SEMMELWEIS EGYETEM

DOKTORI ISKOLA

Ph.D. értekezések

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DEVELOPMENT OF MAGNETIC COMPRESSION ANASTOMOSIS DEVICES FOR MINIMALLY INVASIVE PEDIATRIC SURGERY

PhD Thesis

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List of Abbreviations

ANOVA	Analysis of Variance
BAUS	British Association of Urological Surgeons
BM	balloon model
CA	conventional anastomosis
ChCrM	chicken crop model
ChTM	chicken thigh model
EA	esophageal atresia
EAU	European Association of Urology
EMAD	Esophageal Magnetic Anastomosis Device
ERNICA	European Reference Network for Rare Inherited Congenital Anomalies
ESPES	European Society of Pediatric Endoscopic Surgeons
ESPU	European Society for Paediatric Urology
EUROCAT	European Registry of Congenital Anomalies
FDA	Food and Drug Administration
FGM	finger glove model
IRB	Institutional Review Board
MCA	magnetic compression anastomosis
MIS	minimally invasive surgery
n.d.	no data available
PEG	percutaneous endoscopic gastrostomy
PUJ	pyelo-ureteral junction
PUJO	pyelo-ureteral junction obstruction
PUMA	Pyelo-Ureteral Magnetic Anastomosis
SBT	simulation based training
tCA	construction time of conventional anastomosis
TEF	tracheoesophageal fistula
tMA	construction time of magnamosis

1 Introduction

1.1 The evolution of minimally invasive surgery (MIS) in children

Minimally invasive surgery is defined as a special surgical technique that is done through small incisions with video assistance. Due to its well-known benefits, this method has revolutionized the traditional open surgery (1).

MIS has many advantages over traditional open approach. Patients have less postoperative discomfort, stress, and pain so they require relatively decreased doses of narcotics. Recovery time is obviously faster that allows shorter hospital stay and rapid return to normal life. Smaller size of the incisions and reduced scarring have positive influence on cosmetic satisfaction. With avoiding thoracotomy, later risk for scoliosis and chest wall deformities are lower. Surgeons can visualise obscure areas of abdomen or thorax with the help of a high-definition video camera. In summary, MIS has more potential benefits for patients than open surgery (2).

Minimally invasive laparoscopic surgery began to develop in the 1980s. Initially, this technique was applied only for simple procedures and diagnostic purposes. The first procedure, which later became widely adopted, was laparoscopic cholecystectomy, performed by Philippe Mouret in 1987. Following this, due to advancements in technology, minimally invasive surgery underwent rapid and significant development. The simpler grasping tools initially used were replaced by more refined instruments suitable for dissection, cutting, suturing and haemostasis (3).

The use of laparoscopy in children was introduced by George Berci and Stephen Gans in 1971 (4). Two decades later, Steven Rothenberg was the first to perform thoracoscopic procedures in children (5). Since then, minimally invasive pediatric surgery has become popular worldwide, there is more and more demand for even complex procedures to be completed using this technique (6).

Minimally invasive surgery in children started with simpler rather ablative surgery like cholecystectomy, appendicectomy, empyema surgery, splenectomy. It is now essential in the surgery of undescended intraabdominal testicles. It is more and more used for reduction of intussusception, inguinal hernia repair, pyloromyotomy, pull-through for Hirschprung's disease and high imperforate anus or treatment of intestinal malrotation. There is now a demand for more complex reconstructive procedures where intracorporeal suturing required for example fundoplication. The demand is still growing and abolishing the age limits like that of the minimally invasive pyeloplasty. MIS procedures are now competing with open procedures in neonates like congenital diaphragmatic hernia and esophageal atresia repair (7, 8, 9).

The development of the MIS equipment is noticeable, the simpler surgical instruments like grasping tools initially used were replaced by more refined instruments suitable for dissection, cutting, and haemostasis and suturing (6). Significant miniaturization of the instruments happened as well, to date wide range of instruments are available for infants as well with a diameter of 3 mm.

The development of advanced vessel sealing devices like ultrasonic scalpel and advanced bipolar technology, or self-locking secure clips made ablative surgery quicker and safer.

However, there is a limit of miniaturisation as well, sealing and cutting instruments are mainly available in 5 mm. This applies to purpose made devices especially for those developed to anastomose hollow viscera. Linear and circular staplers are available, but again they are mainly available for adults due to their sizes.

With laparoscopy surgeons can visualise obscure areas of abdomen or thorax with the help of a video camera. The resolution of the video imaging improved significantly in the last decade, to date 4K technology gives the surgeon crystal-clear details even with a 5 mm diameter telescope. The introducing of 3D imaging significantly improved depth perception facilitates precise suturing; however, these telescopes are only available with 10 mm diameter, which are still quite bulky for infants.

Despite the high costs the robot assisted surgery is thought to be superior to laparoscopy and rapidly progressing in children as well. Surgical robots are providing supreme 3D visualisation and extreme manoeuvrability compared to laparoscopy. However, there are some losses as well. For example, the instruments of the most used robotic systems are still too bulky for neonates and toddlers, they usually require 8-10 mm ports. Although surgeons at the Royal Manchester Children's University Hospital reported good initial (not yet published) experience during the ongoing clinical trial with a new robotic system (5 mm instruments and 10 mm telescope) in infants weighting even less than 5 kgs . But keeping the ports 4 fingers away from each other to prevent clashes of the robotic arms remains a challenge. Another anomaly of the most robotic systems is the missing haptic feedback. The robotic driven instruments can cause significant crash marks on the tissue. To avoid these the suturing of the anastomosis is requiring a special non-touch technique, which again may be challenging especially for example in a small calibre pyelo-ureteric anastomosis. Although development in this area is remarkable in the latest generation of surgical robots.

Despite the massive technical advancement detailed above the small volume of body cavities and the small size of the organs are representing the major challenge of MIS in children especially in neonates and infancy (10). Lengthy complex procedures are not well tolerated by immature neonates, the absorption of CO_2 and increased intraabdominal pressure can easily lead to hypercapnia, respiratory acidosis decreases in cerebral oxygenation and neurodevelopmental impairment. The more complex procedures (esophageal atresia repair, pyeloplasty) in more and more smaller children demand mastery of complex skills with a steep learning curve (11, 12).

We believe there is still a space for new innovative technical solutions i.e. purpose built devices to simplify and shorten complex procedures like pyeloplasty or repair of esophageal atresia. New verified models for surgical simulation are essential in testing and development as well as in the training of surgeons to push the boundaries of MIS in children.

The aim of this thesis is to serve all these domains.

1.2 The role of simulation-based surgical training

Simulation-based training (SBT) has a significant role in surgical education (13). It is essential especially in minimally invasive pediatric surgery due to inadequate case volume, wide variety of pediatric diseases and the increasing number of trainees (14).

Complex procedures, such as laparoscopic pyeloplasty and thoracoscopic esophageal atresia repair are associated with steep learning curve and requires advanced skills from the surgeon because of intracorporeal suturing and knot tying.

SBT provides the opportunity to develop surgical skills effectively, repetitively in a safe environment. It may also lead to improved patient outcomes, shorter operative time, lower risks of complications, cost savings and can be used to test novel equipment and procedures (15, 16).

Guidelines of British Association of Urological Surgeons (BAUS) and European Society of Pediatric Endoscopic Surgeons (ESPES) recommend that every trainee should complete a "dry lab" course and practice on simulators to reach a standard laparoscopic skill level (17, 18).

Practice on models is very important not just for trainees, but also for experts (19).

Up to 2018 40 pediatric surgery training models have been described in the literature, but only a few of them are commercially available and validated up to now (20).

Wide range of surgical models can be used for training or experiments (Figure 1). Hybrid models and synthetic models including simple box trainers (pelvic trainers), 3D-printed models with or without sensors, virtual reality models are mainly designed for training purposes. Experimental models include human cadaver models and animal-based models such as animal tissues, non-survival and survival animal models are mainly used to investigate novel surgical techniques but also offer the surgeons to acquire advanced operative skills.

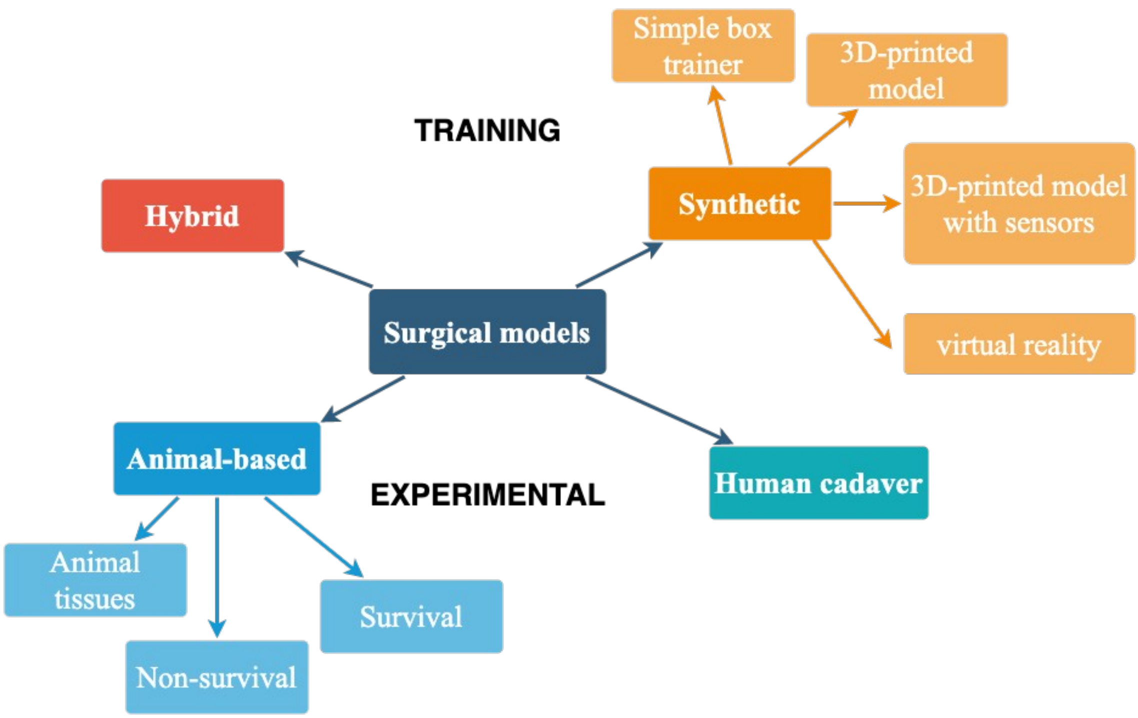

Figure 1: Types of training and experimental surgical models

Properly validated low-fidelity synthetic models have the advantages that they can be made from inexpensive materials, they are easy to replicate and can be available for domestic use and promote repeated practice (21).

Currently, 3D-printed and virtual reality simulators are very trendy and commonly used for surgical training. The potential benefit of these is clear, but they are still expensive, and this limits their access for the trainees especially in low- and middle-income countries (22).

Animal-based 'wet lab' models, such as live animals and animal tissues usually provide the most realistic experience, but these require special handling, cold storage, separate place or laboratory for practice, thorough clean-up and disinfecting procedures after the practice to prevent infections. These models are not suitable and comfortable for domestic use and usually available only in specific institutions or expensive courses.

Rabbits and pigs are the most popular simulation animal models in minimally invasive pediatric surgery due to their anatomic and histological similarity to humans and ease of handling. Pig models seem to be more ideal because rabbits have higher risk of aspiration, they are less hardy, and they are only feasible to simulate neonatal surgical procedures (23).

High-fidelity models however are not always clearly better than low-fidelity models in surgical training (24).

Surgical simulators need to be validated before using them for training. There are several types of validation that can be used to describe a simulator, including content validity (suitability of the simulator for measuring laparoscopic surgical skill), construct validity (capability of the simulator to differentiate between novice and expert surgeons), concurrent validity (comparison with other simulators), predictive validity (suitability for predicting future surgical performance) and face validity. Face validity is the simplest method for validity, refers to the realism of the simulator based on nonexperts' subjective evaluation (21).

1.3 The role of purpose-made anastomosis devices

The introduction of surgical staplers significantly eased operations in small body cavities and narrow surgical spaces. The first type of these machines was developed by the

Hungarian Hümér Hültl, who was the first to create such a device in the world. The stapler was first used in 1908 for creating a stomach wall anastomosis, allowing for the prevention of stomach contents from spilling into the abdominal cavity when the stomach was cut. Thanks to this innovation, the surgical time was greatly shortened, and the number of postoperative complications, such as peritonitis, was significantly reduced. The precursor of modern staplers, which are still used today, was developed by Aladár Petz in 1920. In the two-row stapler, nickel-silver staples were used, and its usability was easier than the original. Today's rechargeable straight or circular staplers use titanium staples and greatly facilitate abdominal, thoracic, and gynaecological surgeries. They are also capable of creating multiple staple rows and cutting through tissues between the rows (25).

Magnetic compression anastomosis (MCA), also known as magnamosis is an alternative anastomotic technique. This sutureless anastomosis has been formed by two rare-earth permanent magnets placed in hollow organs, inducing central necrosis and peripheral remodelling of the tissue (Fig. 2).

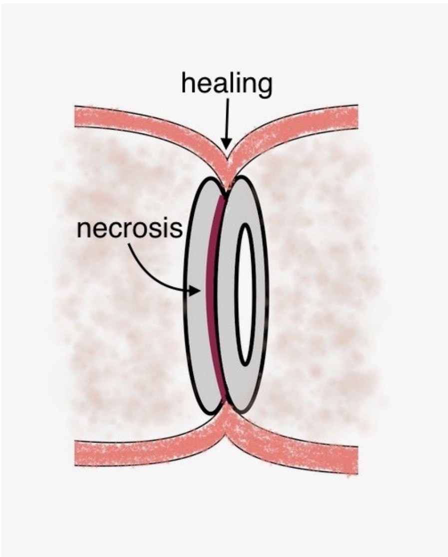

Figure 2: Schematic drawing of magnetic compression anastomosis: compression of two magnets inducing central necrosis and peripheral remodelling of the tissue

The original idea of compression anastomosis came from some innovative surgeons in the mid-nineteenth century who would like to avoid the usually fatal intestinal anastomotic insufficiency. These devices consisted of two metal rings with a central spring or metal buttons (27). These were the forerunners of magnetic anastomosis devices. The method of magnamosis was firstly described by Obora et al. in 1978 creating microvascular magnamosis in experimental animals (28).

The main advantage of magnamosis is the reduction of the potential risk of anastomotic leakage by providing equal and continuous tissue compression compared with conventional hand-sewn anastomosis. Creation of a watertight anastomosis helps reduce postoperative complications, stricture rate and shorten the recovery period (29).

Potentially if the introduction and removal of the magnets into organs may be carried out using minimally invasive approach open procedures can be replaced by minimal invasive ones.

Magnamosis may be advantageous for neonates with limited working space. Performing intracorporeal suturing in them demand experience and complex skills and it can be very time-consuming (10).

Moreover, since there is no suture material remaining in the anastomosed organs' wall when using magnets, there is no need to be concerned about foreign body reactions in the mucosa and submucosa, as well as the potential risk of contamination associated with penetrating the mucosa. These factors can prevent scarring and formation of strictures. The local healing process and tissue remodelling can happen theoretically faster using magnets (30).

Due to their potential toxicity and increased corrosion risk, rare-earth magnets require special coatings when used for medical purposes, usually gold, titanium, or parylene (poly-para-xylene). The choice of material and coating for the magnets must consider the intended location and tissue type in which they will be used. For example, in the small intestine, magnets exposed to gastric acid and digestive juices should have a more resistant coating. The migration of magnets can be prevented by securing one magnet of the pair to the target organ. The use of magnets is not recommended for individuals with pacemakers or implanted defibrillators, as the static magnetic field generated may interfere with their function (31).

After numerous animal experiments, Jansen et al. carried out the first successful magnamosis during colostomy closure (colo-colonic anastomosis) in humans in 1980 using two magnetic rings without any postoperative complications (32). This represented a significant breakthrough in surgery, followed by numerous publications on the potential clinical applications of magnetic anastomosis. In 1989, it was used to treat urethral stricture (Isakov et al.), in 1992 for small bowel fistulas (Stepanov et al.), and in 1993 for biliary stricture (Saveliev et al.). Since then, it has been successfully used for gastrointestinal anastomoses as well as cholecysto-enteric, pancreatico-enteric, and esophageal anastomoses (31).

Mascagni reported the successful treatment of complete hypopharyngeal stenosis in a 72-year-old man using magnetic anastomosis. One ring magnet was introduced through a gastrostomy created due to feeding difficulties, and the other was introduced through the mouth, fixed to a gastroscope, with continuous X-ray monitoring. On the 11th day, after the anastomosis had formed, the magnet pair spontaneously exited, allowing for endoscopic balloon dilation of the stricture (33).

In recent years, magnetic anastomosis has also gained use in cardiovascular surgery. It is now used for the creation of arteriovenous fistulas in patients requiring long-term dialysis. A specialized magnet-tipped catheter is placed in the artery and vein, and their ends are joined using a radiofrequency electrode to establish a new connection between the vessels. This method significantly reduces radiation exposure compared to traditional vascular surgical procedures (34).

During coronary artery surgery, it is also used for creating vessel anastomoses (Ventrica Magnetic Vascular Port System®). Other vascular surgical uses have not yet been established in clinical practice, although animal experimental results are promising (35).

These new techniques introduced into adult surgery are expected to be adapted for pediatric surgery with further modifications.

The first magnetic anastomosis in a child, an ileo-ileal anastomosis, was reported by Toselli in 2017 (36), followed by several successful gastrointestinal and esophageal magnetic anastomoses (37).

According to a summary publication from a Moscow centre, between 1980 and 1995, nearly 250 animal experiments were conducted at the institute focusing on the gastrointestinal and urological surgical use of magnets and magnetic compression anastomoses. During this period, 86 children aged 2 to 10 years underwent magnetic anastomosis, for conditions such as short-segment post-traumatic urethral stenosis, non-sutured esophageal recanalization for esophageal atresia or stenosis, anorectal anastomosis in Hirschsprung's disease, ileostomy closure, and extravesical ureterocystoneostomy formation. Magnetic anastomosis was successful in more than 87% of clinical cases. The most common complications were focal necrosis or perforation caused by excessive compressive force, too thick tissue interposition between the magnets, or anastomosis insufficiency and stricture due to insufficient magnetic strength (38).

In recent decades, several research groups have focused on the treatment of congenital esophageal atresia with magnets, and research on this subject is still ongoing. Although the mortality rate for esophageal atresia has significantly decreased, anastomotic insufficiency remains a relatively common complication, with leakage occurring in 10-15% of cases and esophageal stricture in 30-60% (39, 40).

Magnetic anastomosis has also been successfully used to solve esophageal strictures that did not respond to conservative treatment or endoscopic balloon dilation (41).

Magnets that have been used in various experiments are quite different in characteristics, design and pull force and the anastomosis can be end-to-end or end-to-side with use of them.

