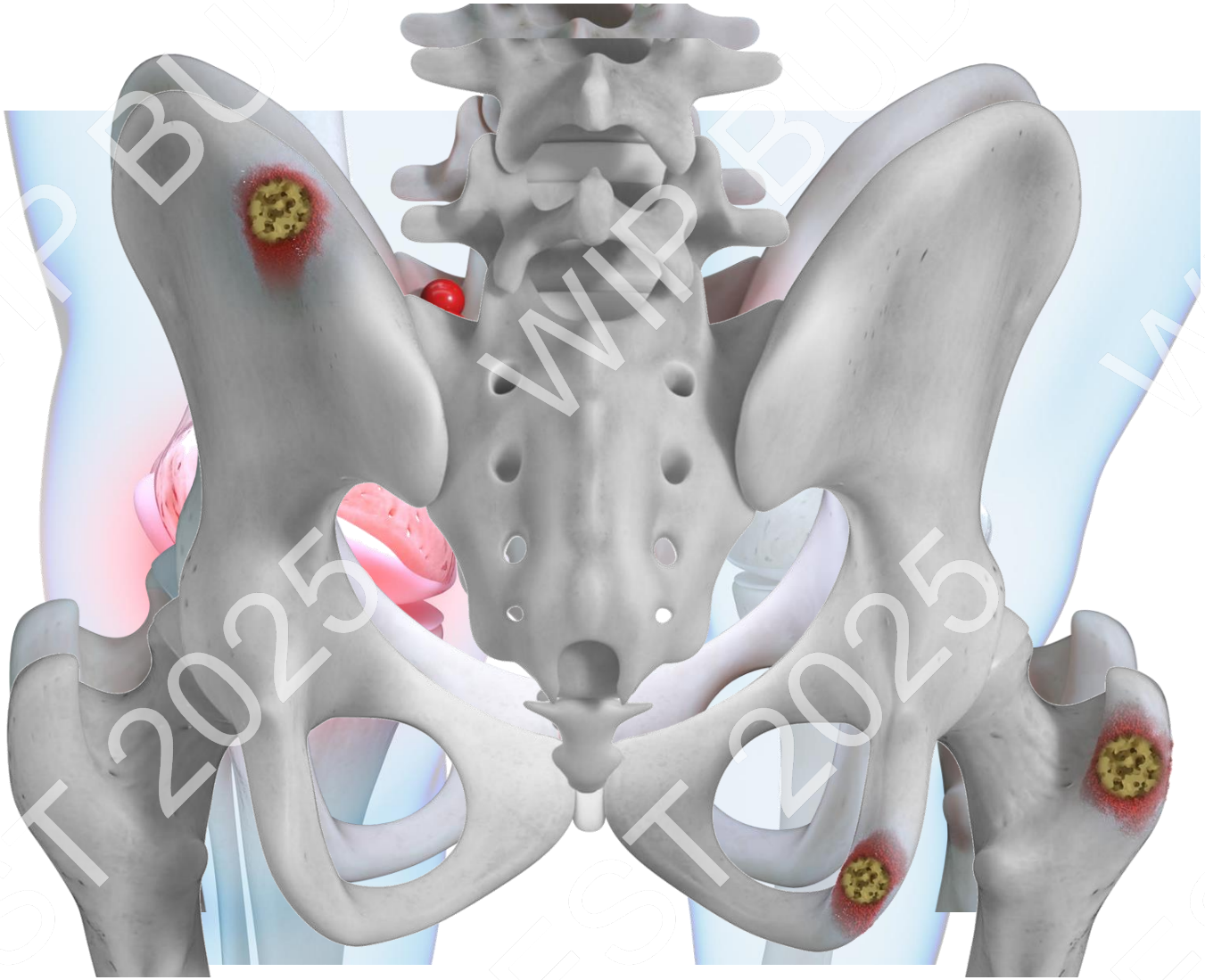
- MRI post-procedure: edema and necrosis at target site
- Histology: coagulative necrosis localized to medial branch nerve
- Preservation of surrounding soft tissue



Beyond Facet Joints

Expanding Indications:

- SIJ pilot
- Knee OA (strip lesion, rapid effect)
- Bone mets (palliative care)



the possibility of repeated treatments without cumulative dose limits.

