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### 3D MRI-Guided Pelvic Floor Dissection in Bladder Exstrophy: A Single Arm Trial

Heather N. Di Carlo<sup>1</sup>, Mahir Maruf<sup>1</sup>, Eric Z. Massanyi<sup>2</sup>, Bhavik Shah<sup>1</sup>, Aylin Tekes<sup>3</sup>, John P. Gearhart<sup>1</sup>

1. Robert D. Jeffs Division of Pediatric Urology, James Buchanan Brady Urological Institutions, Johns Hopkins Hospital, Johns Hopkins Medical Institutions, Charlotte Bloomberg Children's Hospital, Baltimore, MD
2. Pediatric & Adolescent Urology, Inc. and Division of Pediatric Urology, Akron Children's Hospital, Akron, OH
3. Division of Pediatric Radiology and Pediatric Neuroradiology, Russell H. Morgan Department of Radiology and Radiological Science, Johns Hopkins Medical Institutions, Baltimore, MD

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Corresponding author:

John P. Gearhart, MD

The Johns Hopkins University School of Medicine

James Buchanan Brady Urological Institute

Division of Pediatric Urology

Charlotte Bloomberg Children's Hospital

1800 Orleans St, Suite 7304

Baltimore, MD 21287

E-mail: [Jgearha2@jhmi.edu](mailto:Jgearha2@jhmi.edu)

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## ABSTRACT

**Purpose:** To determine the safety and efficacy of intraoperative magnetic resonance imaging (MRI) guided surgical reconstruction of bladder exstrophy for identification of the urogenital diaphragm fibers and the thickened muscular attachments between the posterior urethra, bladder plate and pubic rami.

**Methods:** Institutional review board and Food and Drug Administration approval was obtained for use of Brainlab® (Munich, Germany) intraoperative MRI-guided navigation of the pelvic floor anatomy during closure of CBE and CE at the authors' institution. Pre-operative pelvic 3D MRI was obtained one day prior to closure in patients having pelvic osteotomies. Intraoperative registration was performed after pre-operative planning with a pediatric radiologist utilizing five anatomic landmarks immediately prior to initiation of surgery. Accuracy of identification of pelvic anatomy was assessed by two pediatric urologic surgeons and one pediatric radiologist.

**Results:** Forty three patients with CBE and four patients with CE closed at the authors' institution have successfully utilized Brainlab® technology to navigate and guide the dissection of the pelvic floor intraoperatively. All patients had 100% accuracy in correlation of gross anatomic landmarks with 3D MRI identified landmarks intraoperatively, and all have had successful closure without any major complication.

**Conclusion:** Brainlab® intraoperative 3D MRI-guided pelvic floor navigation and dissection is an effective way to accurately identify pelvic anatomy during CBE and CE closure. This technology offers a unique opportunity for surgical skill education in this complex reconstructive operation.

**Key Words:** Bladder exstrophy, Cloacal exstrophy, Magnetic resonance imaging, Image-guided surgery

## INTRODUCTION

Bladder exstrophy (BE) represents a major congenital anomaly complex characterized by musculoskeletal defects in the abdomen and pelvis, as well as genital and urinary defects. The primary objective of surgical management are a secure newborn closure, later genital reconstruction and eventual voided continence. Williams et al were the first to describe using

three-dimensional (3D) magnetic resonance imaging (MRI) evaluation of the newborn pelvis prior to surgical repair.<sup>1</sup>

Further detailed work by Stec et al compared the shape of the pelvic floor before and after newborn closure with and without osteotomy.<sup>2</sup> After closure, the levator ani group of muscles were redistributed more anterior to the rectum and the muscle contours become smooth and uniform without kinking.

This new detailed definition of pelvic anatomy led us to transfer the findings on preoperative 3D MRI to the operating room for better surgical guidance and definition of our pelvic and posterior vesicourethral dissection. In BE, 3D MRI provides accurate delineation of tissue planes along with better orientation of complex pelvic anatomy.<sup>3</sup> Utilizing the VectorVision BrainLab surgical device and combining this with intraoperative display of the preoperative 3D MRI we were able to define this area, refine our dissection and the results of this new intraoperative technology is reported herein. We hypothesize that intraoperative stereotactic imaging with the BrainLab device will allow the surgeon to safely identify the fibers of the urogenital diaphragm, and then identify important landmarks of the pelvic floor for adequate placement of the vesicourethral unit deep within the pelvis in BE patients undergoing bladder closure. The primary objective of this study was to determine the efficacy and safety of using the BrainLab stereotactic intraoperative imaging device to identify critical anatomic landmarks during bladder closures in patients with BE.