Subsequently, it has been demonstrated in several studies that magnetic compression anastomosis technique is a viable, reliable and effective alternative method to conventional hand-sewn anastomosis: safe and patent gastrojejunal, jejunoileal, colocolonic, cholecysto-enteric, pancreatico-enteric and esophageal anastomoses have been performed (42-46).

One of the major limiting factors of widespread use of magnetic anastomosis devices is introduction magnets in a minimally invasive way.

1.4 Traditional and minimal invasive management of pyelo-ureteral junction obstruction

Pyelo-ureteral junction obstruction (PUJO) is defined as inadequate drainage of urine from the renal pelvis. It can lead to hydronephrosis, increased intrapelvic pressure resulting in progressive deterioration of renal function.

The most common cause of PUJO in infants is a developmental defect of the upper part of the ureter (intrinsic obstruction). In older children the obstruction is usually related to an extrinsic obstruction caused by aberrant crossing pole vessels, fibrous bands adhesions and kinks (47).

Congenital hydronephrosis including PUJO is a relatively common anomaly of the upper urinary tract, prevalence is estimated at 14,88 in 10000 live births with a male predominance according to EUROCAT database (48).

Hydronephrosis is frequently detected antenatally with ultrasound however the majority of these cases do not require surgery due to spontaneous resolution. According to the current European Association of Urology (EAU) and European Society for Paediatric Urology (ESPU) guidelines surgical intervention should be considered when the antero-posterior diameter of the renal pelvis increased (more than 20 mm) on the ultrasonography and calyceal dilatation is present, the split renal function is impaired (less than 40%) and there is poor drainage on the dynamic diuretic isotope renal scintigraphy, or there is a symptomatic obstruction (febrile urinary tract infection, symptomatic stones, intermittent abdominal pain) (49).

Dismembered Anderson-Hynes pyeloplasty has become the gold standard of PUJO treatment. It involves resection of redundant pelvis and PUJ, incision and spatulation of the ureter and performing a pyelo-ureteral anastomosis. Trans-anastomotic stent typically remains in place for 7 days-to few weeks and removal can be conducted with or without general anaesthesia depending on the stent used (50).

This procedure can be performed open, laparoscopically and with robot assistance.

The minimal invasive approach especially the laparoscopic one require complex procedure demands mastery of complex skills with a steep learning curve. The most challenging part of this procedure are intracorporeal suturing and knot-tying (51). Robot assisted procedure seems somewhat easier, however still could be challenging.

In 2020 Cserni et al. came up with an idea to develop a purpose-built device to simplify and shorten laparoscopic pyeloplasty. The Pyelo-Ureteral Magnetic Anastomosis (PUMA) device was made from two neodymium magnets, one fixed on a JJ stent, another one freely moving, and a custom-made needle fixed in the stent. The first experiments have been performed at the University of Szeged Albert Szent-

Györgyi Medical School, Institute of Surgical Research in 2020 (52). The benefits and feasibility of PUMA device have been demonstrated in pig model. In this proof of concept study PUMA were performed in five pigs and anastomoses were found widely patent four weeks after the procedure in two pigs, however the animal model used did not allow longer term observation.

1.5 Surgical training and simulation models of pyeloplasty

The ideal model should be high fidelity, easily reproducible, widely available, cheap, should not pose infection risk and should have long shelf life.

Creating a live animal model for laparoscopic pyeloplasty is challenging. Creation of partial ureteric obstruction and dilated renal pelvis without causing scarring, infection and losing the kidney is not easy. Endoclips, ligature, suture-ligature or electrical injury has been reported with various results (53). Fu et al. trimmed the small intestine to the renal pelvis creating a laparoscopy pyeloplasty model in an anaesthetized pig (54). These models require specific facilities (large animal laboratories) and causing suffering to animals and are expensive.

Animal specimen, hybrid, synthetic and virtual reality simulation models have been described as well (55). All of them have been designed to facilitate a realistic experience with different degree.

The animal specimen models are reconfigured skin of a chicken thigh (56), chicken crop stitched to a pig kidney (57), pig bladder-urethra model (58), carp swim bladder stitched to a pig kidney (59), half a sheep bladder stitched to a loop of bowel (22). These models are realistic, cheap and some of the easily available, however they need special requirements for handling and storage.

Synthetic training models range from latex glove to simple balloon models to 3D-printed silicone based models (60-62). These models are easy to handle and store, some of them are cheap but have various fidelity.

1.6 Traditional and minimal invasive management of congenital esophageal atresia

Esophageal atresia (EA) is a congenital anomaly characterised by the discontinuity of the esophagus with or without tracheoesophageal fistula. Failure of tracheoesophageal separation during embryonic foregut development may be caused by genetic, epigenetic and environmental factors (63).

The birth incidence of this malformation varies between 2,34 in 10000 live births with a slight male predominance in Europe according to EUROCAT database (64).

Classification of EA is based on the presence or absence of tracheoesophageal fistula (TEF) and location of the atresia. The most common variant of EA is associated with distal TEF (Vogt type: IIIb, Gross type: C), accounts for 85% of all EA cases (65).

Due to the early disturbance of organogenesis (fourth to sixth weeks of gestation) EA is often (up to 50%) associated with cardiac, genitourinary, cardiac, vertebral, palate, laryngotracheal and limb anomalies as well as with trisomy 21 and 18 (65).

Although prenatal diagnosis of EA is important since delivery can be planned at a specialised neonatal surgical centre, sensitivity of fetal ultrasonography is only 10%. Nonspecific signs such as polyhydramnios and absence of stomach bubble detected in the third trimester may indicate EA. Shortly after birth inability to swallow saliva can cause episodes of choking, coughing and respiratory distress (66).

In cases of suspected EA impossible introduction of a nasogastric tube into the stomach can confirm the diagnosis of EA. Performing a perioperative plain X-ray is suggested to gain information about gap length and presence of a distal fistula (67).

The overall survival rate of EA is between 85 and 95%, however, postoperative morbidity including anastomotic leakage, stricture, respiratory illness, and gastroesophageal reflux remains significant (68).

After careful preoperative management and stabilization of the neonate, surgical repair should be performed under general anaesthesia.

Right posterolateral thoracotomy was the procedure of choice before the thoracoscopic era. Extrapleural approach through the 4th or 5th intercostal space has been preferred (67).

However, thoracoscopic repair of esophageal atresia demands mastery of complex skills with a steep learning curve. Performing an esophageal anastomosis in a neonatal thorax is considered the most technically challenging minimally invasive procedure in pediatric surgery (69).

In experienced hands rates of anastomotic leakage and stricture formation do not differ between open and thoracoscopy approach (70).

Since operative time of thoracoscopic approach is usually longer compared with the conventional approach, the ERNICA consensus conference suggests that duration of thoracoscopic repair should not be longer than 3 hour and the maximum insufflation pressure of CO_2 should not exceed 5 mmHg. In this way the risk of negative pathophysiological effects of prolonged hypercarbia can be reduced (67).

Ideally, after closure of the fistula with non-absorbable sutures or by placing a clip, and identification and mobilisation of the upper and lower esophageal pouches, an end-to-end primary anastomosis should be accomplished using interrupted full-thickness sutures (67).

If the gap is too long to achieve primary anastomosis (more than 3 cm or greater than the height of 2 vertebral bodies), delayed primary anastomosis after traction or elongation techniques, or even esophageal replacement procedures should be attempted (71).

After feasibility of magnets for esophageal anastomosis has been proven in several animal models, magnamosis has been introduced as a new alternative method for esophageal atresia repair in human neonates.

Hendren first described the use of magnets for the treatment of long gap esophageal atresia in children in 1976 with the use of electromagnetic bougienage to approximate the esophageal ends and to allow easier delayed anastomosis (72).

In 2009, Zaritzky and co-workers reported the first case series of patients with EA who treated by magnetic compression anastomosis using rare-earth permanent magnets (73).

Up to now, 28 successful esophageal magnetic anastomoses cases were reported all over the world (Table 1).

Table 1: Reported esophageal magnamosis cases in the literature

Author, Date	Number of patients	Time to magnamosis (Days)	Stricture (No of patients)	Leak (No of patients)	Follow-up
Zaritzky. 2009	5	4,8	4	none	n.d.
Zaritzky, 2014	9	4,2	8	none	9,3 years
Lovvorn, 2014	2	7,5	2	none	n.d.
Dorman, 2016	1	13	1	none	15 months
Ellebaek, 2018	1	5	1	none	15 months
Slater, 2019	13	6,3	13	none	n.d.
Wolfe, 2020	1	5	1	none	11,4 months
Liu, 2020	1	36	0	1	18 months
Conforti, 2021	5	8	4	none	6 months
Muensterer, 2021	3	10,3	3	none	15,7 months
Muensterer, 2022	1	7	1	none	13 months
TOTAL	**28** (Repetitive cases excluded)		**26 (92,9%)**	**1 (0,04%)**	

In the published cases positioning of magnets into upper and lower esophageal pouches have been delivered endoscopically (through mouth and gastrostomy) under fluoroscopy guidance. All previously developed catheter-based magnetic anastomosis devices (Flourish^{TM} Pediatric Esophageal Atresia Device, Connect-EA Device) consist of two neodymium-iron-boron magnets but design, mating surface geometry and pull force of them were different.

Although recently reported procedures are really promising, they are not offering significant advantages in the most common type of EA with TEF as thoracoscopy or thoracotomy for the ligation of fistula and performing additional gastrostomy for placement of the distal pouch magnet are still required (73, 74).

Therefore, more recent studies propose magnamosis procedure for patients with EA only in selected cases: for patients without a TEF or for whom a TEF has been previously closed, for patients with a maximum gap between the upper and lower esophageal pouches of 4 cm or for patients with severe comorbidities (75, 76).

One limitation of esophageal magnamosis can be the high rate (over 90%) of postoperative anastomotic stricture. However, in the reported cases magnamosis have been mainly performed in patients with long gap and pure EA (without TEF) after failed primary repair or thoracoscopic esophageal lengthening procedures which are potential individual risk factors for anastomotic stricture probably due to the tension on the anastomosis (76, 77).

Anastomotic stricture after hand-sutured, conventional esophageal anastomosis is the most common complication, occurring in 32 to 59% of patients (78).

Furthermore, no anastomotic leakage has been actually reported. This may be the main advantage of magnamosis since it can lead to later anastomotic stricture. Incidence of anastomotic leakage after traditional esophageal atresia repair is 10-15% (79).

Esophageal anastomosis can be achieved after an average of 7 days, though there is a close connection between anastomosis time and the strength of the magnets (80).

Previous case studies have already demonstrated that magnetic compression anastomosis can be successfully used for the treatment of refractory strictures after EA repair (81, 82).

1.7 Surgical training and simulation models of esophageal atresia

A wide variety of esophageal atresia models have been created from cadaveric, animal, hybrid, synthetic and virtual reality, models. Some have been used for improving surgical skills or studying the validation of new methods and devices.

Although human cadaver models can provide a realistic simulation for esophageal atresia repair, they are rarely used due to ethical issues, the limited number of neonatal cadavers and the difficulty of handling them (83).

Animal models are extensively used for planning and performing new surgical techniques. Pig model is one of the most popular animal models for EA, it is appropriate for simulating thoracoscopic surgery in a neonate. Animal tissues and euthanized animals have been utilized for various experiments such as investigation of lengthening, tensile testing and alternative surgical methods (84, 85). They also provide an opportunity to conduct pilot studies prior to perform procedures in live animals (23).

Survival animal models can be used for monitoring of esophageal motility or anastomotic healing and allow for refining and optimizing novel surgical techniques. Overall, the average survival time is about 4 weeks for pigs with PEG tube placement and pigs usually weigh between 10 and 20 kg in most studies (86). Recently, long-term survival pig models have been developed to study long-term outcomes of esophageal anastomosis. In these models esophageal bypass loop and bifurcated esophagus have been created for oral nutrition (87, 88).

Hybrid models consist of real animal tissues such as surgically modified fetal bovine tissue are quite underused for surgical skills training because of its high cost and the risk of contamination (89).

Synthetic models have been mainly used for surgical training. The simplest types of synthetic EA models were made of water balloons and plastic tubes (90, 91).

For more realistic simulation, 3D-printed EA repair models with various types of TEF have been designed. They mimic the texture of anatomical structures of a neonate using a silicone EA/TEF model inserted in a rib cage with synthetic skin overlay (92). 3D-printed models with sensors allow also objective measurement of technical skill, force and motion. They help improve operative performance of trainees (93).

Virtual reality simulators are gaining increasing popularity; however, they are hardly available for trainees in low-income countries.

2 Objectives

2.1 New, easy, cheap training model for laparoscopic pyeloplasty – validity and comparison to existing models

The primary objective of this study was to establish the face validity of the balloon model. We utilized the subjective evaluations of trainees to demonstrate the usability and practical applicability of our balloon model in comparison to other pyeloplasty models.

2.2 Testing the pyelo-ureteral magnetic anastomosis device in domestic pig model

It has been demonstrated PUMA device makes pyelo-ureteral anastomosis significantly shorter and simpler in simulators. The procedure and the removal of the device was feasible in minipigs. Well-formed anastomosis was found 4 weeks after removal of the device, however no long-term observations performed.

Our aim was to reproduce the results in domestic pig model with extended postoperative observation time to achieve long-term results.

2.3 New training model and magnetic device for minimal invasive repair of esophageal atresia

Our aim was to develop the concept of a new magnetic device for thoracoscopic repair of esophageal atresia based on the PUMA device and test it’s feasibility and compare with hand sutured anastomosis in different models of esophageal atresia.

3 Methods

3.1 Methods of comparison of laparoscopic pyeloplasty training models study

3.1.1 Balloon model (BM)

The balloon model proposed by our team was made from commercially available spherical and sausage shape birthday balloon. The spherical balloon (40 mm diameter) represents the dilated renal pelvis while the sausage balloon with diameter of 5 mm represents the proximal ureter. The spherical balloon was cut and sutured to a kidney shaped sponge and was glued to a piece of cardboard (Figure 3).

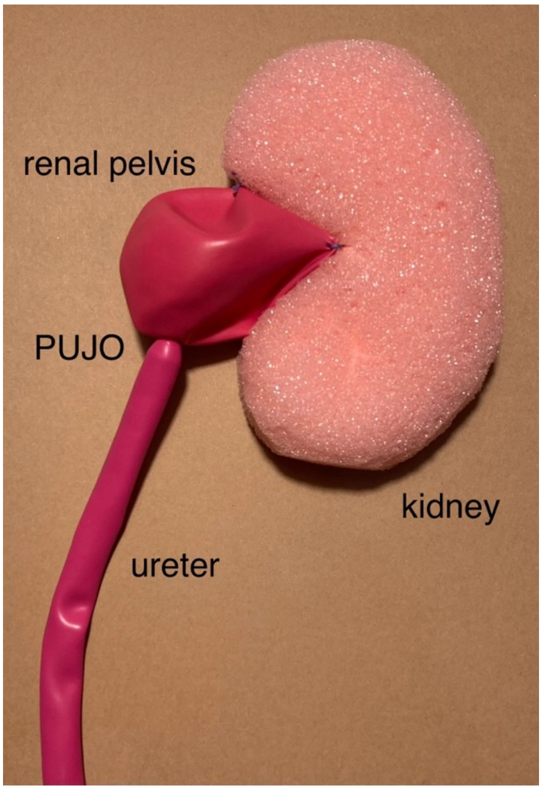

Figure 3: Balloon model

(Source: Hornok Z et al. J Pediatr Urol. 2023;19(4):471-473.)

3.1.2 Finger glove model (FGM)

This model was published by Raza et al. (63). It is made from a latex glove. Palm of the glove (80 mm in diameter) represented the dilated renal pelvis, finger of the glove (20 mm in diameter) represented the proximal ureter and a knot on it was considered as pyelo-ureteral junction obstruction (Figure 4).

Figure 4: Finger glove model

(Reproduced after Raza et al., source: Hornok Z et al. J Pediatr Urol. 2023;19(4):471-473.)

3.1.3 Chicken thigh model (ChTM)

This model was published by Ooi et al. (56). It is made from reconfigured and sutured skin of a chicken thigh represented dilated renal pelvis (40 mm in diameter) and ureter (8 mm in diameter) (Figure 5).

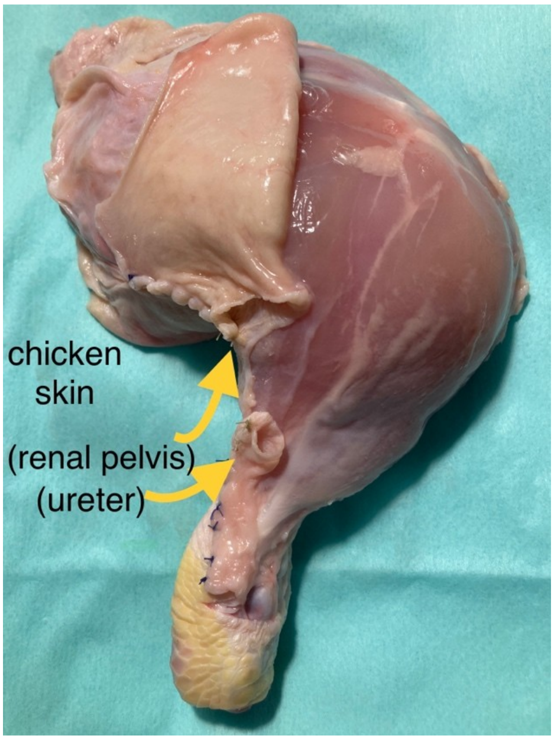

Figure 5: Chicken thigh model

(Reproduced after Ooi et al., source: Hornok Z et al. J Pediatr Urol. 2023;19(4):471-473.)

3.1.4 Chicken crop model (ChCrM)

Jhala et al. reported this model (94). It is made from chicken crop stitched to pig kidney. Crop filled with water simulated the dilated renal pelvis (50 mm in diameter) and chicken esophagus represented the proximal ureter (5 mm in diameter) (Figure 6).

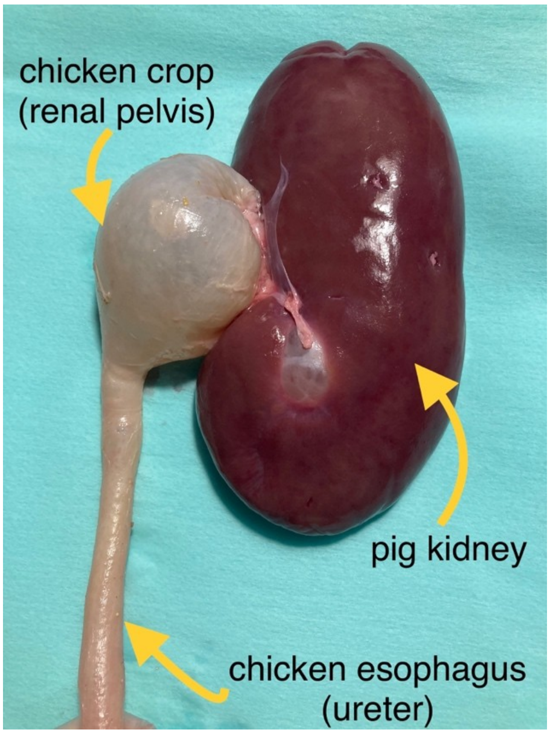

Figure 6: Chicken crop model

(Reproduced after Jhala et al., source: Hornok Z et al. J Pediatr Urol. 2023;19(4):471-473.)

