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

Intrinsic Imaging supported this study’s imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. 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. A displacement measurement is meaningful only in relation to the maneuver during which it was obtained. An apparent difference between visits could reflect altered pelvic support, different straining effort or a mismatch in acquisition timing. The study therefore required attention to the conditions generating motion, as well as to the anatomical landmarks used to describe that motion.

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. Standardized instructions and timing address the functional component of the examination rather than scanner settings alone. Test acquisitions provide a basis for judging whether a site can demonstrate the required maneuver adequately. This is particularly relevant when rest and strain images are compared, because a technically recognizable anatomical image may still fail to represent the intended physiological state.

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. The fixed reference line gives positional measurements a defined anatomical basis across examinations. Bladder neck descent and urethral angle describe related aspects of pelvic mechanics, but neither should be interpreted as a direct substitute for the patient's continence experience. The sampled double reads assess reproducibility of image interpretation, not the consistency of effort across every acquired examination.

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. Flagging inadequate strain separates acquisition limitations from potentially meaningful changes in pelvic mobility. Re-acquisition within the permitted window addresses the missing functional evidence without changing the endpoint definition. Presenting quantitative measurements with qualitative device position assessments preserves their complementary roles: numerical displacement describes movement relative to landmarks, while positional interpretation supplies anatomical context for the device's relationship to those structures.

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

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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 50 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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