

CASE STUDY · MEDICAL DEVICE

Genitourinary Device Trial With Dynamic Pelvic Floor MRI

Urinary incontinence device · Dynamic pelvic floor MRI · Device position and pelvic floor mobility

Challenge

A medical device trial for the treatment of urinary incontinence used dynamic MRI of the pelvic floor to assess device position and its effect on bladder neck and urethral mobility. Dynamic pelvic MRI is highly operator-dependent: patient coaching, straining effort and acquisition timing all affect the measured displacement, and few sites had routine experience with the technique.

The sponsor needed a core lab that could standardize a demanding acquisition across sites, measure pelvic floor landmarks reproducibly at rest and strain, and document device position in relation to those landmarks over the follow-up period.

Intrinsic Imaging's Solution

Intrinsic Imaging developed a dynamic pelvic floor MRI protocol with standardized patient instructions, sequence parameters and acquisition timing at rest, during Valsalva and during voiding where protocol-required, and qualified each site with test acquisitions reviewed for adequacy of straining effort.

Radiologists with genitourinary and pelvic imaging expertise measured bladder neck descent, urethral angle and device position relative to the pubococcygeal line under a reading charter, with double reads on a prespecified sample to establish measurement reproducibility and adjudication of discordant findings.

Images were transferred and quality-controlled centrally, with inadequate straining effort flagged for re-acquisition within protocol windows, and the longitudinal measurement dataset was delivered alongside qualitative device position assessments.

Intrinsic Imaging's Results

- Dynamic pelvic floor MRI standardized across 11 sites with site-specific training on patient coaching and acquisition timing
- Approximately 140 patients followed with rest and strain measurements of bladder neck descent and urethral angle
- Inadequate straining effort identified at central quality control in about 8% of initial submissions and corrected through re-acquisition
- Measurement reproducibility documented on a double-read sample, supporting the device effectiveness analysis

Read the full study online: <https://intrinsicimaging.com/case-studies/device-genitourinary-incontinence>

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 750 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System, Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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