3.1.5 Experimental design

Twenty-two (n=22) trainees attending their mandatory laparoscopic skill training course were recruited in the study. They worked in various surgical specialities, including general surgery (n=10), pediatric surgery (n=4), gynecology (n=4), urology (n=3) and neurosurgery (n=1). All of them had fewer than 6 years operative experience, the mean time was 2.5 years. Most of them (72.73%) had minimal previous laparoscopic experience, while the others had no laparoscopic experience at all (Table 2).

Table 2: Demographic data of trainees

(Source: Hornok Z et al. J Pediatr Urol. 2023;19(4):471-473.)

Surgical specialities	**Number of trainees (%)**
general surgery	10 (45%)
pediatric surgery	4 (18%)
gynecology	4 (18%)
urology	3 (14%)
neurosurgery	1 (5%)
Operative experience	
1 year	1 (5%)
2 years	14 (64%)
3 years	5 (23%)
4 years	0
5 years	1 (5%)
6 years	1 (5%)
Laparoscopic experience	
yes	16 (73%)
no	6 (27%)

None of the trainees were able to carry out the whole pyeloplasty procedure, so they were asked to test the models with performing some intracorporeal knots and continuous suture on each model laparoscopically. Models were placed into a pelvitrainer with a 10-mm, 30 degree laparoscope, three 5-mm instruments (two needle holders and a scissor) and 5/0 Vicryl suture were used (Fig. 7).

The study was conducted after the approval of the ethical committee and obtaining written informed consent of participants.

3.1.6 Assessment of face validity of the models

After receiving a short explanation of the models, participants completed a 7 items Likert-based, non-validated questionnaire about their experience with the models. The 5-point Likert scale is a type of psychometric response scale in which participants specify their level of agreement to a statement in five points: (1) very poor; (2) poor; (3) fair; (4)

good; (5) excellent. The models were assessed based on design, realism, similarity in size, tactile sensation, suturability, usability, and handling.

Then a yes/no question ("Which models would you like to use before a real case?") was asked of them.

Figure 7: Resident doctor is working on chicken thigh model placed in box trainers

3.1.7 Statistical analysis

A one-way Analysis of Variance (ANOVA) calculator was used to compare the models. Data are presented as the mean ± standard error of the mean (SEM).

3.2 Methods for testing the pyelo-utereric magnetic anastomosis device in domestic pig model

The experiment was conducted in 5 female domestic pigs (35 kg) in accordance with the National Institutes of Health guidelines and EU directive 2010/63 for the protection of animals used for scientific purposes and was approved by the National Scientific Ethical Committee (PE/EA/787-7/2019) (95).

The transperitoneal laparoscopic procedure was performed in the left lateral recumbency position. After identifying the unilateral ureter, a rubber vessel string was placed around the ureter and clipped with a titanium clip, ensuring it was not overly tight to avoid complete obstruction, while allowing sufficient expansion of the pyelon for the subsequent laparoscopic pyeloplasty performed 4 and 8 weeks later. The device was then removed 4 weeks after the procedure during cystoscopy or direct vesicostomy. Eight weeks later, the pigs were terminally sacrificed, and the anastomoses were subsequently examined (95).

In the experiment, N35 neodymium nickel coated magnetic cylinders measuring 4 mm outer diameter, 2 mm inner diameter and 8 mm length were used. The magnet inserted into the ureter was fixed to a JJ stent, while the magnet placed into the pelvis was attached to the tip of a Malecot catheter. The JJ stent and the Malecot catheter were secured to the ureter and pelvis using needles attached to their ends, after which the pelvic closure was performed using a V-lock (95).

3.3 Methods of the EMAD application

3.3.1 The concept of the device

The Esophageal Magnetic Anastomosis Device (EMAD) was built with two N35 neodymium magnetic rings (Euromagnet Hungary Kft.). These magnets are made from an alloy of neodymium, iron and boron and are plated with a triple layer of nickel-copper-nickel for protection against corrosion. They have an outer diameter of 4 mm, an inner diameter of 2 mm and a height of 8 mm with a strong pull force of 846 grams (8,3 N).

The first magnet ("lower pouch magnet") was fixed to a 6 Fr soft feeding tube and a special, 3/8 circle, custom-made needle (MEDITŰ Kft., Makó, Hungary). The second magnet is "free" in order to be administered orally into the upper pouch (Figure 8).

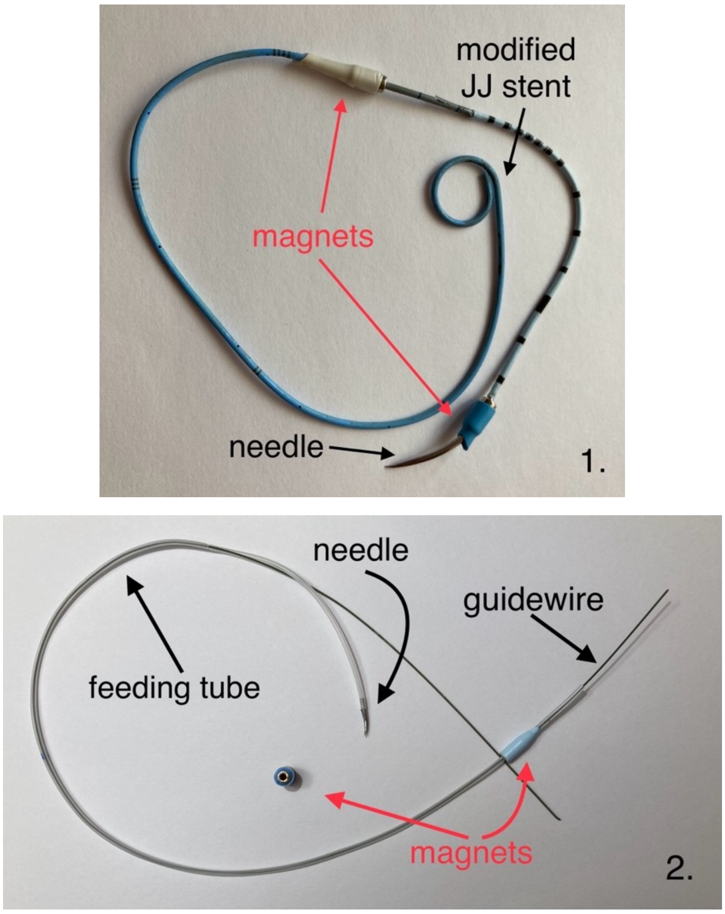

Figure 8: The design of the Esophageal Magnetic Anastomosis Device (2.) is based on the Pyelo-Ureteral Magnetic Anastomosis Device (1.)

3.3.2 Synthetic model

The synthetic model of EA/TEF was made up of spherical and tubular shaped birthday balloons. Trachea, azygos vein and vagus nerve made of plastic tubes represent the real anatomical structure (Figure 9).

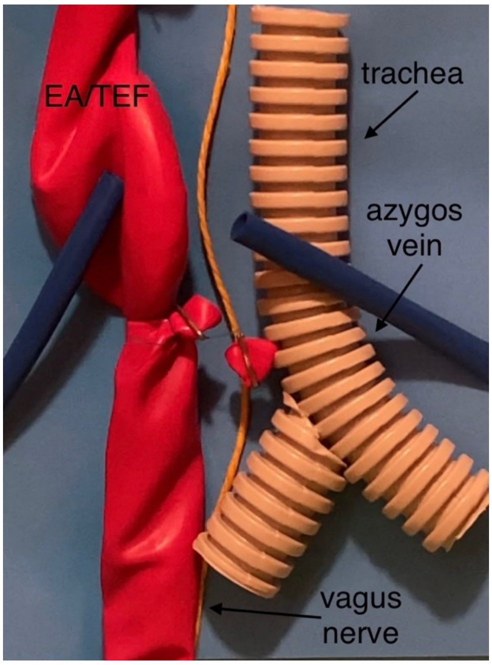

Figure 9: The synthetic EA/TEF model

(Source: Hornok Z et al. J Pediatr Surg. 2022:S0022-3468(22)00631-5.)

It was fixed in a term infant sized baby doll purchased on-line. The doll was cut in half in the sagittal plane to mimic the working space of the neonatal chest. It was arranged in the left hemidecubitus position to simulate the real surgical position. A 5-mm port was inserted in the fifth intercostal space at the lower edge of the scapula for a USB camera that was connected to a personal computer. A 3-mm port was inserted into the right thoracic cavity in the third intercostal space of the midaxillary line and a 5-mm port was inserted in the fifth intercostal space of the dorsal area for instruments (Figure 10).

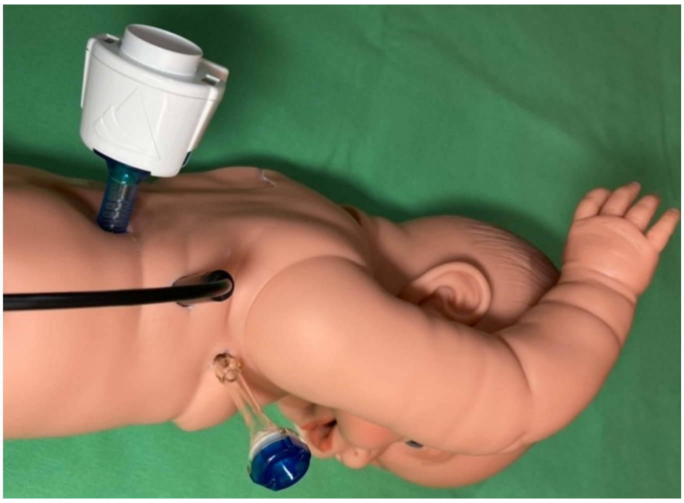

Figure 10: The baby doll simulator with two ports and a USB camera
(Source: Hornok Z et al. J Pediatr Surg. 2022:S0022-3468(22)00631-5.)

3.3.3 Assessment of anastomotic construction time

Ten (n=10) medical students with no previous laparoscopic surgery experience were asked to perform esophageal anastomoses with the EMAD in the synthetic model. Prior to the procedure all participants viewed a short instructional video.

Ten (n=10) general surgical trainees attending on their mandatory laparoscopic skill training were asked to perform conventional laparoscopic single layer hand sutured end-to-end anastomosis with 6 knots in the synthetic model. All the trainees demonstrated competency performing the designated task.

Time was measured from the moment the instruments touched until removal of all instruments. The operating time (t) with the EMAD was recorded and compared to the classic anastomosis (Figure 11).

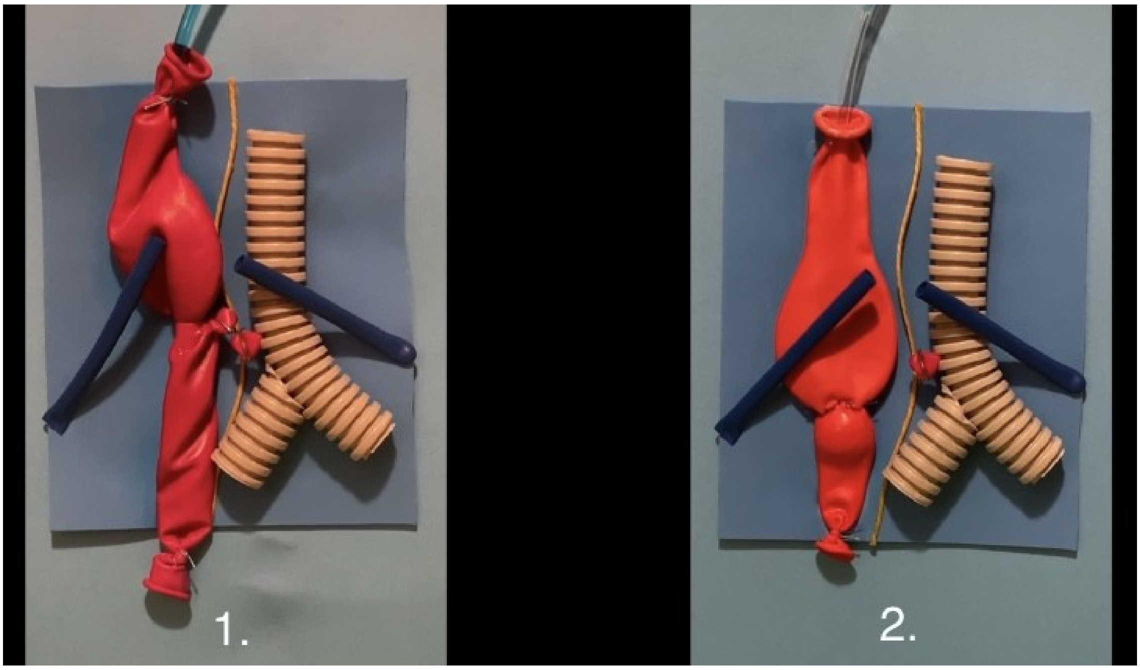

Figure 11: Magnamosis (1.) and hand sutured anastomosis (2.) in the synthetic models

3.3.4 Tissue samples

Rabbit esophagus is similar in size to the human neonatal esophagus. Esophagi were taken from fifty, on-farm sacrificed, adult New Zealand white rabbits (weighing 2,5 to 3 kg) of both sexes. Length of resected esophagi was equal (10 cm).

Esophagi were transected transversely and were randomly divided into two groups. End-to-side magnamosis (MA) in group A (n=25) and end-to-end, hand-sutured, conventional anastomosis (CA) with single layer interrupted suture in group B (n=25) were performed (Figure 12). For the interrupted suture anastomosis, two corner sutures were followed by two sutures each in the anterior and posterior esophageal wall using USP 4-0 polydioxanone sutures. All anastomoses were performed by the same surgeon.

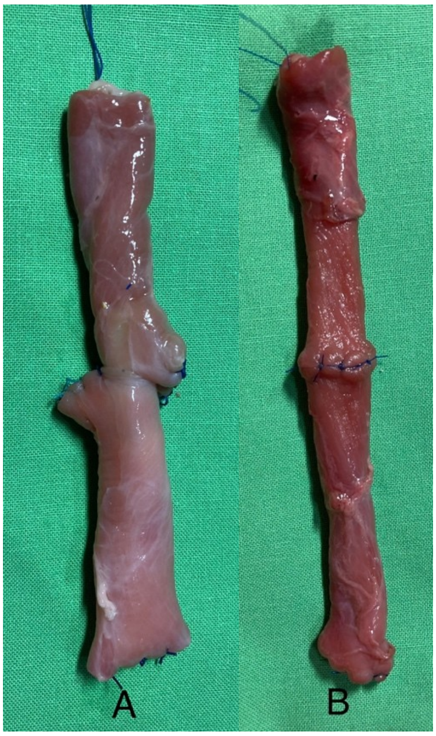

Figure 12: Magnamosis (Group A) and hand sutured anastomosis (Group B) in the ex vivo rabbit esophagi

3.3.5 Assessment of bursting pressure

Bursting pressure was measured in both groups according to the principle of communicating vessels. A clamp was placed on the distal end of the esophagus while through the proximal end it was being filled with methylene blue stained water at a steady rate by elevating infusion bag (Figure 13).

At that point of the hydrostatic pressure where the anastomosis started to leak used to determine the bursting pressure of the anastomosis.

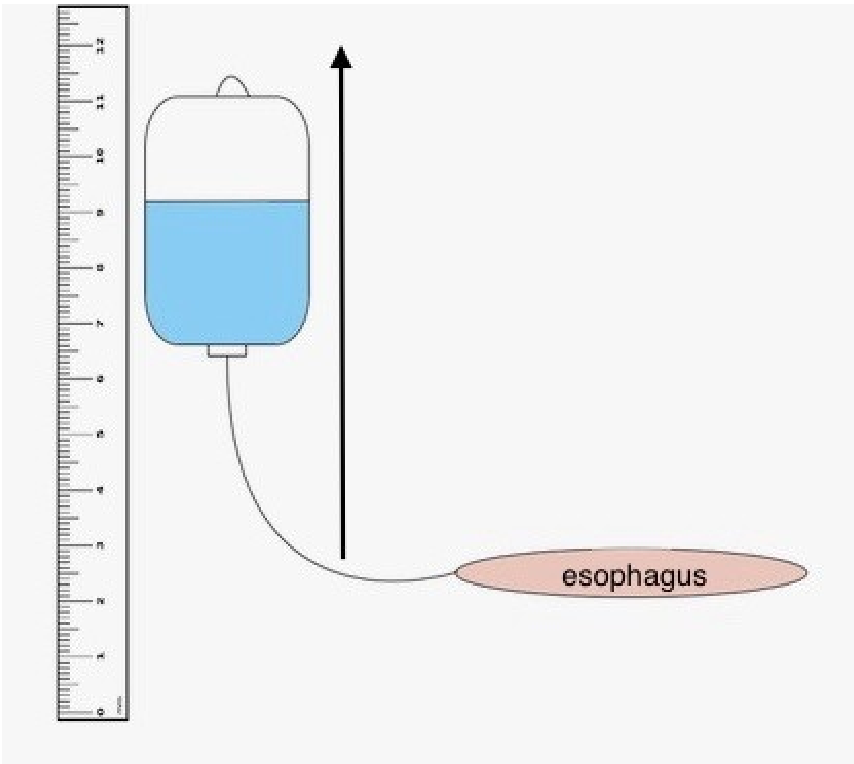

Figure 13: Illustration of bursting pressure measurement by elevating an infusion bag according to the principle of communicating vessels

3.3.6 Assessment of tensile strength

Tensile strength was measured also in these two groups. One end of the resected specimen was mounted on a table, and the other end was attached by traction sutures to a dynamometer. The ends were stretched at a constant speed (Figure 14).

At that point of the pulling force where the ends of the anastomosis started to come apart used to determine the tensile strength of the anastomosis.