Patient Selection & Contraindications

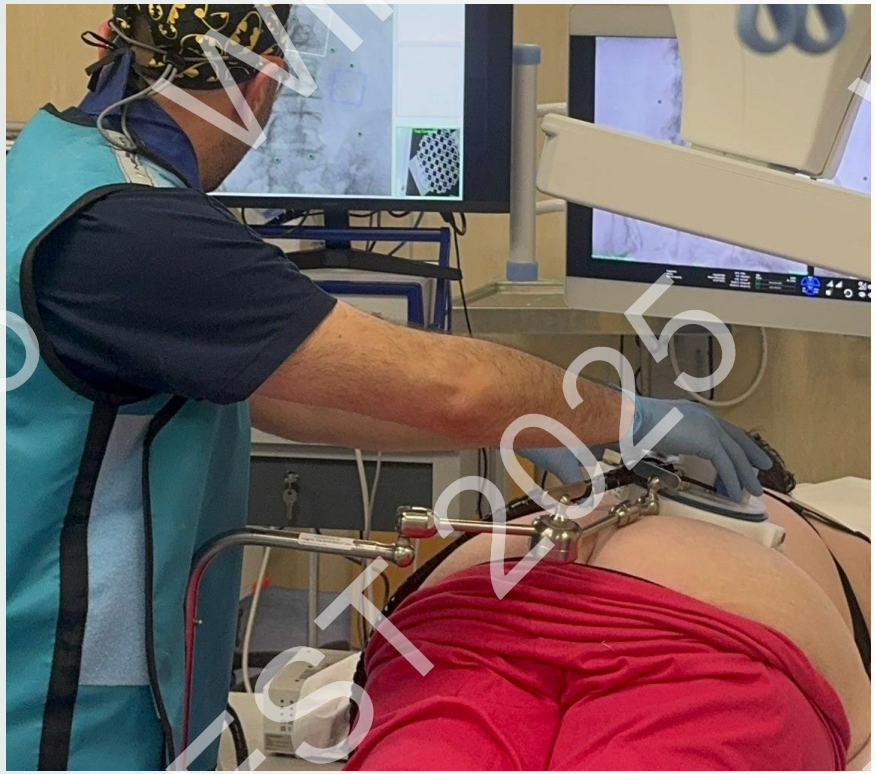
Ideal:

- Chronic lumbar facetogenic pain, positive diagnostic block
- Patients at high bleeding risk or with implanted devices
- Outpatient feasibility

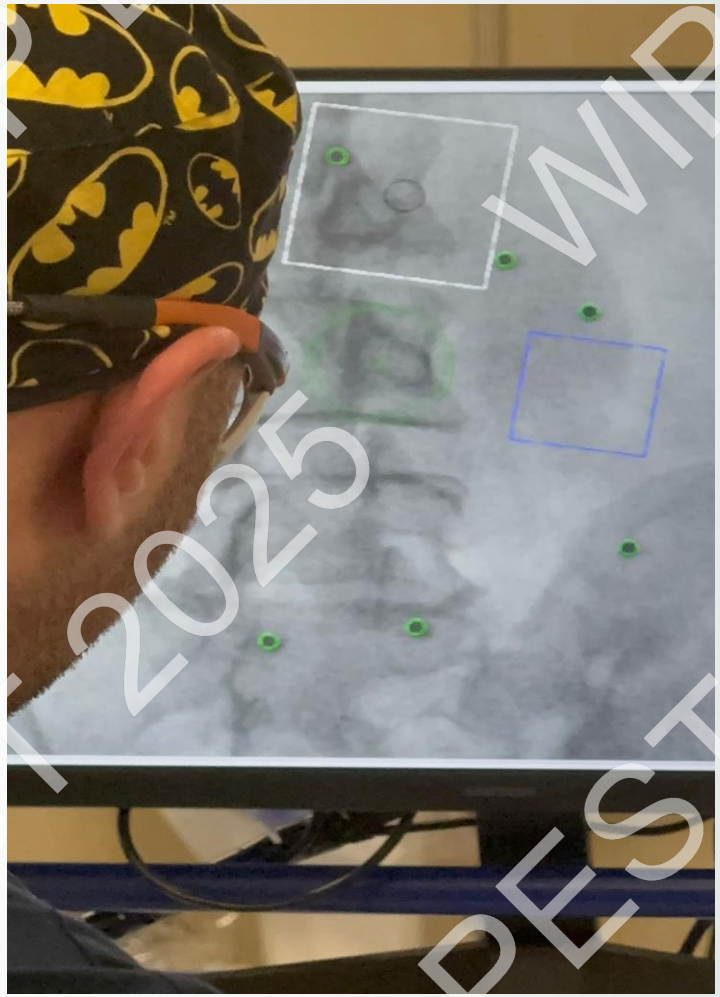
Contraindications:

- BMI > 35 (acoustic penetration limit)
- Severe scoliosis/kyphosis
- Osteoporosis
- Previous surgery / Extensive scar tissue over target
- Skin infection at treatment site

My Clinical Experience



- First in Italy, among the first in Europe
- Treated patients with lumbar facetogenic pain
- Procedures in outpatient setting under fluoroscopic guidance
- Excellent patient tolerance
- 80% of patients reported good outcome at 5 months



- Targeting medial branch at transverse–articular junction
- Limited handpiece inclination (max ~15° lateral)
- Specific gel pads: high vs low BMI
- Double safety aiming system

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- Sensory test (300 J / 20 sec) → avoid radicular pain
- Treatment: 1000 J / 50 sec if only local/gluteal pressure
- Patient-controlled

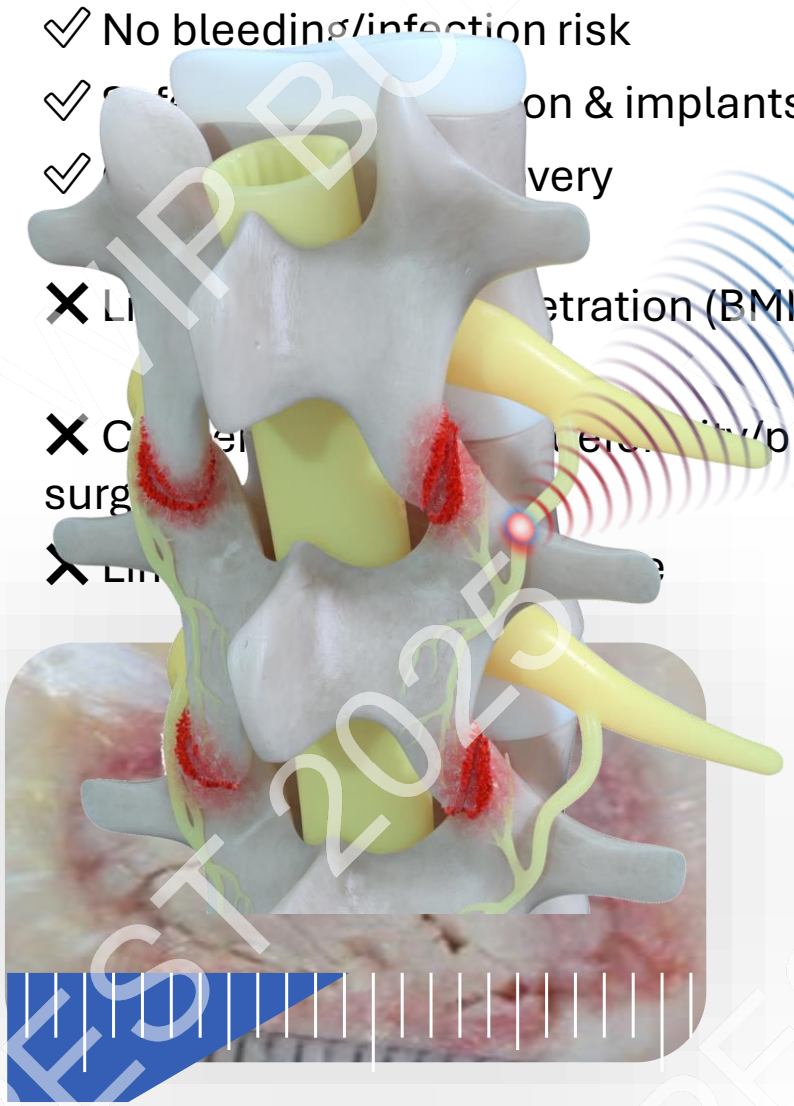
HIFU vs RFA - Comparative Overview

HIFU (High-Intensity Focused Ultrasound)