## METHODS

### *Study Design and Population*

This is a single arm trial evaluating the safety of the intraoperative use of the VectorVision BrainLab ® surgical device (NCT01878500). From July 2012, Institutional

Review Board approval was obtained for use of the VectorVision Cranial Image Guided Surgery System (Brainlab ®, Inc., Munich, Germany) with pre-operative MRIs during the surgical repair of patients with BE. A total of 48 patients with either bladder exstrophy or cloacal exstrophy undergoing repair of the bladder with pelvic osteotomy were prospectively recruited. Patients were recruited consecutively. Patients in which a closure was planned without pelvic osteotomy were not eligible for this study.

### *Imaging Protocol*

MRI scans were obtained the day before the scheduled surgery. Pelvic MRIs with and without contrast were acquired with a 1.5 or 3T scanner (Siemens, Erlangen, Germany). Triplanar images (axial, sagittal, coronal planes) with T1 and T2 weighted sequences were read by a pediatric radiologist experienced with the exstrophy spectrum (Figure 1).<sup>4</sup> With the VectorVision iPlan ® computational system (Brainlab, Inc., Munich, Germany), bony anatomic landmarks (pubic tubercles and anterior superior iliac spines) and pelvic floor landmarks (puborectalis, iliococcygeus, and pubococcygeus) were identified and highlighted. Three-dimensional reconstructions of the triplanar imaging were rendered for intraoperative use.

### *BrainLab Vector Vision System*

The VectorVision BrainLab ® system is an imaging localization system, typically MRI or computed tomography. This system contains a workstation, two infrared cameras and infrared light emitting diodes, a reference array, and stylet pointer. The reference array and stylet pointers use reflective spheres which are detected by the cameras with passive reflection of infrared light. In this manner, the 3-dimensional geospatial location of the stylet can be tracked in

relation to the fixed reference array. These coordinates correspond to a location in the triplanar MRI. The use of this system has been described in detail by a number of other surgical specialties such as neurosurgery and otolaryngology.<sup>5-9</sup>

### *Image-Guided Surgery*

Patients with classic bladder exstrophy undergoing a primary closure were repaired using the modern staged technique (MSRE). Those undergoing a secondary closure were repaired in a similar manner, situating the posterior vesicourethral unit deep within the pelvis. Patients with cloacal exstrophy were repaired using a staged approach, by which the reapproximated bladder was reconstructed 6-9 months following the omphalocele repair.

At on the day of bladder closure, prior to dissection, registration of the patient's anatomy with the MRI is performed. First, a reference array is held around patient's upper abdomen with a head strap. Four bony anatomic landmarks, specifically the anterior superior iliac spines bilaterally and the anterior part of pubic tubercles bilaterally, are identified and the patient's anatomy is registered to the MRI with the stylet and the VectorVision iPlan Cranial Software (Figure 2). In each type of closure, a bilateral combined anterior innominate and vertical iliac osteotomy is used performed by a pediatric orthopedic surgeon prior to the soft tissue dissection.

After pelvic osteotomy and placement of the external fixator pins, the reference array is then re-attached to the pins for infrared communication with the VectorVision BrainLab workstation. Four bony anatomic landmarks (pubic tubercles and anterior superior iliac spines, bilaterally) are again used to register the surgical anatomy to the preoperative MRI with the VectorVision iPlan Cranial Software (Figure 3). With registration complete, the tracked stylet is used intraoperatively with surgical landmarks to correlate with stereotactic imaging. As the

moves the stylet moved during the reconstruction, the view of the MRI on the workstation adjusts in the axial, coronal and sagittal plane. Thus the surgeon can view the triplanar MRI, highlighted muscles, and a juxtaposed 3D reconstruction of the levator muscles. This is used to identify the pelvic floor, both surgically and radiographically with stereotactic imaging, during the dissection (Figure 4).