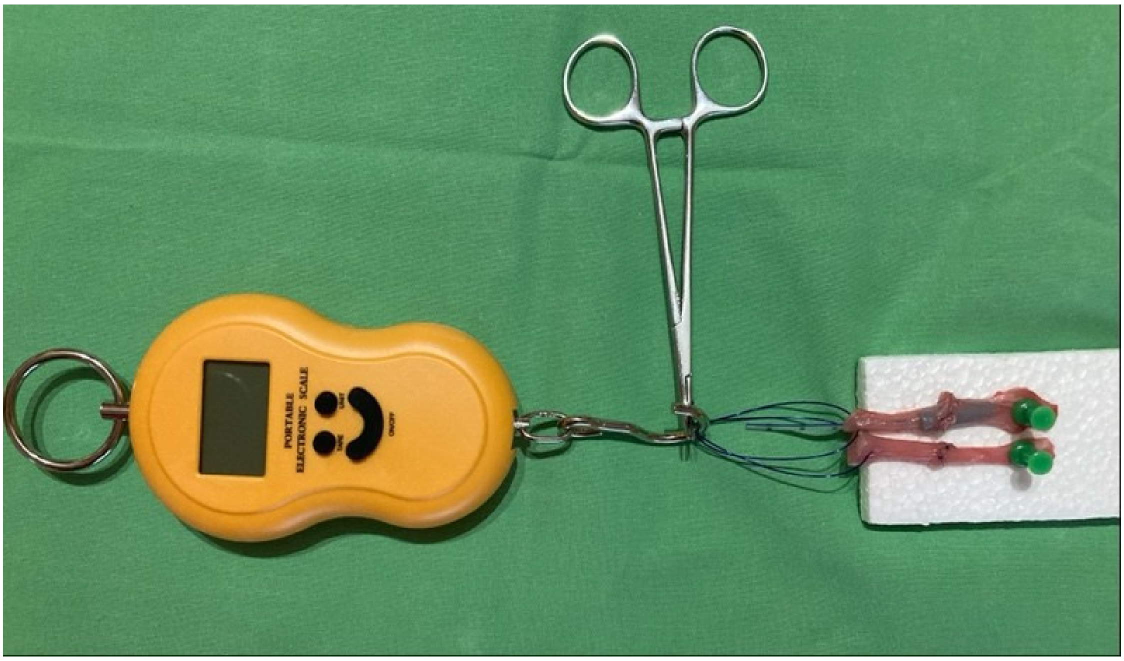

Figure 14: Comparison of tensile strength of classic and magnetic anastomosis on rabbit esophagi by a dynamometer

3.3.7 Euthanized pig model

Five pigs, weighing between 3-4 kg, aged 1 week, obtained from Research Institute for Animal Breeding, Nutrition and Meat Science, Herceghalom were used to establish the procedure.

Pigs were housed under controlled conditions, including a 12 h light-dark cycle and a temperature of 25±2 °C, with free access to breast milk and water. They were kept together in a separate box, equipped with appropriate enrichments.

Pigs were initially sedated with 2 ml ketamine hydrochloride (Calypsol®) in combination with 1 ml xylazine (CP-Xilazin®) intramuscular injection. Thereafter euthanasia was conducted with 2 ml pentobarbital (Euthoxin®) injection infused through the marginal ear vein.

The study was conducted in accordance with the Hungarian Act on Animal Protection 1998/XXVIII and the EU directive 2010/63 for the protection of animals used for scientific purposes. The study was approved by the Animal Experimentation Scientific Ethics Committee (License number: PE/EA/787-7/2019).

3.3.8 Description of the procedure

The instruments needed for the procedure demonstrated in Figure 15.

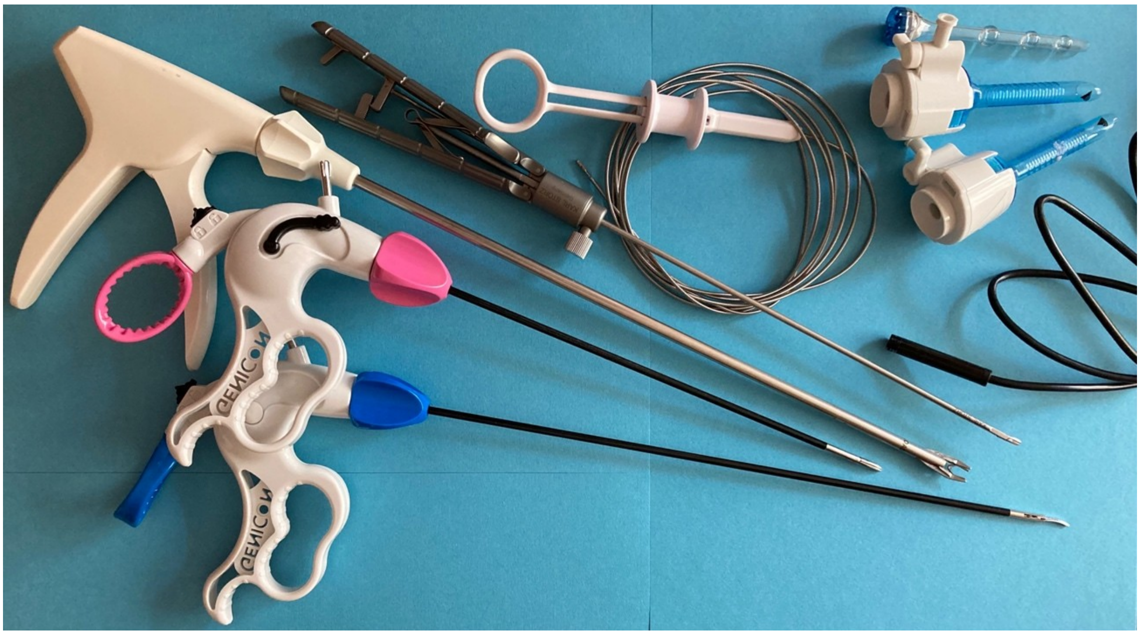

Figure 15: Setup consisted of a curved 3-mm laparoscopic needle holder, a 3-mm laparoscopic forceps, a semi-flexible endoscopic forceps, a 3-mm laparoscopic scissor, 5 and 3 mm trocars and an endoscopic camera with light source *(created by the author)*

The piglets were placed in left recumbency position. Recommend port placement has been adopted based on previous studies (96).

A 5 mm optical visiport trocar was placed under video control at the tip of the scapula. Another 5 mm port was placed in the 4th intercostal space close to the spine and another 3 mm port at the anterior axillary line (Figure 16). 10 Hgmm CO_2 insufflation was used. It is possible to insert another 3 mm port if necessary.

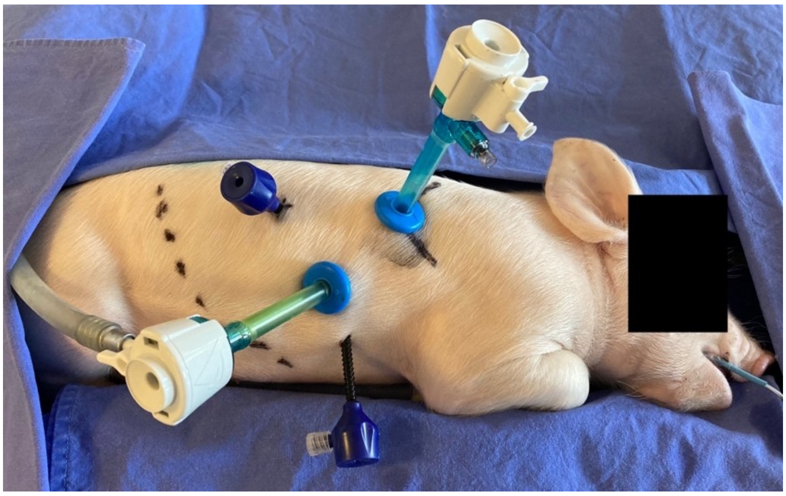

Figure 16: Port sites and position in the euthanized pig model

The azygos vein, the trachea, the esophagus were identified, the parietal pleura was opened. The esophagus mobilized and dissected. The upper pouch ligated with either an endoloop or a 5 mm clip. The first magnet of the EMAD was inserted through the 5 mm port and directed into the lower pouch. The needle of the device was pulled into the chest and stitched in an inside-outside fashion into the lower pouch. The needle was cut and removed. The lower pouch of the esophagus was closed with a clip. A semi-flexible endocopic forceps was introduced into the upper pouch from the mouth and was pushed through the wall of the upper pouch, the end of the stent was grasped and pulled out through the mouth. The 2nd magnet was then introduced and pushed down on the stent into the upper pouch while the stent was pulled cephalad direction until the 2 pouches with the magnets met head on.

3.3.9 Statistical analysis

Two-tailed Student's *t*-test was used for comparison of the results. P-values below 0.05 were considered statistically significant. Data are presented as the mean ± standard error of the mean (SEM).

4 Results

4.1 Results of the comparison of laparoscopic pyeloplasty training models study

4.1.1 Evaluation of the questionnaire

BM received mean score of 4,41±0,59 for design, 4,00±0,76 for realism, 4,23±0,75 for similarity in size, 3,14±0,83 for tactile sensation, 3,45±0,96 for suturability, 4,64±0,49 for handling and 4,09±0,87 for usability.

However, ChCrM was found to be significantly better compared it with the three other models in almost every characteristic, BM seemed to be significantly superior to FGM and ChTM in design, realism and similarity in size (p=0,00001).

86,36% (19/22) of trainees were equally satisfied with BM and ChCrM and would use both to practice before performing the procedure in real patients.

FGM was poorly rated in every characteristic respectively, but regarding handling, all trainees considered it excellent. The differences were statistically significant (p=0,00001) (Table 3).

BM received mean score of 4.41 ± 0.59 for design, 4.00 ± 0.76 for realism, 4.23 ± 0.75 for similarity in size, 3.14 ± 0.83 for tactile sensation, 3.45 ± 0.96 for suturability, 4.64 ± 0.49 for handling and 4.09 ± 0.87 for usability.

Based on a yes/no question ("Which models would you like to use before a real case?") 86.36% (19/22) of trainees were equally satisfied with ChCrM and BM and would use both to practice before performing the procedure in real patients.

Table 3: Trainees subjective scores on the models, based on a 5-point Likert scale

(Source: Hornok Z et al. J Pediatr Urol. 2023;19(4):471-473.)

	BM	**FGM**	**ChTM**	**ChCrM**
design	4.41 ± *0.59*	2.59 ± *1.05*	3.82 ± *0.91*	4.82 ± *0.50*
realism	4.00 ± *0.76*	2.14 ± *0.99*	3.45 ± *1.06*	4.77 ± *0.43*
size	4.23 ± *0.75*	3.00 ± *0.69*	3.86 ± *0.56*	4.45 ± *0.74*
tactile sensitivity	3.14 ± *0.83*	2.32 ± *0.72*	3.86 ± *0.64*	4.64 ± *0.49*
handling	4.64 ± *0.49*	5.00 ± *0*	2.09 ± *0.61*	1.50 ± *0.51*
suturability	3.45 ± *0.96*	2.95 ± *0.95*	3.91 ± *0.68*	4.23 ± *0.61*
usefulness	4.09 ± *0.87*	3.14 ± *0.89*	4.09 ± *0.75*	4.73 ± *0.46*
MEAN SCORE	**3.99 ± *0.53***	**3.02 ± *0.95***	**3.58 ± *0.69***	**4.16 ± *1.19***

4.1.2 Face validity mean scores of the models

On a 5-point Likert-scale, face validity mean score of the FGM was 3.02 ± 0.95, the ChTM scored 3.99 ± 0.53, the BM reached 3.58 ± 0.69 and the ChCrM scored 4.16 ± 1.19. The differences between face validity mean scores were statistically significant (p=0.00001) (Fig. 17).

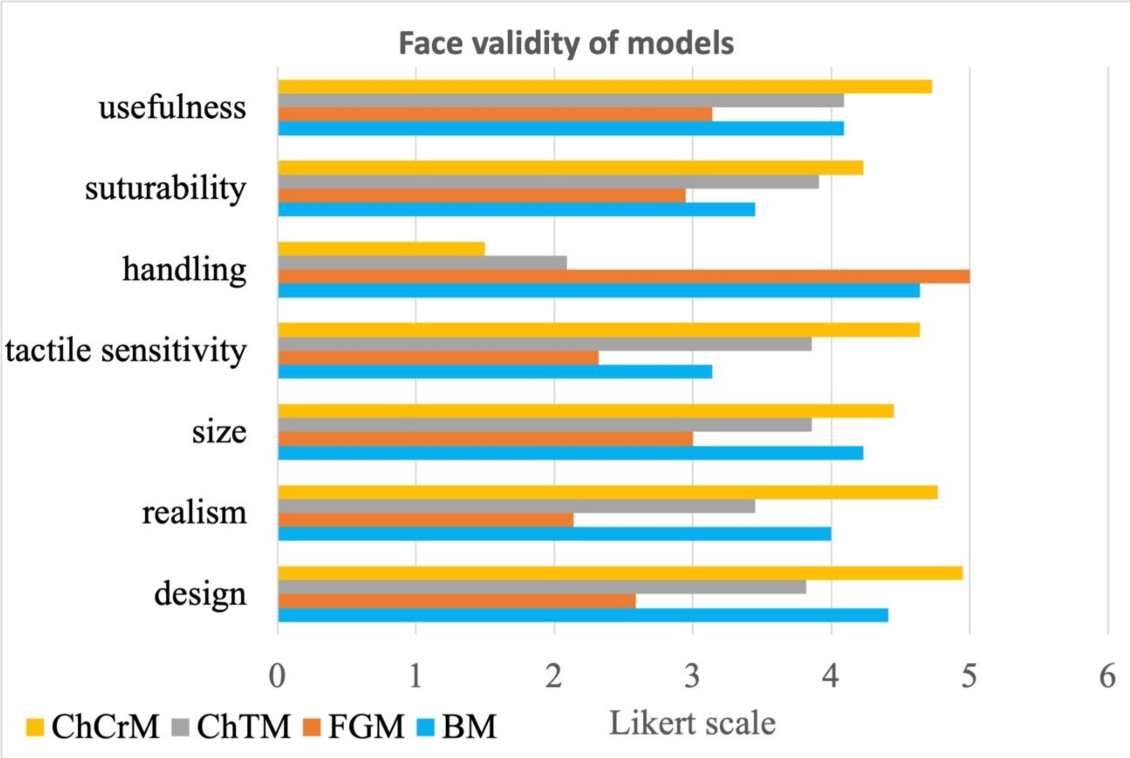

Figure 17: Analysis of face validity of models

(Source: Hornok Z et al. J Pediatr Urol. 2023;19(4):471-473.)

4.2 Results of the PUMAd study

Pig Nr 1 died shortly after the ureter ligation, though the cause of death remained unknown (95).

Due to the small caliber of the distal ureters, it was not possible to insert the PUMA device in pig Nr 2 (49 kg). As a result, pig Nr 2 was terminally sacrificed at the end of the second surgery (95).

In pig Nr 3 (49 kg), the device could only be inserted after the removal of the plastic coating around the magnet placed in the ureter. Four weeks later, X-rays revealed that the two magnets had moved further apart from each other, and consequently, the animal was terminally sacrificed. Hydronephrosis and inflammation were observed; however, the anastomosis was successfully formed and exhibited a good caliber (95).

The PUMA device was easily inserted into the distal ureters of pig Nr 4 (96 kg) and pig Nr 5 (68 kg) eight weeks after the initial surgery. However, pig Nr 4 died following the second surgery due to malignant hyperthermia. No autopsy was performed (95).

The device was removed from pig Nr 5 four weeks later, and an antegrade contrast study performed eight weeks thereafter showed a patent anastomosis. At this point, the animal was terminally sacrificed, and an autopsy was conducted. No stenosis of the anastomosis was observed (95).

4.3 Results of the EMAD study

4.3.1 Anastomotic construction time

The construction time of magnamosis (tMA) (n=10) was significantly shorter (4,6±2,06 min and 11,14±2,78 min) compared with tCA (n=10) (30,8±4,29 min), p<0,001.

Performing magnamosis with the EMAD took medical students significantly longer than experienced surgical trainees (11,14±2,78 min vs. 4,63±2,06 min, p<0.001).

Medical students were unable to complete CA at all (Fig. 18).

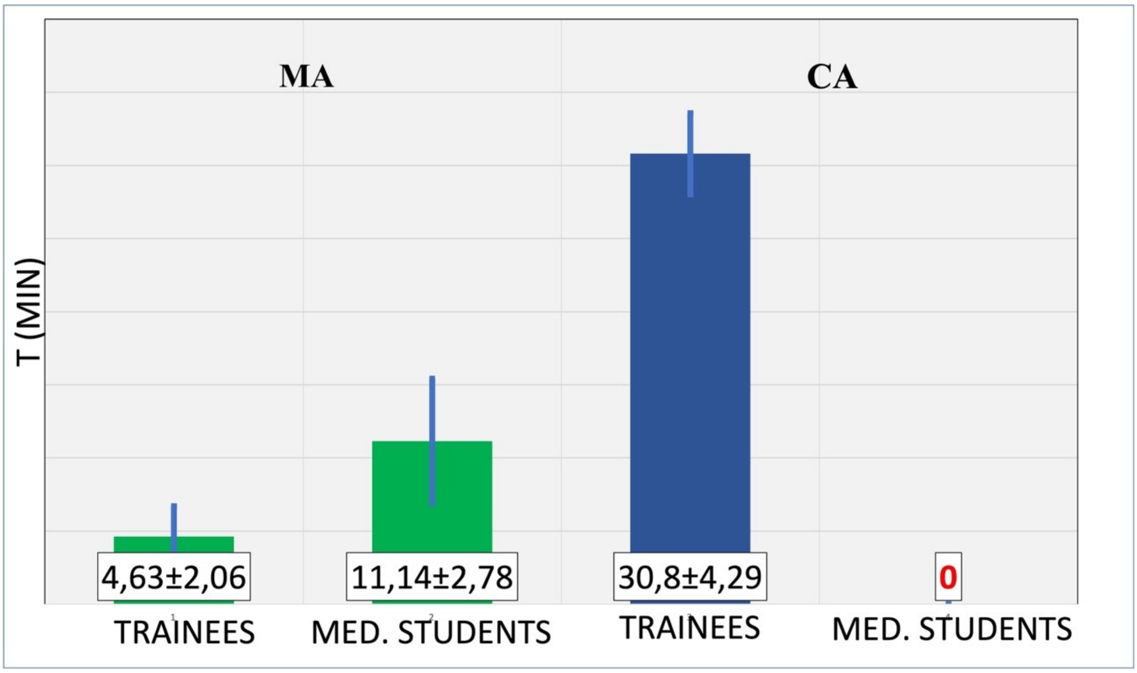

Figure 18: Comparison of construction time for magnamosis (MA) and conventional anastomosis (CA) performed by medical students and surgical trainees in the synthetic model *(Source: Hornok Z et al. J Pediatr Surg. 2022:S0022-3468(22)00631-5.)*

4.3.2 Bursting pressure

Mean bursting pressure of the MA (n=25) was significantly higher (90 cmH_2O<) compared with the CA (n=25) (14,08±3,32 cmH_2O), p<0,001. Bursting pressure was above 90 cmH_2O in all cases of magnamosis (Fig. 19).