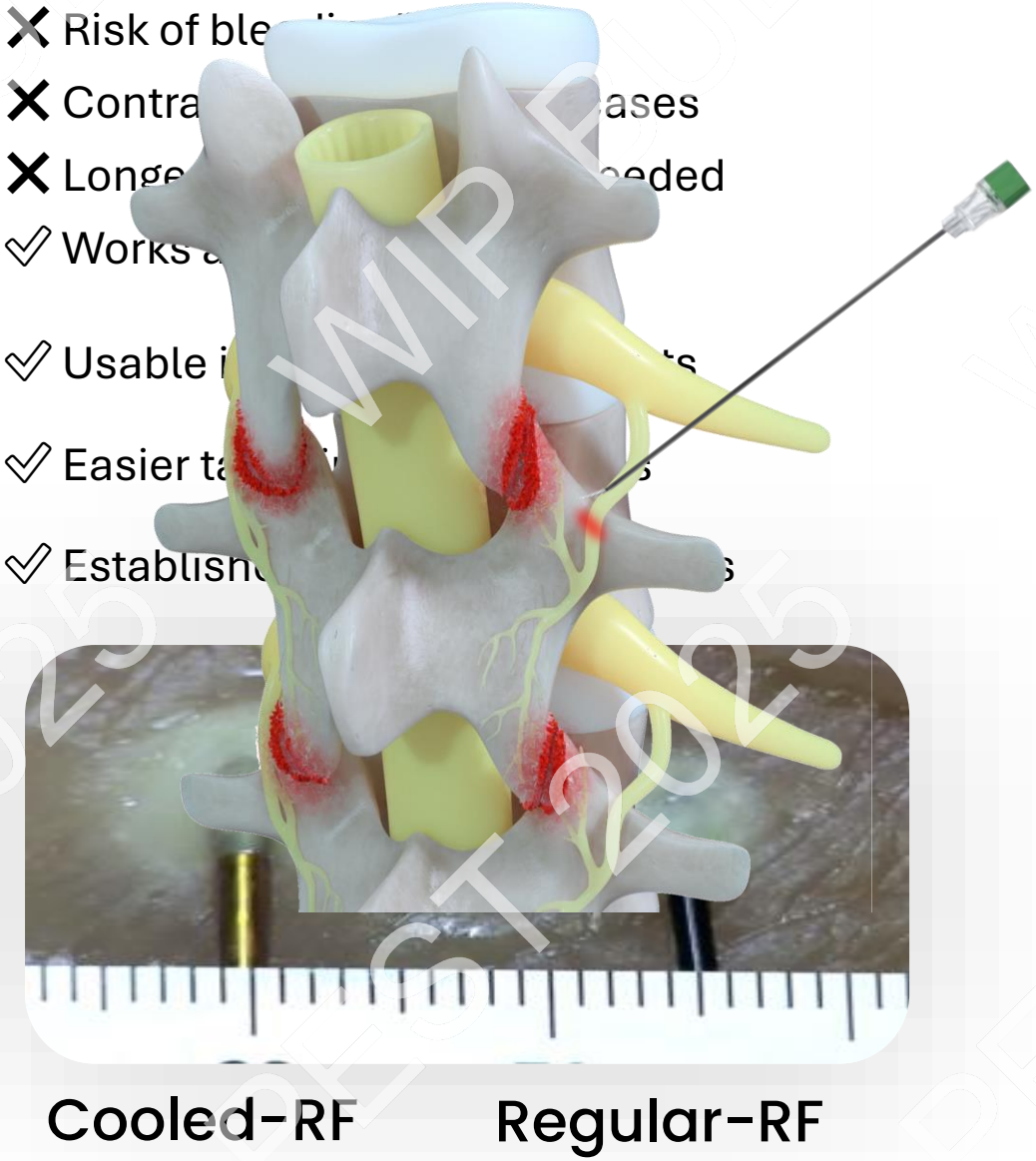
- ✓ Completely non-invasive (no needle)
- ✓ No bleeding/infection risk
- ✓ [illegible]on & implants
- ✓ [illegible]very
- ✗ Li[illegible]etration (BMI >35)
- ✗ C[illegible]/previous surg
- ✗ Li[illegible]e