#### *Feasibility and Surgical Outcomes*

The safety and feasibility of implementing this technology was investigated. As such, the ability to accurately register and correlate the surgical anatomy with stereotactic imaging was assessed during the bladder closure as the primary objective. The first critical anatomic landmarks identified were inferior pubic rami levator hiatus during the dissection of the fibers of the urogenital diaphragm (UGD), which connects the posterior vesicourethral unit to pubic rami bilaterally. The Brainlab's ability to correlate the radiographic and intraoperative location of the inferior pubic rami and levator hiatus during radical dissection of the UGD fibers was assessed after radical dissection of the UGD fibers. This was done by placing the point of the stylet at the patients inferior pubic rami, and observing the displayed structures on the MRI. The second anatomic landmarks identified were the puborectalis, pubococcygeus, and iliococcygeus muscles of the levator group during placement of the closed vesicourethral unit in the posterior and inferior location within the pelvis. The visualization of the levator muscle group and correlation with radiographic anatomy on the BrainLab system was assessed. The correlation of surgical and radiographic anatomy were performed by a senior pediatric urologist and a pediatric radiologist experienced with the exstrophy spectrum. While the pediatric urologist used the stylet

to identify the landmarks intraoperatively, the pediatric radiologist confirmed the radiographic location of the stylet. In this manner, surgical and radiographic anatomy were correlated.

Intraoperative and post-operative outcomes were also investigated as a secondary objective. These include the operative time, estimated blood loss, pre- and post-operative hemoglobin, blood transfusion rate, surgical complication rate, length of hospital stay, and the outcome of the bladder closure. A failed bladder closure was defined as either bladder prolapse, dehiscence, outlet obstruction, persistent vesicourethral fistula, a combination of these, or complication that requires a reclosure.

## RESULTS

### *Patient and surgical characteristics*

Since 2012, 47 patients with bladder exstrophy have undergone image-guided bladder surgeries (28 male, 19 female) with bladder or cloacal exstrophy (CBE and CE). Forty-four patients had bladder exstrophy (36 classic bladder exstrophy, 7 variants) and 4 patients had cloacal exstrophy.

Of the 47 bladder surgeries, 3 were simple cystectomies with urinary diversions. Thus, a total of 44 surgeries were closures of the bladder. Of these, 28 were primary closures of BE, 12 were repeat closures of failed primary CBE closures, and 4 were primary closures of CE. Table 1 displays the patient characteristics and perioperative outcomes of the entire cohort and each closure. All 47 bladder surgeries were performed with pelvic osteotomies and all 44 closures were successful. The median follow-up time after surgery was 112.5 weeks (range 3.7-282.9).

### *Safety and efficacy*

In all 47 surgeries, registration and pelvic floor navigation were performed safely and without complication with the VectorVision BrainLab system. Registration of the pubic tubercles and anterior superior iliac spines surgically with the preoperative MRI resulted in accurate correlation of the surgical and radiographic anatomy. All 47 patients had correct registration of the anatomical landmarks as verified by a pediatric urologist and pediatric radiologist.

During the surgery, the UGD fibers were identified in all patients. Dissection was performed until the level of the inferior pubic rami bilaterally and levator hiatus. In all 47 surgeries, the BrainLab device confirmed the radiographic correlation of the inferior pubic rami and levator muscle group during the dissection of the UGD fibers.

In the 44 patients undergoing bladder closure, the bladder was placed in the posterior-inferior position. In these closures, the BrainLab device confirmed the radiographic correlation of the levator muscles during placement of the vesicourethral unit. The median operative time was 619 minutes [IQR 503-647]. There were no intra-operative complications of using the BrainLab device and any of the cases.

#### *Post-operative closure outcomes*

Post-operative complications were rare in the 47 surgeries. Using the Clavien-Dindo classification scheme, there were 3 grade I (6.3%), 3 grade II (6.3%), and 4 grade IIIb (8.5%) complications, all of which were appropriately managed. None of the complications required reclosure of the bladder, and as such, none of these complications constituted a failure of the bladder closure. Details of the complications may be viewed in Table 2.

## DISCUSSION

The complex anatomy of both the soft tissue and pelvis in BE, and necessity for accurate dissection lends itself to benefits of stereotactic image-guided surgery (IGS). Over the last 20 years, this tool has been increasingly utilized, largely by fields such as neurosurgery and otolaryngology. ENREF 1<sup>5-9</sup> Stereotactic MRI-guided procedures have only recently been used in urology, particularly with the emergence MRI/ultrasound fusion-guided prostate biopsies for prostate cancer.<sup>10,11</sup> As such, the current study is the first to show the safety and efficacy of this emerging technology in the reconstruction of BE, a surgery that has seen relatively few implementations of new technologies.