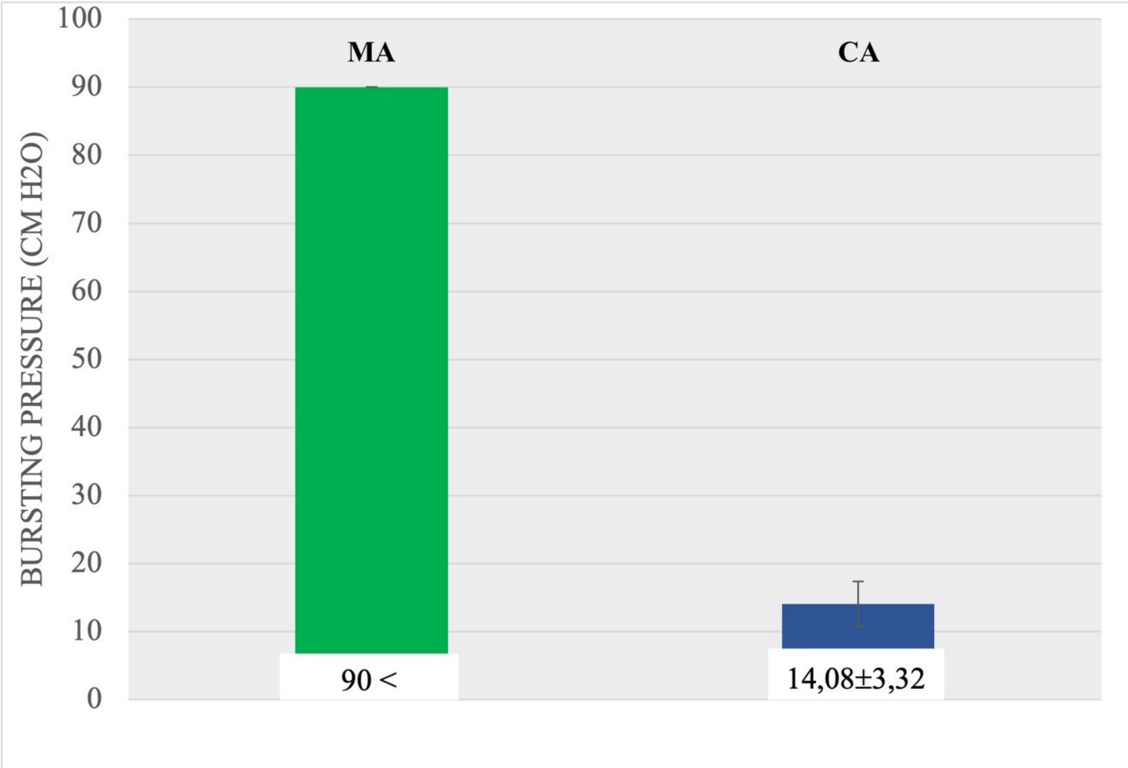

Figure 19: Comparison of bursting pressure of magnamosis (MA) and conventional anastomosis (CA) in rabbit esophagi *(Source: Hornok Z et al. J Pediatr Surg. 2022:S0022-3468(22)00631-5.)*

4.3.3 Tensile strength

Mean tensile strength of the MA (n=25) (1,83±0,29 N) was significantly lower than the CA (n=25) (3,55±0,43 N), $p<0,0001$ (Fig. 20).

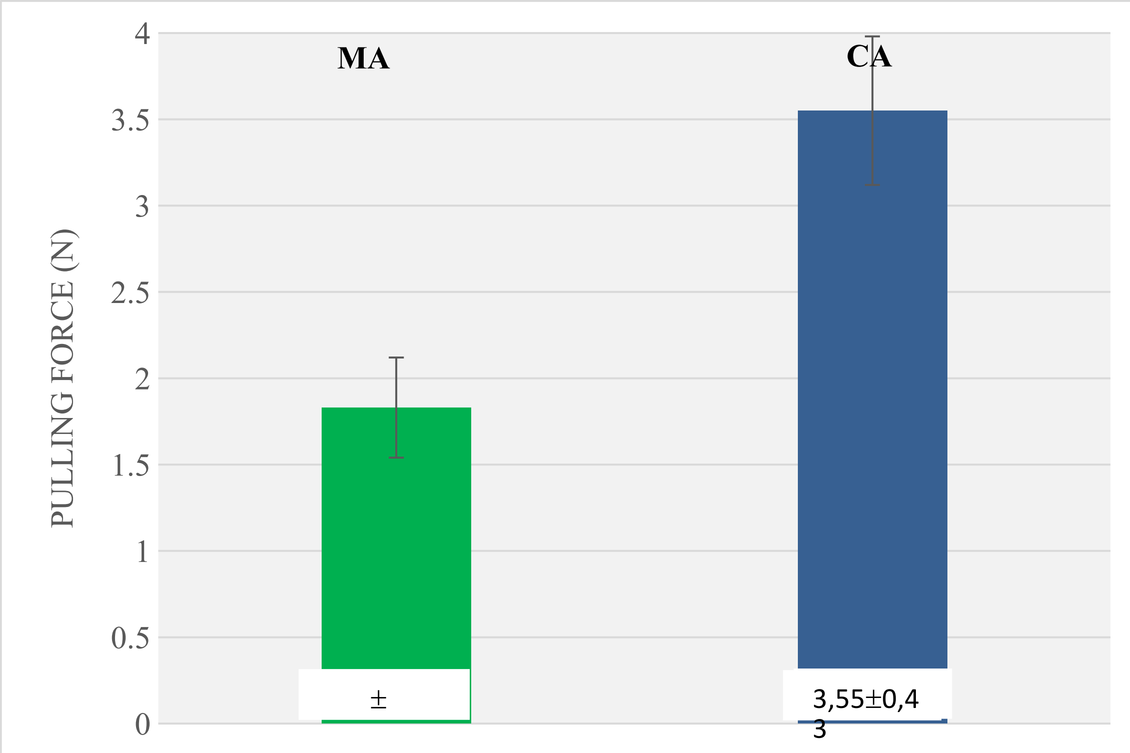

Figure 20: Comparison of tensile strength of magnamosis (MA) and conventional anastomosis (CA) in rabbit esophagi *(Source: Hornok Z et al. J Pediatr Surg. 2022:S0022-3468(22)00631-5.)*

4.3.4 Feasibility of EMAD in euthanized pigs

The procedure was feasible in five euthanized pigs. No handheld suturing of anastomosis was necessary.

5 Discussion

5.1 Laparoscopic pyeloplasty training models study

It was not unexpected both of the animal tissue models scored better mean values than the plastic models and the candidates felt they could replicate human hydronephrosis well.

It was surprising the simplest FGM, which was poorly rated in every characteristic respectively, but regarding handling, all trainees considered it excellent.

The BM was found to be significantly superior to FGM and ChTM in design, realism and similarity in size (p=0.00001), however it seemed better only than FGM in terms of tactile sensitivity (p=0.0011). In handling and suturability BM just hardly lagged behind FGM and ChTM however the differences were not statistically significant. BM received generally high values, it scored below 4 only in tactile sensitivity and suturability.

Both synthetic, homemade model can be easily built with few, very low-cost materials (negligible compared to the 3D-printed kidney model, which is available for 70 GBP) and can be find in general stores. The costs of chicken thigh and pig kidney are low too and easily available, however the chicken crop is just by-products of meat industry, and one can only get it from slaughterhouse.

Our new synthetic model has proven validity as a cost-effective, clean, cheap, hygienic and easy access alternative to other laparoscopic pyeloplasty models, and it seems to be suitable for teaching, training and workshops. It can be an appropriate tool for practice of intracorporeal suturing and hand-eye coordination which are prerequisite for successful laparoscopic pyeloplasty.

At the end of the study, every trainee stated that they would be willing to use the BM for practice before a real surgery.

The fact that of trainees were equally satisfied with ChCrM and BM that almost all trainees said they would you like to use the BM before a real case indicates the *BM* can be considered as useful high-fidelity, easy access, cheap, hygienic, domestic use training tool for laparoscopic pyeloplasty.

5.2 PUMAd study

Cserni et al. previously demonstrated the concept of the PUMA device in laparoscopic pyeloplasty in six Vietnamese minipigs. The longest follow-up period after the removal of the PUMA device was four weeks. In all six cases, the anastomosis was successfully completed and remained patent (52). In the most recent study, the follow-up period was doubled again, lasting 8 weeks (95). In the case of pig Nr 3, the removal of the plastic coating caused asymmetry in the magnet pair, which may explain the separation of the magnets.

5.3 EMAD study

We built a fully synthetic, simple and low-cost EA/TEF model using the same birthday balloons we used for the pyeloplasty balloon model. The size of the balloon (with diameter 15 mm) is closer to the esophagus than the ureter. To limit the working space for the EA-TEF repair we placed the balloons into a realistic newborn sized baby doll.

Using PUMA or EMA required no previous laparoscopic skills only a few minutes video tutorial and some verbal advice. Medical students were able to perform the manoeuvre, while they were not able to perform laparoscopic suturing and knot tying without basic training. Anastomosis construction time was significantly shorter with the magnetic device because it eliminated the need of hand-held suturing and intracorporeal knot tying. To complete EMA they required one third of the time their more experienced counterparts with the laparoscopic suturing. This is clear evidence the EMA simplifies and shortens the procedure and cuts learning curve.

Rabbit esophagus has been widely used for practice and training of thoracoscopic EA repair and study anastomotic failure on esophagus (97). The size of the adult rabbit esophagus is comparable to that of a human newborn (on average 5 mm in diameter and 8-10 cm in length) and was easy to access from slaughterhouse (98, 99).

Rabbit esophagi were used to evaluate bursting pressure. Anastomotic leak was not observed in any of the magnamosis until 90 cmH_2O pressure, so bursting pressure of the magnamosis was significantly higher compared to conventional anastomosis. The anastomotic leak point of the hand sutured anastomosis was much closer to the physiological intraluminal pressure (around 18 cmH_2O) reported in neonates than that of the MA (100). This suggests the MA provides better seal and may explain why less anastomotic leak seen after MA in clinical studies (37, 46, 72).

MA is probably eliminating human error with suturing too.

Tension between the two ends of the anastomosis is a significant problem in EA-TEF repair. Anastomosis under significant tension is one of the most common reasons of anastomotic leak.

It remains very difficult to assess how much tension the anastomosis can bear and there is no tool available except the surgeons experience. In one study the estimated safe tension should not exceed 0.75 N (is equals to 76,48 gram-force) (84).

The anastomosis performed with EMAD results in end-to-side anastomosis. Previous studies described end-to-side repair of esophageal atresia with ligation of the fistula as a possible alternative method to end-to-end anastomosis and anastomotic leakage is not higher in neonates who underwent end-to-side anastomosis compared to end-to-end (101, 103).

Use of endoclips for TEF closure makes the procedure faster and more effective. However, there are no reported long-term complications with this method (103).

6 Conclusions

Anastomotic leakage rate remains an important cause of postoperative morbidity and mortality after esophageal atresia repair with or without fistula, with poor suturing techniques and anastomotic tension being the main pathophysiological factors (104).

Performing minimally invasive procedures in neonates, partially due to the limited working space demands mastery of complex skills with a steep learning curve (2). The most challenging part of these procedures is intracorporeal suturing and knot-tying (51).

Since case volume of various rare and complex reconstructive operations such as surgical management of EA and PUJO is low, opportunities for trainees to gain sufficient practical experience are limited. Therefore, simulation models play an important role in surgical training, especially in minimally invasive surgery but only several validated specific pediatric surgical training models are available so far (20).

However, the above-mentioned complex procedures require advanced minimally invasive surgical skills, before operating on a real patient, the most crucial step should be achieving the necessary basic endoscopic suturing skills on simulators.

This is supported by the observation that there is an increased risk of complications after laparoscopic pyeloplasty during the learning curve (Parsons et al. 2004) (105).

Frede et al. (2000) found that regular practice on low-fidelity surgical training models can reduce surgery time by 50% and knot-tying time by 75% (106).

Fu et al. (2007) found that improper surgical technic and lack of essential laparoscopic skills correlate with anastomotic failure. Incidence of postoperative complication rate can be reduced by development of surgical skills. It has been demonstrated that the quality of an anastomosis is primarily determined by the quality of the first knot and the appropriate distance between sutures (54).

Scott et al. (2000) demonstrated that regular practice on simple, synthetic training models can clearly improve operative performance (107).

Katz et al. (2003) asked trainees to perform laparoscopic tasks on a chicken leg model and studied the importance of continuous training. They found that continuous practice significantly improved the surgical performance of trainees who had no prior experience with laparoscopic procedures. After a short period of time, they were able to perform urethrovesical anastomosis as well (108).

Low-cost, inanimate, simple models are suitable for trainees to improve their eye-hand coordination, depth perception in 2D space and gain proficiency in manipulation of the instruments. These low-fidelity, easily reproducible models can be used by trainees at home or in the hospital outside the operating room, without the assistance of an expert.

Barsness et al. (2015) has previously determined that it is not necessarily required to use real tissue to acquire basic laparoscopic suturing and knot-tying skills; a low-cost, synthetic model is sufficient for this purpose (109).

After acquiring sufficient laparoscopic suturing and knot-tying skills on low-fidelity models, trainees can focus on practising more precise movements. More realistic high-fidelity animal tissue, euthanized and anaesthetized animal models or simulators with advanced technology can be used to reproduce the entire operative procedures. However, high-fidelity models are not necessarily superior to low-fidelity models (24).

Models made from ex vivo animal tissues require special handling and storage to prevent the spread of germs. They are not reusable and portable but behave similarly to living human tissues. In certain countries, use of human cadavers and live animals for surgical training is not permitted due to ethical considerations. The high cost of 3D printed models, virtual reality, augmented reality simulators limit their usage in low- and middle-income countries.

Since pyeloplasty is the most common pediatric urological complex procedure, we reviewed the pyeloplasty models published in the literature so far and selected one synthetic and two animal tissue models of them. We compared the face validity of these models to that of the balloon model, which was previously used for planning the preliminary experiments using the PUMA device.

Our results demonstrates that a low-fidelity model constructed from synthetic materials at low cost like our balloon model can be an excellent tool for basic laparoscopic surgical training. Placing this simple, easily available and reproducible model into a conventional box trainer enables regular practice at home, thereby shortening learning curve and improving basic skills.

The main advantage of magnetic compression anastomosis is to reduce the potential risk of leakage by eliminating the need of suturing and by providing equal and continuous tissue compression compared with conventional hand-sewn anastomosis.

The principle of the esophageal clamp anastomosis technique published by Okmian et al. (1969), tested in piglets, bears resemblance to magnamosis. In contrast to the sutureless clamp anastomosis and magnamosis, in the traditional sutured anastomosis the magnetic compressive force and tension are not evenly distributed throughout the entire circumference of the esophageal end but rather concentrated on the sutured sections (110).

Oetzmann's study (2019) also provides evidence for the benefits of the even distribution of traction forces at the anastomotic site, showing that continuous esophageal anastomosis is advantageous compared to simple interrupted sutures and provides a larger contact surface (111).

Due to the high tension exerted on the sutures, microchannels caused by needle punctures can widen, leading to leakage (Livaditis et al., 1969) (112).

Using a rabbit model, Blair at al. (1988) demonstrated that a similar microleakage can be caused by the inflammatory process that develops around the sutures, which can eventually result in the formation of strictures (113).

Recently, the feasibility of magnetic compression anastomosis technique with PUMA device has been demonstrated for pyeloureteral anastomosis in pigs (52).

The esophageal anastomosis is in many ways similar to the pyelo-ureteral anastomosis. In both a smaller calibre tube (ureter and the lower pouch) should be anastomosed to a larger calibre tube (renal pelvis, upper pouch). Each anastomosis has to be made meticulously without leak to reduce postoperative stricture rate.

Both the ureter and the esophagus are very similar. They contain the same layers in their walls and have the ability to dilate in cases of distal obstruction (114).

The created EA/TEF balloon model, similar to the pyeloplasty balloon model, was not only suitable for practicing laparoscopic suturing and knot-tying but also for testing the novel magnetic method by placing it inside a doll, simulating the limited working space in a neonate.

Our findings show that creating a magnamosis is much less time-consuming than conventional hand-sewn anastomosis and can be easily mastered. The results of a large-scale study showed that thoracoscopic hand-sewn anastomosis performed in neonates required an average of 217 minutes (115).

Our investigations indicate that this operative time can be significantly reduced with the use of magnets, although precise clinical data regarding the time required for esophageal magnamosis is not available in the literature.

To demonstrate the tissue fragility of a human neonate's esophagus, we used ex vivo rabbit esophagi for assessment of bursting pressure and tensile strength.

In this study, both the bursting pressure and the tensile strength were used to assess the integrity of the anastomosis. Bursting pressure accurately reflects the intraluminal pressure generated during swallowing in the esophagus and its circular distribution around the anastomosis. It allows for immediate detection of any potential surgical technical errors. The quality of anastomoses can be primarily determined by its watertightness. On the other hand, tensile strength values gradually decrease during the early postoperative period due to collagenolysis occurring during the healing process of the anastomosis. Tensile strength reflects the resistance of the esophageal wall to forces exerted longitudinal direction, in contrast to the bursting pressure (116).

Based on our results, it can be presumed that despite the expected lower tensile strength values in a live model during the early postoperative period, the anastomosis maintains its stability. We assume that the well-sealing magnamosis prevents leakage.

The cause of anastomotic failure (leakage and subsequent stricture) is multifactorial.

Oetzmann et al. (2019) investigated the effect of extent of esophageal resection on esophageal blood flow in anaesthetized pigs using laser Doppler flowmetry. They found that the magnitude of tension exerted on the anastomosis does not influence the blood flow of the anastomotic suture line. In such cases, the overall circulation of the organ deteriorates uniformly. As a consequence, the inadequate circulation of the anastomosis is most likely induced by the inappropriate surgical technique itself (117).

Referring to the clamp anastomosis experiments conducted by Okmian we can conclude that the absence of direct mucosa-to-mucosa contact does not increase the frequency of stricture occurrence (109). From this, we can infer that a similar situation can be observed in magnamosis as well.

Although our study does not focus on the design of the magnets themselves but rather on the completely thoracoscopic placement of the magnets into the esophagus, various experiments using magnetic devices containing magnets of different shapes, strengths and gradient force distribution on the compressed tissue have been published in the literature, aiming to reduce the possibility of stricture formation. There are numerous studies that investigate the appropriate and safe force required between the magnets without causing the development of fistulas or ulcers.

Takada et al. findings suggest that over-tension, damage to blood supply and leakage at the anastomotic site can be avoided if the tension between the two pouches does not exceed the safe value of 0,75 N, and the level of tension between the pouches can be regulated by using magnets of properly selected strength (84).

Magnamosis can be created in cases where hand-sewn primary anastomosis is feasible. In 85% of all EA cases, distal fistula is present, and in such cases, there is generally no significant tension between the pouches, allowing for the feasibility of primary anastomosis, including magnamosis. Thus, the risk of compromised blood supply and subsequent anastomotic insufficiency is low.

Our assumption is that if these properly selected magnets, after being placed in the pouches, do not attach or easily separate, it indicates that the esophageal anastomosis would not be secure, and the surgeon needs to switch to a different method such as Foker process.

Moreover, using the EMAD, ligation of the fistula can be performed thoracoscopically in cases with fistula.

Furthermore, magnamosis can also be used in long gap cases following elongation procedures when the gap length has decreased to a point where an anastomosis can be created with minimal tension, and it can be useful for the treatment of refractory postoperative esophageal strictures as well (118).

One of the major advantages of the EMAD over previously demonstrated magnetic anastomosis devices for EA treatment is that there is no need for gastrostomy for the introduction of magnets into the pouches. The procedure can be fully performed thoracoscopically.

In our preliminary experiments, the method of EMAD was successfully feasible in terminated pigs as well. This is encouraging because the size and anatomy of a few days old pig are very similar to that of a human neonate.