RFA (Radiofrequency Ablation)

- ✗ Invasive (needle placement)
- ✗ Risk of ble[illegible]
- ✗ Contra[illegible]ases
- ✗ Longe[illegible]eeded
- ✓ Works [illegible]
- ✓ Usable i[illegible]ts
- ✓ Easier ta[illegible]s
- ✓ Establish[illegible]s



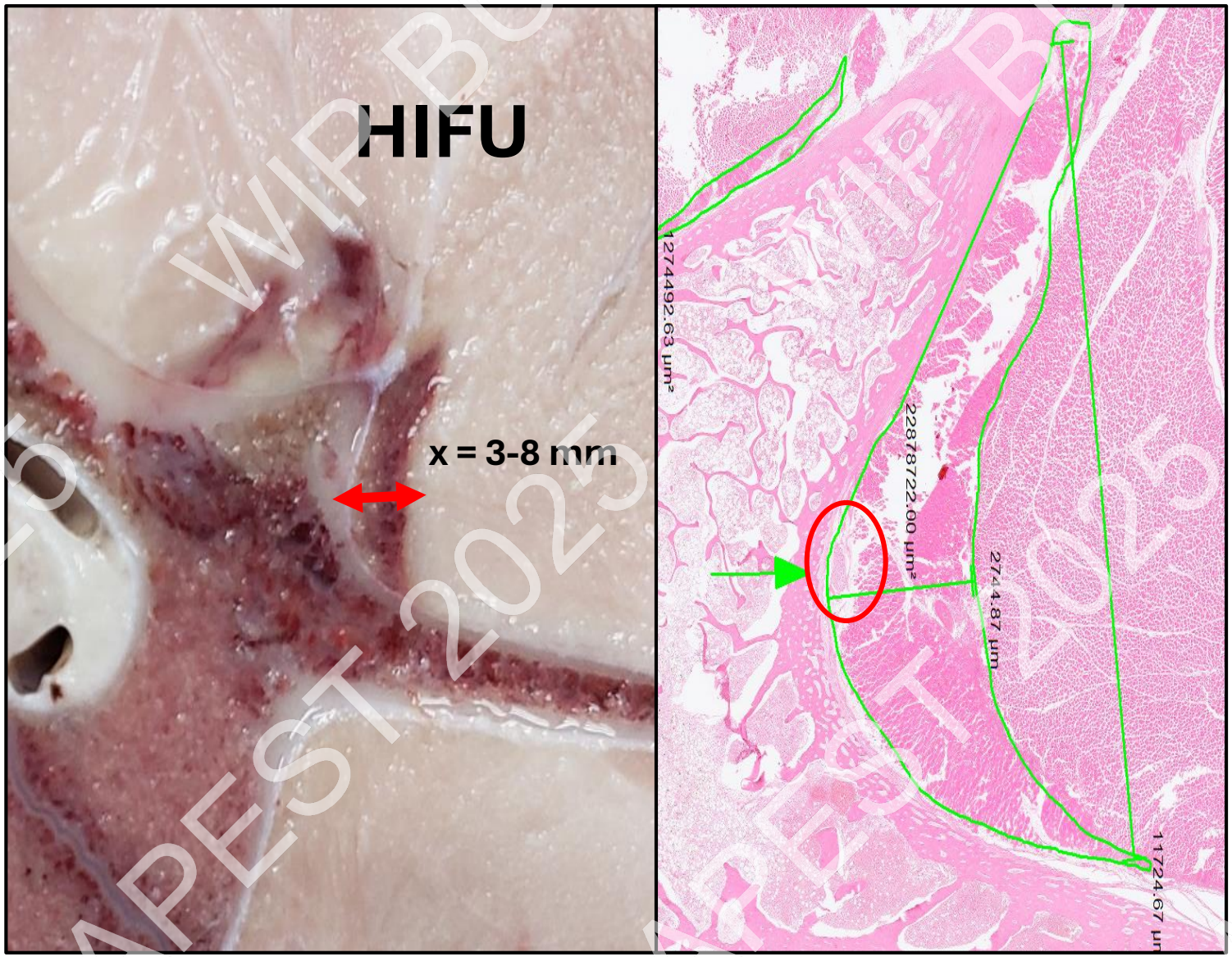