All patients in this study had a successful bladder closure without major complications. Indeed, the success of the modern staged repair (MSRE), the technique used at the authors' institution, is contingent on a multitude of factors, both intra- and post-operative.<sup>12,13</sup> As with all exstrophy surgical techniques, the mobilization of the posterior vesicourethral unit and its deep positioning in the pelvis plays a large role in closure outcomes and eventual possibility of voided continence. Effective mobilization results in redistribution of the levator ani muscle group from the posterior to the anterior compartment of the pelvis.<sup>2,14</sup> Thus, a critical component of the surgery is identification and dissection of the levator muscle group. Visually identifying this muscle group amidst the complex anatomy, sometimes compounded by prior surgeries, is on a learning curve that may be reduced by IGS. The actual learning curve of IGS during exstrophy repair will require further investigation, but evidence from other studies of IGS in neurosurgery seems to suggest that assisted navigation results in a lower learning curve and lower complication rate.<sup>15,16</sup>

Such a learning curve in exstrophy repair depends on a number of factors. There are patient, hardware, and operating room considerations to account for when performing an image-

guided BE repair. These may all play a role in the margin of error during the registration process. Initial registration of the preoperative MRI with the patient is crucial for accurate navigation, and neurosurgical studies show a rather unforgiving margin for error.<sup>17,18</sup> The anatomical landmarks for registration in BE closure, the pubic tubercles and anterior superior iliac crests, are easily identifiable in the patient and on the MRI. Still, the surgeon needs to frequently validate the accuracy of the registration in real time. Registration of the intraoperative anatomy to the radiographic anatomy is performed before the soft tissue dissection and after the pelvic osteotomy to ensure validity of the anatomic correlation. Each time, the correlation was checked by the surgeon and radiologist. This requires a new skillset in BE repair of intra-operative instrumentation with image-based orientation. Furthermore, troubleshooting errors in intra-operative navigation may also include both the interrogation of the equipment and its placement. For example, any obstruction or interference between the infra-red camera and the reference probe will impede navigation, and exstrophy surgeon must be cognizant of such potential snares. The cost of implementing this technology should also be considered. For the BrainLab Vector Vision system, the cost is \$225,000. But as this technology has been routinely used in neurosurgical and otolaryngological procedures, many centers may already have this system available to them through those departments.

Though accurate identification of important structures with IGS may offer benefits associated with the dissection and radical mobilization of the vesicourethral unit, IGS may also offer increased patient safety. In BE, the pelvic floor musculature has been well characterized by prior imaging studies,<sup>4,19</sup> but there remains a certain degree of variability regarding the location and course of other structures on an individual level, and preoperative assessment with pediatric radiology provides the surgeon with additional information. On an individual level, pre-operative

assessment with 3D MRI provides the surgeon with additional information regarding the anatomy of the surrounding structures. It should be noted however, that this technology is not a replacement for knowing the fundamentals of exstrophy anatomy and the steps of the surgical repair. Rather, this technology should be used to verify that the proper steps have completed.

Herein, the authors report their experience with BrainLab® assisted 3D MRI-guided exstrophy closure in a single arm trial. Findings from this study should be considered with limitations in mind. First, this is a medium size cohort study validating the safety and efficacy of this tool in correlating surgical and radiographic anatomy during exstrophy repair. As such, further investigation into safety will likely require multi-institutional collaboration. Second, though secondary outcomes, such as closure outcome status, were assessed, these were not compared to patients who were repaired without IGS. Still, with other significantly more influential factors in closure outcomes, it is likely that outcome differences from IGS will be imperceptible and will require a randomized clinical trial with a large number of patients to assess. The feasibility of a randomized clinical trial is currently being assessed, but the rarity of this condition poses challenges. With randomized clinical trial, many perioperative outcomes may be assessed in addition to outcome of the closure. Ultimately with adequate follow-up time, the effect on urinary continence may also be assessed.

## CONCLUSIONS

Whether a primary or secondary closure, intraoperative 3D-guided pelvic floor dissection with the BrainLab Vector Vision system allows for safe and accurate correlation of the surgical and radiographic anatomy. This adds to the completeness during the important steps of radical dissection of the urogenital fibers as well as the placement of the bladder deep within the pelvis.