7 Summary

1) The new birthday balloon model is valid, simple, synthetic, inexpensive, hygienic, easily reproducible and readily available for regular daily practice of the pyeloplasty procedure and testing new innovative concepts like the magnetic pyeloplasty and magnetic esophageal anastomosis.
2) Despite the limitations (significant scar formation, and relatively small ureter diameter) the domestic pig model with surgically induced hydronephrosis was suitable for testing the laparoscopic application of PUMA device.
3) The laparoscopic application of the device and the removal of the device was feasible.
4) The pyelo-ureteral anastomosis remained patent as long as the follow-up was technically possible (8 weeks after the removal of the magnetic device).
5) The thoracoscopic magnetic compression anastomosis is feasible with the EMAD in synthetic and newborn animal model of EA.
6) The EMAD may significantly simplify the procedure and shortens the operative time while providing the benefits of watertight magnetic anastomosis with the potential that it eliminates the need for gastrostomy formation to introduce the second magnet.
7) The significant difference seen in tensile strength between the magnetic and hand sawn anastomosis suggests an EMAD could help surgeons to avoid creating tens anastomosis and reduce risk of later anastomotic stricture.
8) The magnetic anastomosis proved superior over the hand sawn anastomosis in bursting pressure. This may explain the clinical experience of Zaritzky et al. with the Flourish device and suggests EMAD may reduce risk of anastomotic leak.

8 References

1. Mitul AR, Sarin YK. Minimal Access Surgery in Neonates. J Neonatal Surg. 2017;6(3):59.
2. Blinman T, Ponsky T. Pediatric minimally invasive surgery: laparoscopy and thoracoscopy in infants and children. Pediatrics. 2012;130(3):539-49.
3. Arezzo A. The past, the present, and the future of minimally invasive therapy in laparoscopic surgery: a review and speculative outlook. Minim Invasive Ther Allied Technol. 2014;23(5):253-60.
4. Gans SL, Berci G. Peritoneoscopy in infants and children. J Pediatr Surg. 1973;8(3):399-405.
5. Rothenberg SS, Middlesworth W, Kadennhe-Chiweshe A, Aspelund G, Kuenzler K, Cowles R, Bodenstein L, Kay S, Shipman K, Rothenberg C, Stolar C, Stylianos S. Two decades of experience with thoracoscopic lobectomy in infants and children: standardizing techniques for advanced thoracoscopic surgery. J Laparoendosc Adv Surg Tech A. 2015;25(5):423-8.
6. Meinzer A, Alkatout I, Krebs TF, Baastrup J, Reischig K, Meiksans R, Bergholz R. Advances and Trends in Pediatric Minimally Invasive Surgery. J Clin Med. 2020;9(12):3999.
7. Davenport M. Laparoscopic surgery in children. Ann R Coll Surg Engl. 2003;85(5):324-30.
8. Ure BM, Schmidt AI, Jesch NK. Thoracoscopic surgery in infants and children. Eur J Pediatr Surg. 2005;15(5):314-8.
9. Parra JL, Reddy KR. Diagnostic laparoscopy. Endoscopy. 2004;36(4):289-93.
10. Uecker M, Kuebler JF, Ure BM, Schukfeh N.Minimally Invasive Pediatric Surgery: The Learning Curve. Eur J Pediatr Surg. 2020;30(2):172-180.
11. Kalfa N, Allal H, Raux O, Lopez M, Forgues D, Guibal MP, Picaud JC, Galifer RB. Tolerance of laparoscopy and thoracoscopy in neonates. Pediatrics. 2005;116(6):e785-91.
12. Pacilli M, Pierro A, Kingsley C, Curry JI, Herod J, Eaton S. Absorption of carbon dioxide during laparoscopy in children measured using a novel mass spectrometric technique. Br J Anaesth. 2006;97(2):215-9.

13. Barsness K. Simulation-based education and performance assessments for pediatric surgeons. Eur J Pediatr Surg. 2014;24(4):303-7.
14. Gozen AS, Akin Y. Are structured curriculums for laparoscopic training useful? A review of current literature. Curr Opin Urol. 2015;25(2):163-7.
15. Badash I, Burtt K, Solorzano CA, Carey JN. Innovations in surgery simulation: a review of past, current and future techniques. Ann Transl Med. 2016;4(23):453.
16. See WA, Cooper CS, Fisher RJ. Predictors of laparoscopic complications after formal training in laparoscopic surgery. JAMA. 1993;270(22):2689-92.
17. Esposito C, Escolino M, Saxena A, Montupet P, Chiarenza F, De Agustin J, Draghici IM, Cerulo M, Sagaon MM, Di Benedetto V, Gamba P, Settimi A, Najmaldin A. European Society of Pediatric Endoscopic Surgeons (ESPES) guidelines for training program in pediatric minimally invasive surgery. Pediatr Surg Int. 2015;31(4):367-73.
18. Keeley FX Jr, Eden CG, Tolley DA, Joyce AD. The British Association of Urological Surgeons: guidelines for training in laparoscopy. BJU Int. 2007;100(2):379-81.
19. Agha RA, Fowler AJ. The role and validity of surgical simulation. Int Surg. 2015;100(2):350-7.
20. Patel EA, Aydın A, Desai A, Dasgupta P, Ahmed K. Current status of simulation-based training in pediatric surgery: A systematic review. J Pediatr Surg. 2019;54(9):1884-1893.
21. McDougall EM. Validation of surgical simulators. J Endourol. 2007;21(3):244-7.
22. McClelland TJ, Ford K, Dagash H, Lander A, Lakhoo K. Low-fidelity Paediatric Surgical Simulation: Description of Models in Low-Resource Settings. World J Surg. 2019;43(5):1193-1197.
23. Glenn IC, Bruns NE, Gabarain G, Craner DR, Schomisch SJ, Ponsky TA. Creation of an animal model for long gap pure esophageal atresia. Pediatr Surg Int. 2017;33(2):197-201.
24. Sutherland LM, Middleton PF, Anthony A, Hamdorf J, Cregan P, Scott D, Maddern GJ. Surgical simulation: a systematic review. Ann Surg. 2006;243(3):291-300.

25. Gaidry AD, Tremblay L, Nakayama D, Ignacio RC Jr. The History of Surgical Staplers: A Combination of Hungarian, Russian, and American Innovation. Am Surg. 2019;85(6):563-566.
26. Seguier-Lipszyc E, Samuk I, Almog A, Silbermintz A, Kravarusic D. Multiple magnet ingestion in children: A problem on the rise. J Paediatr Child Health. 2022;58(10):1824-1828.
27. Hardy KJ. Non-suture anastomosis: the historical development. Aust N Z J Surg. 1990;60(8):625-33.
28. Obora Y, Tamaki N, Matsumoto S. Nonsuture microvascular anastomosis using magnet rings: preliminary report. Surg Neurol. 1978;9(2):117-20.
29. Jamshidi R, Stephenson JT, Clay JG, Pichakron KO, Harrison MR. Magnamosis: magnetic compression anastomosis with comparison to suture and staple techniques. J Pediatr Surg. 2009;44(1):222-8.
30. Carachi R, Stokes KB, Brown TC, Kent M. Esophageal anastomosis-an experimental model to study the anastomotic lumen and the influence of a transanastomotic tube. J Pediatr Surg. 1984;19(1):90-3.
31. Lee WG, Evans LL, Johnson SM, Woo RK. The Evolving Use of Magnets in Surgery: Biomedical Considerations and a Review of Their Current Applications. Bioengineering (Basel). 2023;10(4):442.
32. Jansen A, Keeman JN, Davies GA, Klopper PJ. Early experiences with magnetic rings in resection of the distal colon. Neth J Surg. 1980;32(1):20-7.
33. Mascagni P, Tringali A, Boškoski I, Bove V, Schepis T, Perri V, Costamagna G. Magnetic kissing for the endoscopic treatment of a complete iatrogenic stenosis of the hypopharynx. Endoscopy. 2023;55(S 01):E499-E500.
34. Lok CE, Rajan DK, Clement J, Kiaii M, Sidhu R, Thomson K, Buldo G, Dipchand C, Moist L, Sasal J; NEAT Investigators. Endovascular Proximal Forearm Arteriovenous Fistula for Hemodialysis Access: Results of the Prospective, Multicenter Novel Endovascular Access Trial (NEAT). Am J Kidney Dis. 2017;70(4):486-497.
35. Klima U, Falk V, Maringka M, Bargenda S, Badack S, Moritz A, Mohr F, Haverich A, Wimmer-Greinecker G. Magnetic vascular coupling for distal

anastomosis in coronary artery bypass grafting: a multicenter trial. J Thorac Cardiovasc Surg. 2003;126(5):1568-74.

36. Toselli L, Martinez-Ferro M, Cervio G, Kwiat D, Imamura-Ching J, Graves CE, Gaston B, Harrison M. Magnetic Compression Anastomosis (Magnamosis) for Functional Undiversion of Ileostomy in Pediatric Patients. J Laparoendosc Adv Surg Tech A. 2017;27(12):1314-1317.
37. Zaritzky M, Ben R, Johnston K. Magnetic gastrointestinal anastomosis in pediatric patients. J Pediatr Surg. 2014;49(7):1131-7.
38. Kotlovsky AM, Muensterer OJ, Nikolaev VV, Razumovskiy AY. Magnetic Compression Anastomosis-Past Experience and Current Proposals for Further Development in Pediatric Minimally Invasive Surgery. Children (Basel). 2023;10(8):1328.
39. Morini F, Conforti A, Bagolan P. Perioperative Complications of Esophageal Atresia. Eur J Pediatr Surg. 2018;28(2):133-140.
40. Guyton KL, Hyman NH, Alverdy JC. Prevention of Perioperative Anastomotic Healing Complications: Anastomotic Stricture and Anastomotic Leak. Adv Surg. 2016;50(1):129-41.
41. Woo R, Wong CM, Trimble Z, Puapong D, Koehler S, Miller S, Johnson S. Magnetic Compression Stricturoplasty for Treatment of Refractory Esophageal Strictures in Children: Technique and Lessons Learned. Surg Innov. 2017;24(5):432-439.
42. Mimuro A, Tsuchida A, Yamanouchi E, Itoi T, Ozawa T, Ikeda T, Nakamura R, Koyanagi Y, Nakamura K. A novel technique of magnetic compression anastomosis for severe biliary stenosis. Gastrointest Endosc. 2003;58(2):283-7.
43. Russell KW, Rollins MD, Feola GP, Scaife ER. Magnamosis: a novel technique for the management of rectal atresia. BMJ Case Rep. 2014;2014:bcr2013201330.
44. Liu XM, Li Y, Zhang HK, Ma F, Wang B, Wu R, Zhang XF, Lv Y. Laparoscopic Magnetic Compression Biliojejunostomy: A Preliminary Clinical Study. J Surg Res. 2019;236:60-67.
45. Kamada T, Ohdaira H, Takeuchi H, Takahashi J, Ito E, Suzuki N, Narihiro S, Yoshida M, Yamanouchi E, Suzuki Y. New Technique for Magnetic Compression

Anastomosis Without Incision for Gastrointestinal Obstruction. J Am Coll Surg. 2021;232(2):170-177.e2.

46. Graves CE, Co C, Hsi RS, Kwiat D, Imamura-Ching J, Harrison MR, Stoller ML. Magnetic Compression Anastomosis (Magnamosis): First-In-Human Trial. J Am Coll Surg 2017;225(5):676-681.e1.
47. Kohno M, Ogawa T, Kojima Y, Sakoda A, Johnin K, Sugita Y, Nakane A, Noguchi M, Moriya K, Hattori M, Hayashi Y, Kubota M. Pediatric congenital hydronephrosis (ureteropelvic junction obstruction): Medical management guide. Int J Urol. 2020;27(5):369-376.
48. EUROCAT Network. Prevalence charts and tables (2005 to 2023). Congenital hydronephrosis including ureter obstruction. Retrieved 2025 Jul 26 from https://eu-rd-platform.jrc.ec.europa.eu/eurocat/eurocat-data/prevalence_en
49. Radmayr C, Bogaert G, Burgu B et al. (2023). Dilatation of the upper urinary tract (UPJ and UPV obstruction). In EAU Guidelines on paediatric urology (p. 67)
50. Szavay P, Zundel S. Surgery of uretero-pelvic junction obstruction (UPJO). Semin Pediatr Surg. 2021;30(4):151083.
51. Mei H, Pu J, Yang C, Zhang H, Zheng L, Tong Q. Laparoscopic versus open pyeloplasty for ureteropelvic junction obstruction in children: a systematic review and meta-analysis. J Endourol. 2011;25(5):727-36.
52. Cserni T, Urban D, Hajnal D, Erces D, Varga G, Nagy A, Cserni M, Marei M, Hennayake S, Kubiak R. Pyeloureteric magnetic anastomosis device to simplify laparoscopic pyeloplasty: a proof-of-concept study. BJU Int. 2021;127(4):409-411.
53. Díaz-Güemes Martín-Portugués I, Hernández-Hurtado L, Usón-Casaús J, Sánchez-Hurtado MA, Sánchez-Margallo FM. Ureteral obstruction swine model through laparoscopy and single port for training on laparoscopic pyeloplasty. Int J Med Sci. 2013;10(8):1047-52.
54. Fu B, Zhang X, Lang B, Xu K, Zhang J, Ma X, Li HZ, Zheng T, Wang BJ. New model for training in laparoscopic dismembered ureteropyeloplasty. J Endourol. 2007;21(11):1381-5.

55. Zhang X, Zhang GX, Wang BJ, Ma X, Fu B, Shi TP, Lang B, Wang C, Ju ZH, Ai X, Wu Z. A multimodal training program for laparoscopic pyeloplasty. J Endourol. 2009;23(2):307-11.
56. Ooi J, Lawrentschuk N, Murphy DL. Training model for open or laparoscopic pyeloplasty. J Endourol. 2006;20(2):149-52.
57. Jiang C, Liu M, Chen J, Wang P, Lin T, Xu K, Han J, Huang H, Huang J. Construct validity of the chicken crop model in the simulation of laparoscopic pyeloplasty. J Endourol. 2013;27(8):1032-6.
58. Teber D, Guven S, Yaycioglu O, Ugurlu O, Sanli O, Gozen AS, Rassweiler J. Single-knot running suture anastomosis (one-knot pyeloplasty) for laparoscopic dismembered pyeloplasty: training model on a porcine bladder and clinical results. Int Urol Nephrol. 2010;42(3):609-14.
59. Yang B, Zhang ZS, Xiao L, Wang LH, Xu CL, Sun YH. A novel training model for retroperitoneal laparoscopic dismembered pyeloplasty. J Endourol. 2010;24(8):1345-9.
60. Rod J, Marret JB, Kohaut J, Aigrain Y, Jais JP, de Vries P, Lortat-Jacob S, Breaud J, Blanc T. Low-Cost Training Simulator for Open Dismembered Pyeloplasty: Development and Face Validation. J Surg Educ. 2018;75(1):188-194.
61. Raza SJ, Soomroo KQ, Ather MH. "Latex glove" laparoscopic pyeloplasty model: a novel method for simulated training. Urol J. 2011;8(4):283-6.
62. Cheung CL, Looi T, Lendvay TS, Drake JM, Farhat WA. Use of 3-dimensional printing technology and silicone modelling in surgical simulation: development and face validation in pediatric laparoscopic pyeloplasty. J Surg Educ. 2014;71(5):762-7.
63. Durkin N, De Coppi P. Anatomy and embryology of tracheo-esophageal fistula. Semin Pediatr Surg. 2022;31(6):151231.
64. Pedersen RN, Calzolari E, Husby S, Garne E; EUROCAT Working group. Oesophageal atresia: prevalence, prenatal diagnosis and associated anomalies in 23 European regions. Arch Dis Child. 2012;97(3):227-32.
65. Pinheiro PF, Simões e Silva AC, Pereira RM. Current knowledge on esophageal atresia. World J Gastroenterol. 2012;18(28):3662-72

66. van Lennep M, Singendonk MMJ, Dall'Oglio L, Gottrand F, Krishnan U, Terheggen-Lagro SWJ, Omari TI, Benninga MA, van Wijk MP. Oesophageal atresia. Nat Rev Dis Primers. 2019;5(1):26.
67. Dingemann C, Eaton S, Aksnes G, Bagolan P, Cross KM, De Coppi P, Fruithof J, Gamba P, Husby S, Koivusalo A, Rasmussen L, Sfeir R, Slater G, Svensson JF, Van der Zee DC, Wessel LM, Widenmann-Grolig A, Wijnen R, Ure BM. ERNICA Consensus Conference on the Management of Patients with Esophageal Atresia and Tracheoesophageal Fistula: Diagnostics, Preoperative, Operative, and Postoperative Management. Eur J Pediatr Surg. 2020;30(4):326-336.
68. Lee S. Basic Knowledge of Tracheoesophageal Fistula and Esophageal Atresia. Adv Neonatal Care. 2018;18(1):14-21.
69. Teague WJ, Karpelowsky J. Surgical management of oesophageal atresia. Paediatr Respir Rev. 2016;19:10-5.
70. Drevin G, Andersson B, Svensson JF. Thoracoscopy or Thoracotomy for Esophageal Atresia: A Systematic Review and Meta-analysis. Ann Surg. 2021;274(6):945-953.
71. Dingemann C, Eaton S, Aksnes G, Bagolan P, Cross KM, De Coppi P, Fruithof J, Gamba P, Goldschmidt I, Gottrand F, Pirr S, Rasmussen L, Sfeir R, Slater G, Suominen J, Svensson JF, Thorup JM, Tytgat SHAJ, van der Zee DC, Wessel L, Widenmann-Grolig A, Wijnen R, Zetterquist W, Ure BM. ERNICA Consensus Conference on the Management of Patients with Long-Gap Esophageal Atresia: Perioperative, Surgical, and Long-Term Management. Eur J Pediatr Surg. 2021;31(3):214-225.
72. Hendren WH, Hale JR. Esophageal atresia treated by electromagnetic bougienage and subsequent repair. J Pediatr Surg. 1976;11(5):713-22.
73. Zaritzky M, Ben R, Zylberg GI, Yampolsky B. Magnetic compression anastomosis as a nonsurgical treatment for esophageal atresia. Pediatr Radiol. 2009;39(9):945-9.
74. Muensterer OJ, Evans LL, Sterlin A, Sahlabadi M, Aribindi V, Lindner A, König T, Harrison MR. Novel Device for Endoluminal Esophageal Atresia Repair: First-in-Human Experience. Pediatrics. 2021;148(5):e2020049627.