HI-FU Lesion

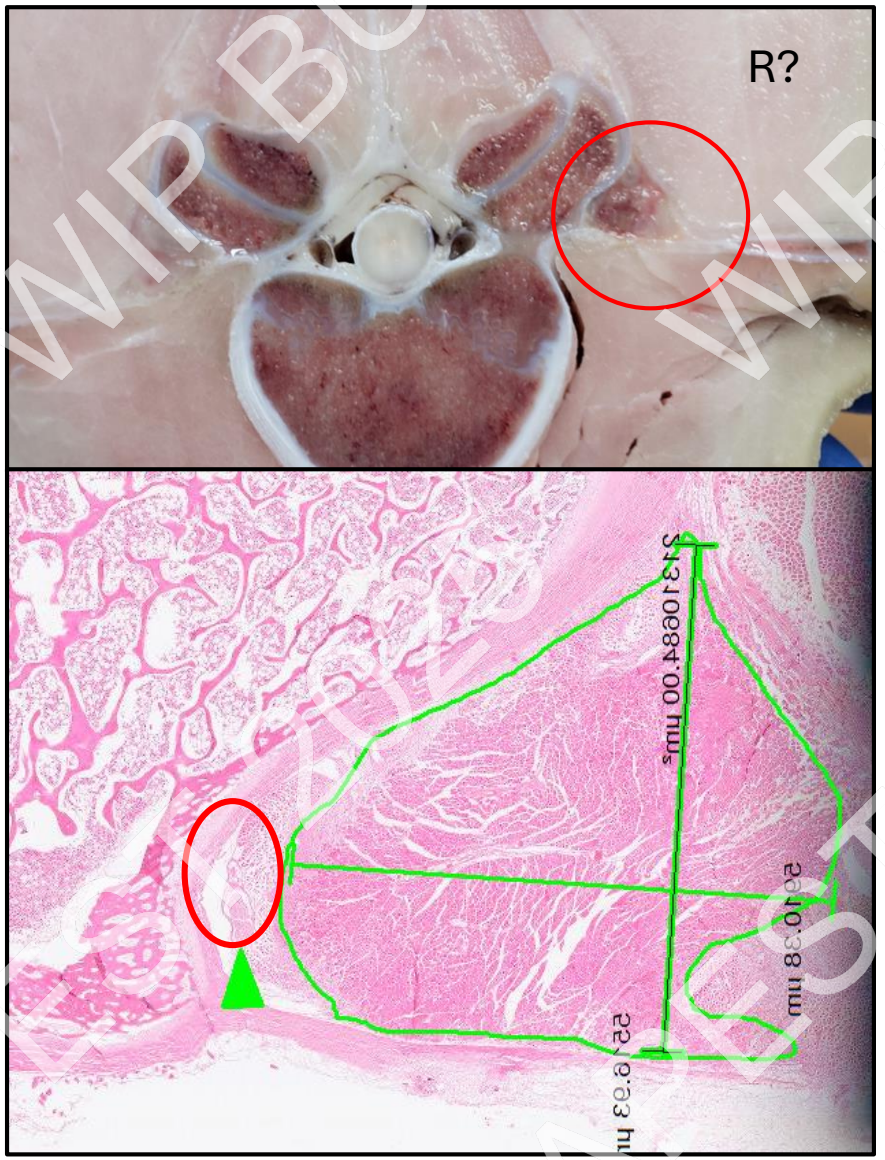


Cooled-RF Regular-RF

Lesion size correlates with durability – Pain Physician

Compared to RFA, HIFU produces larger lesions at the bone-nerve interface, a finding confirmed by MRI and histology.