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**Table 1.** Patient and surgical characteristics of the 44 bladder and cloacal exstrophy undergoing bladder closure. (Abbreviations: BE, bladder exstrophy; CE cloacal exstrophy; IQR, interquartile range; EBL, estimated blood loss)

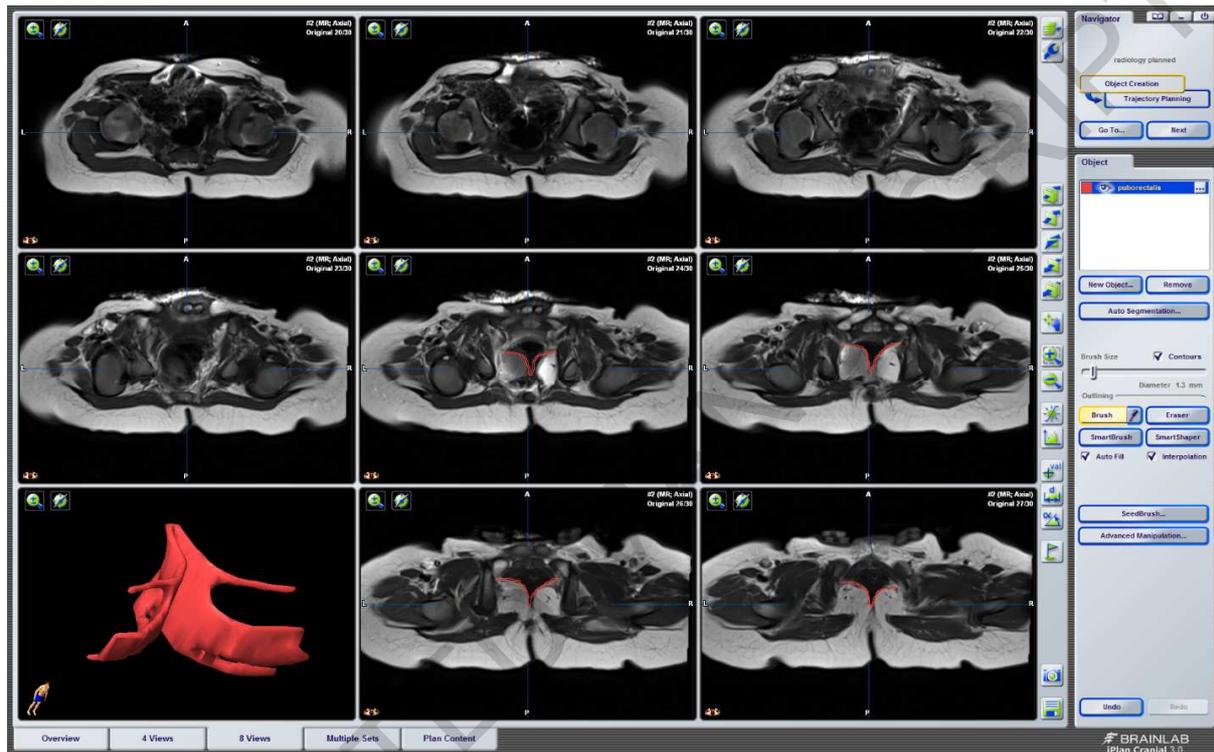
Variable	Closure cohort (n=44)	Closure group		
		Primary BE (n=28)	Repeat BE (n=12)	Primary CE (n=4)
Pubic diastasis, cm [IQR]	4.4 [3.8-5.0]	4.1 [3.5-4.6]	4.8 [4.2-5.5]	7.0 [6.8-7.5]
Age at closure, weeks (range)	28.6 (0.9-287.1)	15.6 (0.9-287.1)	104.4 (21-214)	108.2 (52-158.9)
Operative length, minutes [IQR]	619 [503-647]	619 [535-647]	592 [496.8-633.8]	608.5 [527.8-689.3]
EBL, ml [IQR]	50 [25-75]	50 [20-50]	50 [50-100]	70 [35-135]
Median pre-operative Hct, % [IQR]	33.6 [30.3-36.3]	33.8 [31-38.6]	33.1 [30.6-34.7]	29.1 [26.8-31.1]
Median post-operative Hct, % [IQR]	31.2 [27.2-34.6]	31.2 [27.2-35.6]	31 [26.8-32.4]	31.6 [31.2-31.9]
Transfusion, n (%)	33 (75%)	23 (82%)	9 (75%)	1 (25%)
<i>intra-operative*</i>	13 (33%)	11 (48%)	2 (22%)	0
<i>post-operative*</i>	13 (39%)	8 (35%)	5 (56%)	0
<i>both*</i>	7 (21%)	4 (17%)	2 (22%)	1 (100%)
Length of stay, days [IQR]	50 [45-54]	47 [45-52.5]	52 [50-54.5]	56 [49-57]

**Table 2.** Clavien-Dindo classification of post-operative complications in the 47 bladder surgeries, including closures and cystectomies.