75. Shieh HF, Jennings RW, Manfredi MA, Ngo PD, Zendejas B, Hamilton TE. Cautionary tales in the use of magnets for the treatment of long gap esophageal atresia. J Pediatr Surg. 2022;57(10):342-347.
76. Holler AS, König TT, Chen C, Harrison MR, Muensterer OJ. Esophageal Magnetic Compression Anastomosis in Esophageal Atresia Repair: A PRISMA-Compliant Systematic Review and Comparison with a Novel Approach. Children (Basel). 2022;9(8):1113.
77. Donoso F, Lilja HE. Risk Factors for Anastomotic Strictures after Esophageal Atresia Repair: Prophylactic Proton Pump Inhibitors Do Not Reduce the Incidence of Strictures. Eur J Pediatr Surg. 2017;27(1):50-55.
78. Morini F, Conforti A, Bagolan P. Perioperative Complications of Esophageal Atresia. Eur J Pediatr Surg. 2018;28(2):133-140.
79. Guyton KL, Hyman NH, Alverdy JC. Prevention of Perioperative Anastomotic Healing Complications: Anastomotic Stricture and Anastomotic Leak. Adv Surg. 2016;50(1):129-41.
80. Liu SQ, Lv Y, Fang Y, Luo RX, Zhao JR, Luo RG, Li YM, Zhang J, Zhang PF, Guo JZ, Li QH, Han MX. Magnetic compression for anastomosis in treating an infant born with long-gap oesophageal atresia: A case report. Medicine (Baltimore). 2020;99(42):e22472.
81. Takamizawa S, Yamanouchi E, Muraji T, Nishijima E, Satoh S, Tsugawa J. MCRA of an anastomotic stenosis after esophagoesophagostomy for long gap esophageal atresia: a case report. J Pediatr Surg. 2007;42(5):769-72.
82. Woo R, Wong CM, Trimble Z, Puapong D, Koehler S, Miller S, Johnson S. Magnetic Compression Stricturoplasty for Treatment of Refractory Esophageal Strictures in Children: Technique and Lessons Learned. Surg Innov. 2017;24(5):432-439.
83. Herbella FA, Del Grande JC. Human cadavers as an experimental model for esophageal surgery. Dis Esophagus. 2001;14(3-4):218-22.
84. Takada Y, Kent G, Filler RM. Circular myotomy and esophageal length and safe esophageal anastomosis: an experimental study. J Pediatr Surg. 1981;16(3):343-8.
85. Wall J, Perretta S, Diana M, Dhumane P, Haro JI, Dallemagne B, Becmeur F, Krummel T, Marescaux J. Submucosal endoscopic myotomies for esophageal

lengthening: a novel minimally invasive technique with feasibility study. Eur J Pediatr Surg. 2012;22(3):217-21.

86. Tannuri U, Teodoro WR, de Santana Witzel S, Tannuri AC, Lupinacci RM, Matsunaga P, Matsumura N, Naufal RR. Livaditis' circular myotomy does not decrease anastomotic leak rates and induces deleterious changes in anastomotic healing. Eur J Pediatr Surg. 2003;13(4):224-30.
87. Oetzmann von Sochaczewski C, Lindner A, Heimann A, Balus A, Patel VH, Harrison MR, Muensterer OJ. Beyond Magnamosis: A Method to Test Sutureless Esophageal Anastomotic Devices in Living Swine by Creating an Esophageal Bypass Loop for Natural Oral Nutrition. J Laparoendosc Adv Surg Tech A. 2019;29(6):852-855.
88. Glenn IC, Bruns NE, Schomisch SJ, Ponsky TA. Creation of an Esophageal Atresia Animal Model Using a Bifurcated Esophagus to Maintain Digestive Tract Continuity. J Laparoendosc Adv Surg Tech A. 2017;27(10):1079-1084.
89. Barsness KA, Rooney DM, Davis LM, Chin AC. Validation of measures from a thoracoscopic esophageal atresia/tracheoesophageal fistula repair simulator. J Pediatr Surg. 2014;49(1):29-32; discussion 32-3.
90. Bökkerink GM, Joosten M, Leijte E, Lindeboom MY, de Blaauw I, Botden SM. Validation of low-cost models for minimal invasive surgery training of congenital diaphragmatic hernia and esophageal atresia. J Pediatr Surg. 2021;56(3):465-470.
91. Maricic MA, Bailez MM, Rodriguez SP. Validation of an inanimate low cost model for training minimal invasive surgery (MIS) of esophageal atresia with tracheoesophageal fistula (AE/TEF) repair. J Pediatr Surg. 2016;51(9):1429-35.
92. Hong D, Kim H, Kim T, Kim YH, Kim N. Development of patient specific, realistic, and reusable video assisted thoracoscopic surgery simulator using 3D printing and pediatric computed tomography images. Sci Rep. 2021;11(1):6191.
93. Wells JM, Nair D, Cook N, Yi M, Moorhead A, Maoate K, Beasley SW. End-User Input into the Design and Validation of a Synthetic Thoracoscopic Esophageal Atresia/Tracheo-Esophageal Fistula Simulator. J Laparoendosc Adv Surg Tech A. 2020;30(6):685-691.

94. Jhala T, Zundel S, Szavay P. Surgical simulation of pediatric laparoscopic dismembered pyeloplasty: Reproducible high-fidelity animal-tissue model. J Pediatr Urol. 2021;17(6):833.e1-833.e4.
95. Kubiak R, Hornok Z, Csukas D, Ferencz A, Cserni T. Feasibility and Challenges of Pyeloureteral Magnetic Anastomosis Device in Domestic Pigs: A Stepwise Approach with Extended Observation. Eur J Pediatr Surg. 2025;35(4):316-321. doi: 10.1055/a-2507-8135.
96. Bidarkar SS, Deshpande A, Kaur M, Cohen RC. Porcine models for pediatric minimally invasive surgical training--a template for the future. J Laparoendosc Adv Surg Tech A. 2012;22(1):117-22.
97. Villegas-Alvarez F, Olvera-Durán J, Rodríguez-Aranda E, Carmona-Mancilla A, Vigueras-Villaseñor RM, Méndez-Ramírez I. Esophageal anastomotic failure: an experimental study. Arch Med Res. 2003;34(3):171-5.
98. Till H., Kirlum H.-J., Boehm R., Joppich I. Thoracoscopic Correction of Esophageal Atresia: Training in Rabbits Provides Valuable Surgical Expertise and Shortens the Learning Curve. Pediatric Endosurgery & Innovative Techniques, 2001;5(3),235–239.
99. Loff S, Diez O, Ho W, Kalle TV, Hetjens S, Boettcher M. Esophageal Diameter as a Function of Weight in Neonates, Children and Adolescents: Reference Values for Dilatation of Esophageal Stenoses. Front Pediatr. 2022;10:822271.
100. Pokora TJ, Mammel MC, Thompson TR, Ebert J, Boros SJ. Measurement of esophageal pressure in newborn infants using an esophageal balloon gastric catheter. Crit Care Med. 1982;10(8):522-4.
101. Askarpour S, Ostadian N, Peyvasteh M, Alavi M, Javaherizadeh H. End-to-end versus end-to-side anastomosis in the treatment of esophageal atresia or tracheo-esophageal fistula Arq Bras Cir Dig. 2016;29(1):48-49.
102. Touloukian RJ, Seashore JH. Thirty-five-year institutional experience with end-to-side repair for esophageal atresia. Arch Surg. 2004;139(4):371-4
103. Chiarenza SF, Bleve C, Zolpi E, Costa L, Mazzotta MR, Novek S, Bonato R, Conighi ML. The Use of Endoclips in Thoracoscopic Correction of Esophageal Atresia: Advantages or Complications? J Laparoendosc Adv Surg Tech A. 2019;29(7):976-980.

104. Askarpour S, Peyvasteh M, Javaherizadeh H, Askari N. Evaluation of risk factors affecting anastomotic leakage after repair of esophageal atresia. Arq Bras Cir Dig. 2015;28(3):161-2.
105. Parsons JK, Varkarakis I, Rha KH, Jarrett TW, Pinto PA, Kavoussi LR. Complications of abdominal urologic laparoscopy: longitudinal five-year analysis. Urology. 2004;63(1):27-32.
106. Frede T, Stock C, Rassweiler JJ, Alken P. Retroperitoneoscopic and laparoscopic suturing: tips and strategies for improving efficiency. J Endourol. 2000;14(10):905-13
107. Scott DJ, Bergen PC, Rege RV, Laycock R, Tesfay ST, Valentine RJ, Euhus DM, Jeyarajah DR, Thompson WM, Jones DB. Laparoscopic training on bench models: better and more cost effective than operating room experience? J Am Coll Surg. 2000;191(3):272-83.
108. Katz R, Nadu A, Olsson LE, Hoznek A, de la Taille A, Salomon L, Abbou CC. A simplified 5-step model for training laparoscopic urethrovesical anastomosis. J Urol. 2003;169(6):2041-4.
109. Barsness KA, Rooney DM, Davis LM, O'Brien E. Evaluation of Three Sources of Validity Evidence for a Synthetic Thoracoscopic Esophageal Atresia/ Tracheoesophageal Fistula Repair Simulator. J Laparoendosc Adv Surg Tech A. 2015;25(7):599-604.
110. Okmian L, Livaditis A, Björck G, Ivemark B. Esophageal clamp anastomosis. An experimental study in piglets. Scand J Thorac Cardiovasc Surg. 1969;3(2):151-62.
111. Oetzmann von Sochaczewski C, Tagkalos E, Lindner A, Lang H, Heimann A, Schröder A, Grimminger PP, Muensterer OJ. Esophageal Biomechanics Revisited: A Tale of Tenacity, Anastomoses, and Suture Bite Lengths in Swine. Ann Thorac Surg. 2019;107(6):1670-1677.
112. Livaditis A, Okmian L, Eklöf O. Esophageal atresia. I. Anastomotic strictures following primary surgical management. Scand J Thorac Cardiovasc Surg. 1968;2(3):151-8.

113. Blair GK, Castner P, Taylor G, Newman D, Santoso B. Esophageal atresia--a rabbit model to study anastomotic healing and the use of tissue adhesive fibrin sealant. J Pediatr Surg. 1988;23(8):740-3.
114. Uygun I, Otcu S, Ozekinci S, Okur MH, Arslan MS, Aydogdu B. Dilated ureter for esophageal substitution: a preliminary experimental study in the rat. Clin Res Hepatol Gastroenterol. 2014;38(1):92-8.
115. Etchill EW, Giuliano KA, Boss EF, Rhee DS, Kunisaki SM. Association of operative approach with outcomes in neonates with esophageal atresia and tracheoesophageal fistula. J Pediatr Surg. 2021;56(12):2172-2179.
116. Ikeuchi D, Onodera H, Aung T, Kan S, Kawamoto K, Imamura M, Maetani S. Correlation of tensile strength with bursting pressure in the evaluation of intestinal anastomosis. Dig Surg. 1999;16(6):478-85.
117. Oetzmann von Sochaczewski C, Heimann A, Linder A, Kempski O, Muensterer OJ. Esophageal Blood Flow May Not Be Directly Influenced by Anastomotic Tension: An Exploratory Laser Doppler Study in Swine. Eur J Pediatr Surg. 2019;29(6):516-520.
118. Magdi LA, Gergess YS, Saad IS, Osama IA. Role of magnetic compression power in esophageal anastomosis: an experimental study. Egypt J Surg 2021;40(1):192-200.

9 Bibliography of the candidate's publications

1. **Hornok Z**, Ferencz A, Kubiak R, Cserni T.
   Cheap and clean dry balloon training model for laparoscopic pyeloplasty.
   J Pediatr Urol. 2023;19(4):471-473.
   IF: 2,0

2. Kubiak R, **Hornok Z**, Csukas D, Ferencz A, Cserni T
   Feasibility and challenges of pyeloureteral magnetic anastomosis device in domestic pigs: a stepwise approach with extended observation
   Eur J Pediatr Surg. 2025;35(4):316-321.
   IF: 1,4

3. **Hornok Z,** Kubiak R, Csukas D, Ferencz A, Cserni T.
   Esophageal Magnetic Anastomosis Device (EMAD) to simplify and improve outcome of thoracoscopic repair for esophageal atresia with tracheoesophageal fistula: A proof of concept study.
   J Pediatr Surg. 2023;58(8):1489-1493.
   IF: 2,4

Σ IF: 5,8

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Feasibility and Challenges of Pyeloureteral Magnetic Anastomosis Device in Domestic Pigs: A Stepwise Approach with Extended Observation

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Abstract

Objective The pyeloureteral anastomosis remains the most challenging part of pyeloplasty. A purpose-built anastomotic device could simplify this step and potentially improve outcomes. The concept of a pyeloureteral magnetic anastomosis device (PUMA) was proven in minipigs, but only in short term. Our aim was to test the PUMA in domestic pigs and achieve a prolonged follow-up period.

Methods Five female domestic pigs underwent laparoscopy and ligation of the left ureter. Four weeks later, laparoscopic implantation of the PUMA was planned. Removal of the device and a retrograde contrast study were scheduled after another 4 weeks. The experiment was terminated when the animals could no longer be properly cared for due to their weight.

Results Due to unexpected smaller ureteric diameters, a modified PUMA could only be successfully inserted in pig number 3 (49 kg). Four weeks later, the device was found to be dislocated, but the anastomosis remained patent. After modifying the study protocol, the PUMA was successfully implanted in pigs number 4 (96 kg) and 5 (68 kg) 8 weeks after ureteric ligation. Pig 4 developed malignant hyperthermia and died. In pig 5, the magnets were removed 4 weeks later. After an additional 8 weeks, the animal reached 135 kg and was terminated. The anastomosis remained patent and preserved its diameter.

Conclusion Despite limitations, our study successfully demonstrated that the PUMA can achieve a patent ureteric anastomosis in domestic pigs. This suggests a potential for minimally invasive ureteric anastomosis in clinical settings. Further research is needed to optimize the technique and validate its effectiveness in humans.

Keywords
- laparoscopy
- magnamosis
- surgical innovation
- PUMA device
- pyeloplasty

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Introduction

The Anderson–Hynes pyeloplasty is the gold standard procedure for the surgical management of ureteropelvic junction (UPJ) obstruction and has evolved over the past decades. Although the open approach in young children remains a targeted, quick, and effective option, with access via an approximately 4-cm incision, the advantages of minimally invasive techniques such as laparoscopy and robotic surgery outweigh those in older children and adolescents (i.e., less postoperative pain, shorter hospital stay, smaller scar, and quicker recovery).[1,2] The outcomes between the different techniques are comparable, with a success rate of more than 90%.[3,4] The most crucial part of the procedure is the quality of the pyeloureteral anastomosis. An insufficient anastomosis may lead to urinary leakage and/or stricture formation, resulting in an unsatisfactory outcome.[5,6] Laparoscopic suturing of the anastomosis is significantly more challenging than the open surgery; it is time-consuming and has a steep learning curve. The robotic technique, with its superior instrument maneuverability, offers some relief in suturing, but due to the lack of haptic feedback in most robots, it only allows the nontouch technique when performing the anastomosis. Moreover, while robots have reduced the learning curve, they have not improved outcomes, operating time, or hospital stay.[4] Currently, the relatively large, bulky robotic instruments (5 mm) and the clashing of robotic arms limit their use in smaller patients, while with transperitoneal laparoscopy, there is technically no age limit when performed by experienced hands.[7]

Suturing the pyeloureteral anastomosis remains the most critical and demanding part of the procedure, regardless of the technique used. In this context, there is a clear need for an anastomotic suturing device, similar to the circular stapler used in intestinal anastomoses, to ease, and improve the quality of the anastomosis. However, designing and manufacturing such a miniature instrument presents a significant challenge.

Magnetic compression anastomosis (MCA) was originally developed to simplify and shorten hand-sutured procedures and reduce the risk of leakage by providing a constant and uniform tissue seal.[8–10] Neodymium magnets are known for their extreme magnetic strength, allowing for miniaturization and leading us to the idea of developing the pyeloureteral magnetic anastomosis device (PUMA).[11] Using a synthetic simulator,[12] we verified that the procedure became significantly shorter and easier to perform. Furthermore, in a pilot study, we demonstrated that laparoscopic pyeloplasty using the PUMA was feasible in an artificially induced hydronephrotic animal model (i.e., Vietnamese miniature pigs), resulting in a patent pyeloureteral anastomosis. However, the laboratory facilities only allowed for a short-term follow-up of 4 weeks.[11]

Adapting to the circumstances, we changed laboratories and switched to domestic pigs. The aim of the present study was to reproduce our previous results with an extended postoperative observation period to achieve follow-up as long as technically possible.

Materials and Methods

The study was conducted by a stepwise approach[13] in five female domestic pigs in accordance with the National Institutes of Health guidelines and the European Union directive 2010/63 for the protection of animals used for scientific purposes and was approved by the National Scientific Ethical Committee (PE/EA/787-7/2019).

All animals, weighing ± 35 kg on average at the beginning, were positioned in a left recumbent position and underwent a transperitoneal laparoscopy. In a first step, a dilation of the proximal ureter/renal pelvis (i.e., hydronephrosis model) was achieved as similarly described previously.[14] In brief, a small incision was made to the peritoneum and the proximal left ureter was loosely encircled at 360 degrees with a 20-cm-long rubber vessel loop that was fixed with a 5-mm clip. According to the study protocol, laparoscopic pyeloplasty with insertion of the PUMA was performed 4 weeks later followed by removal of the device via the ureterovesical junction (UVJ) after another 4 weeks. Finally, a retrograde contrast study, autopsy, and assessment of the anastomosis were planned (i.e., depending on the weight of the animals ± 12 weeks after insertion).

Pyeloureteral Magnetic Anastomosis Device

In all cases, N35 neodymium nickel-coated magnetic cylinders with a 4-mm outer diameter, 2-mm inner diameter, and 8-mm length were applied to a 4.8 Fr, 22-cm-long JJ-stent. The "ureteric" magnet was fixed to the stent. The free "pelvic" magnet was inserted into a Malecot catheter tip to prevent early dislocation and keep the magnets in place after fusion. To improve the quality of the anastomosis by creating a low-pressure zone away from the immediate union, both magnets were coated with a 0.5-mm insulation plastic layer. A surgical needle (31 mm 1/2 c tapered) was integrated into the proximal end of the stent using cyanoacrylate glue (►Fig. 1).

Pyeloplasty

After resection of the narrow ureteric segment, the stent with the (fixed) "ureteral" magnet was threaded into the (distal) ureter. The proximal part of the stent with the integrated needle was stitched inside-out from the ureter 10 mm below the free end, which was closed with a 5-mm clip. The stent was then stitched into the "pelvis" (i.e., dilated proximal ureter) in an outside–inside fashion. Subsequently, the (free) "pelvic" magnet was threaded onto the stent aiming for a side-to-side anastomosis. The "pelvis" was closed with a 4/0 barbed suture (V-loc, Medtronic Limited, Watford, United Kingdom) without the need for handheld knot tying (►Fig. 2).

Results

Pig number 1 was lost 3 weeks after ligation of the ureter for unknown reasons. In the remaining, a moderate hydronephrosis and tortuous dilatation of the proximal ureter was present during the second laparoscopy that was accompanied by considerable intraabdominal scarring.