Future Directions

01	Larger randomized controlled trials
02	Long-term follow-up data
03	Comparative studies vs. RFA in specific populations
04	Cost-effectiveness analyses

Take-Home Messages

- HIFU: a promising, non-invasive technique for pain management
- Safe, well tolerated, with encouraging results
- Not a universal replacement for RFA
- Need for robust, long-term evidence
- *Ongoing FDA Pivotal Trial (LBP-003).*

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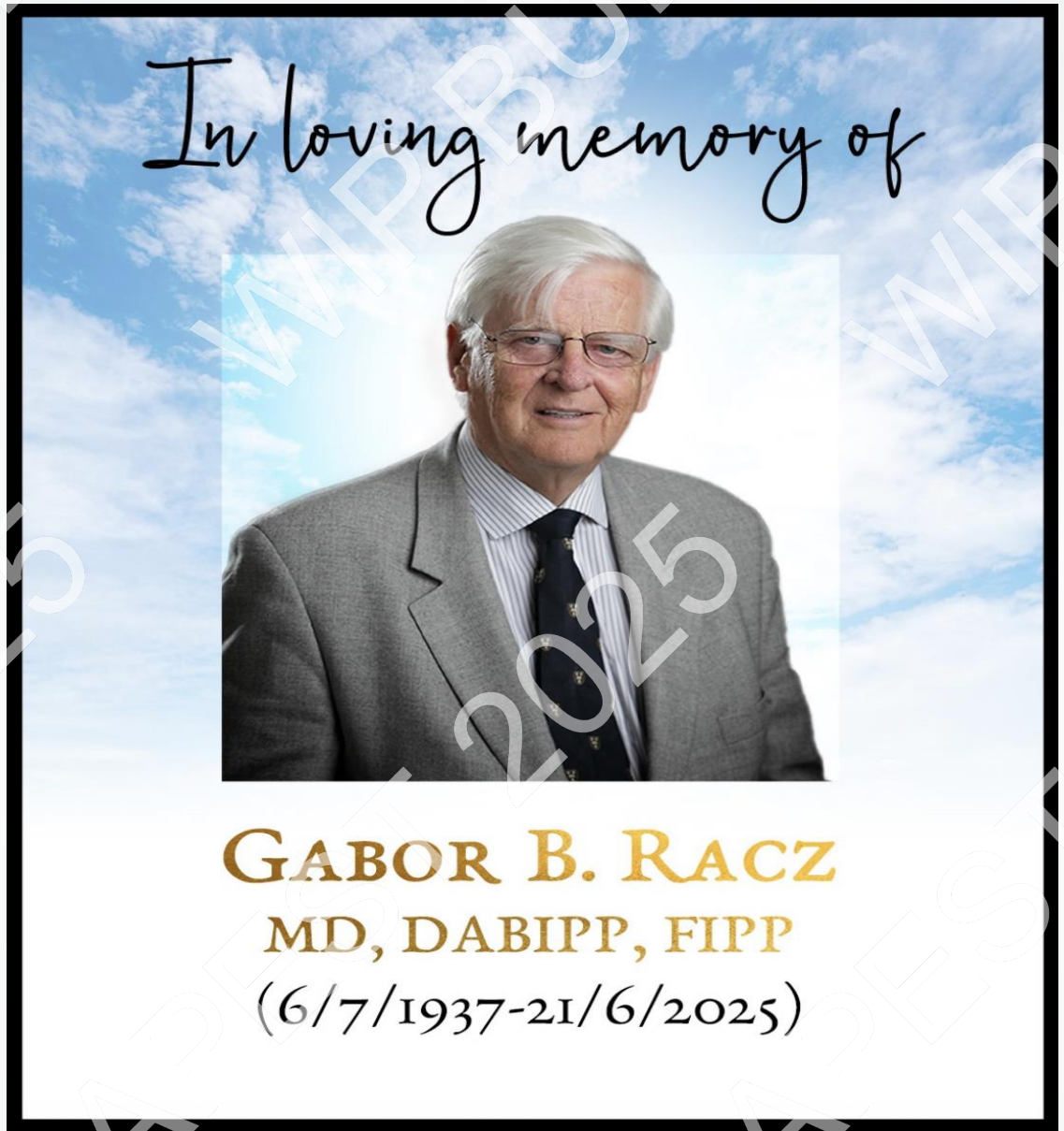
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GABOR B. RACZ
MD, DABIPP, FIPP
(6/7/1937-21/6/2025)

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