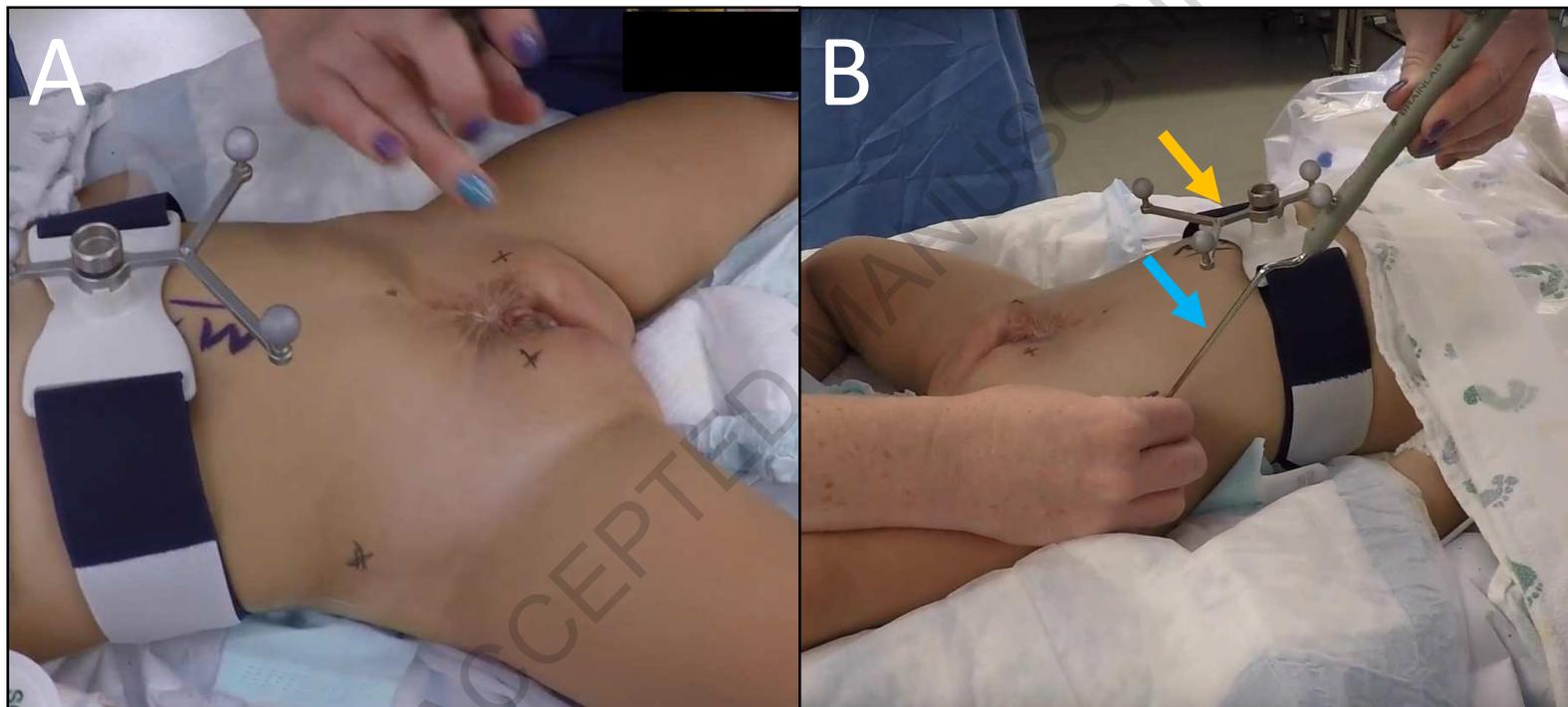
<b>Clavien-Dindo classification</b>	<b>Management</b>	
I	Wound dehiscence	Dressing change 1 (2.1%)
	Acute kidney injury	self-resolved 2 (4.3%)
II	Wound infection	antibiotics 2 (4.3%)
	Pin site infection	antibiotics 1 (2.1%)
III	Urine leak	vacuum-assisted closure 1 (2.1%)
	Wound infection	vacuum-assisted closure 2 (4.3%)
	Ureteral obstruction	nephrostomy tube placement 1 (2.1%)

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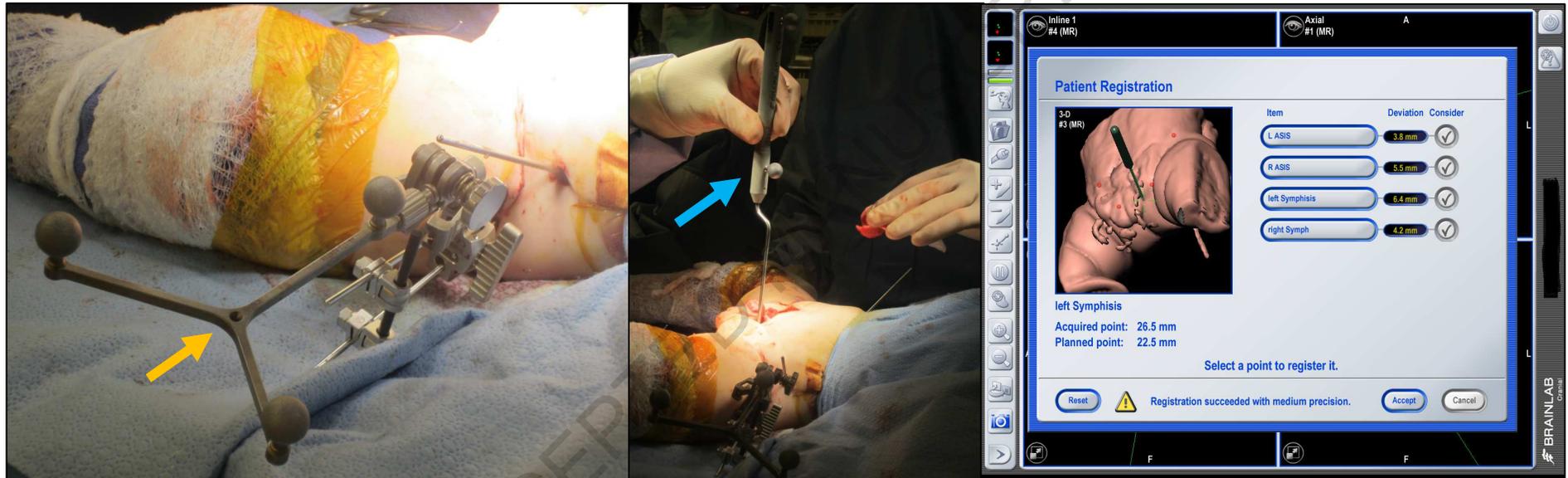
**Figure 1.** The first step of the workflow is obtaining the pre-operative MRI and identification of the levator muscle group. Here, the puborectalis in red is outlined in multiple axial slices to create a 3 dimensional reconstruction. The iliococcygeus and pubococcygeus are not shown, however these muscles are reconstructed as well. Thus, the levator muscle group serve as an anatomic landmark during image guided surgery after the pubic tubercles and anterior superior iliac spines are used as registration points.



**Figure 2.** After pre-operative planning, the pediatric urologist and pediatric radiologist register the patient's anterior superior iliac spines and pubic tubercles to MRI which is loaded onto the BrainLab workstation. The four bony landmarks are identified prior to the start of the procedure (A). The reference array is attached to the patient with a head strap (orange arrow) and the stylet (blue arrow) is used to register the bony anatomic landmarks to the MRI. Afterwards, the pelvic osteotomy is performed (B).



**Figure 3.** The external fixator pins are placed at the time of the osteotomies. The reference array (orange arrow) is attached to the external fixator pins, and stylet (blue arrow) is used to re-acquire the intraoperative bony landmarks. Once accuracy of the landmarks is confirmed, the soft tissue dissection may begin with the aid of image guided surgery.



**Figure 4.** During the dissection, the surgeon confirms surgical anatomy with radiologic anatomy. This is performed at two critical steps of the bladder closure. First, when the bladder template and urethral plate are dissected from the urogenital diaphragm fibers and thickened smooth and striated fibers, complete dissection to the pelvic floor and inferior pubic rami is confirmed radiographically (shown here). Second, when the vesicourethral unit is placed at its most postero-inferior position, radiographic placement by the levator muscle group is confirmed. The surgeon and the radiologist both confirm the correct anatomic landmarks as the surgeon uses the stylet.