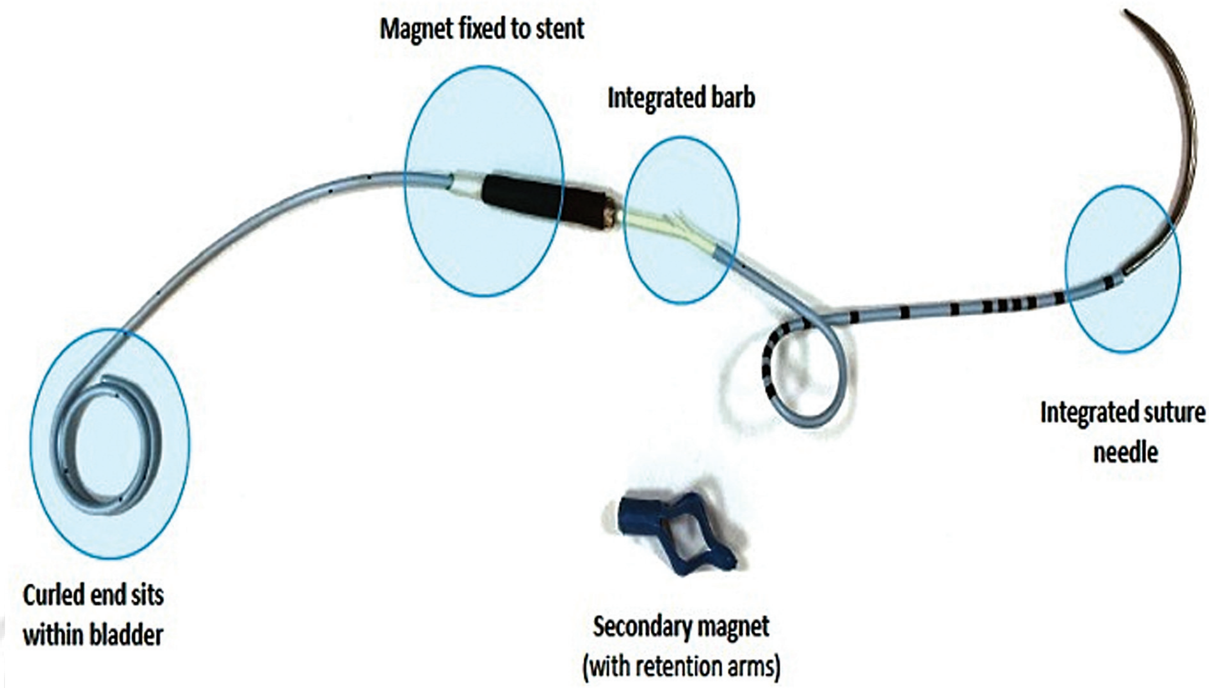

Fig. 1 Pyeloureteral magnetic anastomosis device (PUMA).

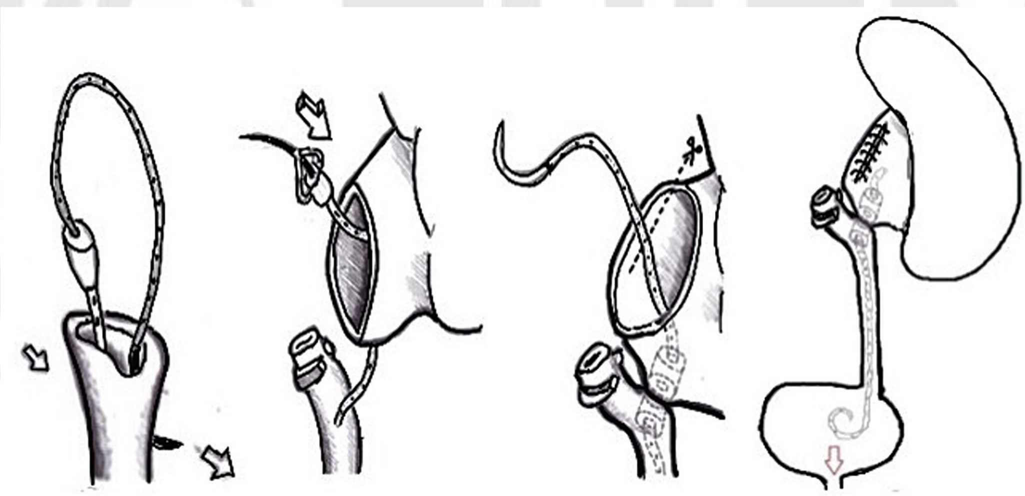

Fig. 2 Application of the pyeloureteral magnetic anastomosis device (PUMA; step 1–4) following resection of the stenotic ureteric segment to create a side-to-side anastomosis based on magnetic compression force (magnamosis).

Application of Pyeloureteral Magnetic Anastomosis Device in Pigs Number 2 and 3

In pigs number 2 and 3, weighing 49 kg each at the time of the second operation, the diameter of the distal ureter was small and a 5-mm device could not be introduced. Finally, we were able to insert the PUMA in animal number 3, but only after the outer 0.5-mm thick insulation layer of the ureteric magnet had been removed. Four weeks later X-rays revealed a dislocation of the magnets above the anastomotic site with the end of the device being slipped up from the bladder into the ureter, and termination of the animal was decided. Nevertheless, at autopsy, a patent anastomosis was noted (►Table 1).

Change of Protocol and Application of Pyeloureteral Magnetic Anastomosis Device in Pigs Number 4 and 5

Based on our experience we changed our protocol and decided to delay the insertion of the PUMA for another 4 weeks to possibly come upon ureters with a bigger lumen. Subsequently, the magnets could be inserted in pig number 4 (weighing 96 kg) with ease. Unfortunately, the animal deteriorated at the end of the procedure and died due to malignant hyperthermia. Finally, the PUMA was successfully applied in pig number 5 (weighing 68 kg) 8 weeks after ligation of the ureter. The large size of the animal with a long urogenital sinus made cystoscopy difficult, for which

Table 1 Study results

Animal number	First operation Hydronephrotic model[a]	Second operation Application of PUMA	Third operation Removal of PUMA	Fourth operation X-rays and autopsy
1	Successful[b]	NA	NA	NA
2	Successful	Weight: 49 kg Timing: 4 wk after first op Outcome: failure to insert PUMA/first ("ureteric") magnet due to small-sized distal ureter	NA	NA
3	Successful	Weight: 49 kg Timing: 4 wk after first operative Outcome: small-sized distal ureter; insertion of PUMA only feasible after reduction in diameter of the first magnet by removing plastic insulation	Weight: 90 kg Timing: 4 wk after second operative Outcome: cystoscopy not possible due to long urogenital sinus; PUMA moved up into the upper ureter; autopsy performed; gross hydronephrosis and UTI noted; patent anastomosis formed	NA
4[c]	Successful	Weight: 96 kg Timing: 8 wk after first operative Outcome: good-sized ureter; insertion of PUMA performed with ease; animal developed malignant hyperthermia and subsequently died	NA	NA
5[c]	Successful	Weight: 68 kg Timing: 8 wk after first operative Outcome: good-sized ureter; insertion of PUMA performed with ease	Weight: 80 kg Timing: 5 wk after the second operative Outcome: cystoscopy not possible due to long urogenital sinus; removal of PUMA/magnets via vesicostomy without problems; retrograde contrast study revealed patent anastomosis	Weight: 135 kg Timing: 8 wk after the third operative Outcome: retrograde study showed easy passage of contrast through the anastomosis; good caliber anastomosis at autopsy

Abbreviations: PUMA, pyeloureteral magnetic anastomosis device; NA, not applicable; UTI, urinary tract infection.
[a]Laparoscopy and ligation of the left ureter with a 20-cm rubber loop. Animals weighed 35 kg on average at the first operation.
[b]Animal number 1 died of unknown reasons 3 weeks after minimally invasive ligation of the left ureter.
[c]Change of study protocol in animal number 4 and 5 toward a delay of the PUMA insertion for another 4 weeks.

reason the device was rather retrieved by vesicostomy. The magnets passed easily through the UVJ 4 weeks after the insertion. A retrograde contrast study revealed a patent anastomosis of good caliber (►Fig. 3A). After another 8 weeks, the animal weighed 135 kg and reached the limits of the animal laboratory (►Table 1). At autopsy (including histology), a patent anastomosis was found at the same caliber as the magnets with only minimal scarring (►Fig. 3B, C).

Discussion

In the development of the PUMA prototype for in vivo testing, we assumed that neodymium cylinders with a nickel coating and N35 magnetization, with an external diameter of 4 mm, an internal diameter of 2 mm, and a length of 8 mm, would provide the necessary conditions to create a sufficient anastomosis in children.[11] A 4-mm external diameter, hence the formation of a 4-mm high-pressure zone between the magnet pair, would create a sufficiently wide anastomosis (i.e., the formation of necrosis between the ureter wall and the renal pelvis), corresponding to a diameter of 12 F. Moreover, an internal diameter of 2 mm would allow the integration of a 4.8 to 6 F JJ stent to ensure postinterventional drainage of the renal pelvis. Additionally, we applied a 0.5-mm insulation layer (i.e., the sheath of a Malecot catheter) around the magnetic cylinders to create an external low-pressure zone, allowing the tissue/anastomosis to heal in a controlled manner, ideally without the formation of a stricture. The overall diameter of the device of 5 mm should generally fit easily into the ureter of most patients, as a 5-mm stone can pass spontaneously through the pelviureteric junction and UVJ in children aged 6 to 9 years.[15,16]

In light of our previous experience with six mini-pigs weighing around 33 kg,[11] we anticipated no problems with the ureter size in domestic pigs weighing 49 kg, which

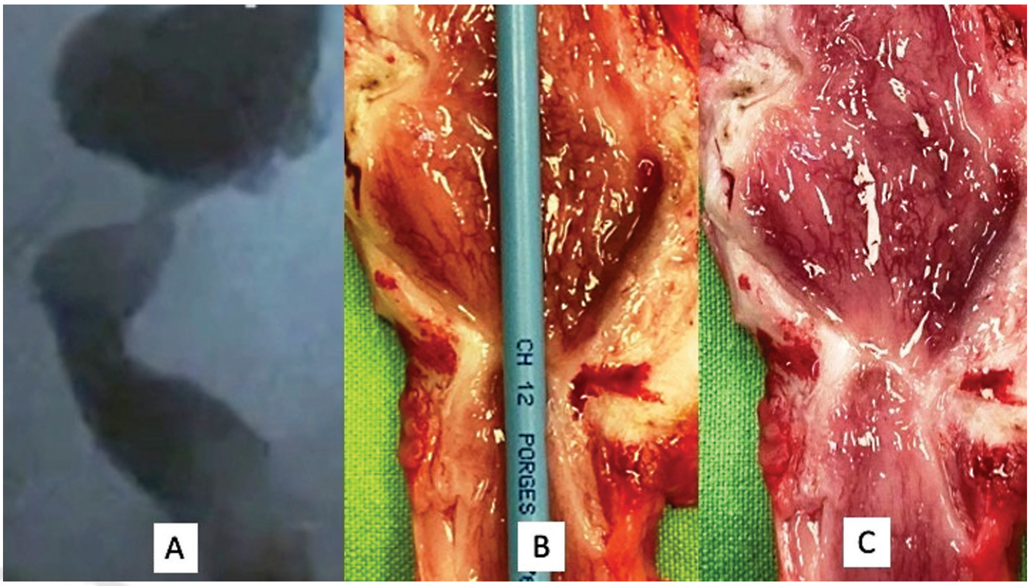

Fig. 3 Following removal of the pyeloureteral magnetic anastomosis device (PUMA) a retrograde contrast study revealed a patent anastomosis (**A**), which was confirmed on autopsy (**B**, **C**).

corresponds to the weight of a 13-year-old boy according to UK growth charts. In retrospect, we have learned that the size of the ureter in young domestic pigs is significantly smaller compared with humans. In Clavica et al's study, ureters of eight domestic pigs (aged between 6 and 8 months) were harvested, cut at 15 points from the UPJ to the UVJ, and the inner and outer diameters were measured. At the junction between the upper and mid-portion, the internal diameter of the ureter was 3.0 ± 0.6 mm, and the upper part of the mid-ureter was only 2.4 to 2.6 mm.[17] This clearly explains our difficulties with the first two animals when trying to insert the 5-mm diameter device. The ureter was not stretchable enough to accommodate the few-centimeter-long device.

In animal number 3, removal of the insulation from the ureteric magnet reduced the diameter to 4 mm, which enabled us to pass the device into the distal ureter. However, this resulted in an asymmetric magnetic pair (i.e., loss of a symmetric low-pressure zone) and may have been the reason for the magnets dislodging above the newly formed anastomosis. In any case, we believe it is mandatory to keep the lumen open for some time once the anastomosis has been established to prevent early scarring and subsequent stricture formation. In fact, the outcome after pediatric pyeloplasty with a temporary stent left in situ seems superior to stent-less procedures.[18]

In addition to the need to create a symmetric anastomosis, the spare magnet in our device was attached to the tip of a Malecot catheter. This seemed to prevent early dislocation of the catheter after fusion and formation of the anastomosis.

Ultimately, our decision to alter the study protocol and wait an additional 4 weeks in the hope of finding ureters with larger lumens was successful. The implantation of the PUMA in the last two animals (number 4 and number 5) was unproblematic.

Unfortunately, we lost one animal (pig number 4) due to malignant hyperthermia. A careful evaluation of the anesthesia protocol revealed that vital parameters began to deteriorate even before the insertion of the device. Therefore, we speculate that not the PUMA itself, but some of the anesthetic drugs, environmental factors, or unknown medical conditions must have triggered the reaction.

Although the insertion of the device was performed with ease in animal number 5, the maximum observation time was limited due to a subsequent rapid weight gain in the domestic pig. Subsequently, the experiment was discontinued at a weight of 135 kg, as both the capacity of the animal laboratory and the accompanying infrastructure (i.e., the operating table rated for a maximum total weight of 140 kg) had reached their limits.

This experimental series in five domestic pigs has clear limitations. Finally, we were only able to complete the planned protocol and achieve a longer follow-up time in one animal (i.e., a 20% success rate). In retrospect, it would have been more sensible to wait initially until the ureter size in the test animals was sufficiently large (i.e., weight $\geq$ 68 kg) to allow the device with a 5 mm diameter to be inserted without difficulty. In theory, reducing the diameter of the magnets while maintaining the same magnetic strength might have been another option to overcome our problem with the small ureteric diameter in domestic pigs. However, in a test series, we found that smaller magnets (i.e., 3 mm outer diameter, 1.7 mm inner diameter, 8 mm length, and a maximum N52 magnetization) did not seem to provide adequate magnetic force to create a sufficient anastomosis. Another possible way to reduce the magnet diameter while maintaining the same strength, which should be tested in the future, might be achieved through an oblique alignment of the contact surfaces.

In selecting the animal model, we relied on previous experience, where minipigs and farm pig models appear to be optimal for experimental research on upper urinary tract surgery using an endoscopic approach.[19] While the study on ureteric magnetic anastomosis itself is promising, the present model does not seem suitable for achieving a follow-up time beyond 12 weeks. Recently, An et al reported a successful formation of ureterovesical anastomoses using magnetic compression force in New Zealand rabbits. For this, magnets with a diameter of 5 mm were applied 4 weeks after the initial ligation of the ureters at the level of the UVJ.[20] However, it is questionable whether the rabbit model, due to the short ureters and differing histology,[19] is suitable for our experimental purposes.

Ultimately, in this test series, a patent pyeloureteral anastomosis could be achieved by laparoscopic application of the PUMA, considering the technical limits of the prototype and the hydronephrotic domestic pig model. To the best of our knowledge, this is the longest observation ever reported on a magnetic upper ureteric anastomosis in vivo in animals.

Clearly, in recent years, MCA ("magnamosis") has become an innovative tool and has already been sporadically applied in adult[21,22] and pediatric urology.[10] Nevertheless, we believe it is important to further extend the follow-up period with the PUMA in a different experimental setting before transferring it into medical practice, especially since cases have been described after renal transplantation in which pyeloureteral stenosis was observed as a late complication.[23]

Authors' Contribution

R.K. collected the data (animal laboratory), participated in data analysis and interpretation, and wrote the manuscript. Z.H. participated in data collection (animal laboratory) and data analysis. D.C. participated in data collection (animal laboratory) and data analysis. A.F. participated in data collection (animal laboratory) and data analysis. T.C. designed the study, collected the data (animal laboratory), and participated in data analysis and interpretation. All authors have approved the final manuscript.

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Conflict of Interest

None declared.

References

1 Pérez-Marchán M, Pérez-Brayfield M. Comparison of laparoscopic pyeloplasty vs. robot-assisted pyeloplasty for the management of ureteropelvic junction obstruction in children. Front Pediatr 2022;10(10):1038454
2 Silay MS, Spinoit AF, Undre S, et al. Global minimally invasive pyeloplasty study in children: results from the Pediatric Urology Expert Group of the European Association of Urology Young Academic Urologists working party. J Pediatr Urol 2016;12(04):229.e1–229.e7
3 Blanc T, Abbo O, Vatta F, et al. Transperitoneal versus retroperitoneal robotic-assisted laparoscopic pyeloplasty for ureteropelvic junction obstruction in children. A multicentre, prospective study. Eur Urol Open Sci 2022;41:134–140
4 Esposito C, Masieri L, Castagnetti M, et al. Robot-assisted vs laparoscopic pyeloplasty in children with uretero-pelvic junction obstruction (UPJO): technical considerations and results. J Pediatr Urol 2019;15(06):667.e1–667.e8
5 Doublet JD, Janetschek G, Joyce A, Mandressi A, Rassweiller J, Tolley D. The difficulty scoring system of laparoscopic procedures. In: European Association of Urology Guidelines on Laparoscopy; pp14–16. Accessed May 10, 2024 at: https://d56bochluxqnz.cloudfront.net/media/laparoscopy.pdf
6 Echeverria P, Reed L F, Gatti JM, et al. Latitudes and attitudes: a multinational study of laparoscopic pyeloplasty in children. J Pediatr Urol 2023;19(01):86.e1–86.e6
7 Langreen S, Ludwikowski B, Dingemann J, Ure BM, Hofmann AD, Kuebler JF. Laparoscopic pyeloplasty in neonates and infants is safe and efficient. Front Pediatr 2024;12:1397614
8 Jamshidi R, Stephenson JT, Clay JG, Pichakron KO, Harrison MR. Magnamosis: magnetic compression anastomosis with comparison to suture and staple techniques. J Pediatr Surg 2009;44(01):222–228
9 Graves CE, Co C, Hsi RS, et al. Magnetic compression anastomosis (Magnamosis): first-in-human trial. J Am Coll Surg 2017;225(05):676–681.e1
10 Kotlovsky AM, Muensterer OJ, Nikolaev VV, Razumovskiy AY. Magnetic compression anastomosis-past experience and current proposals for further development in pediatric minimally invasive surgery. Children (Basel) 2023;10(08):1328
11 Cserni T, Urban D, Hajnal D, et al. Pyeloureteric magnetic anastomosis device to simplify laparoscopic pyeloplasty: a proof-of-concept study. BJU Int 2021;127(04):409–411
12 Hornok Z, Ferencz A, Kubiak R, Cserni T. Cheap and clean dry balloon training model for laparoscopic pyeloplasty. J Pediatr Urol 2023;19(04):471–473
13 MacArthur Clark J. The 3Rs in research: a contemporary approach to replacement, reduction and refinement. Br J Nutr 2018;120(s1):S1–S7
14 Bowen J, Cranley J, Gough D. The flank approach to the porcine upper urinary tract: safe and reliable. Lab Anim 1995;29(02):204–206
15 Hellström M, Hjälmås K, Jacobsson B, Jodal U, Odén A. Normal ureteral diameter in infancy and childhood. Acta Radiol Diagn (Stockh) 1985;26(04):433–439
16 Radmayr C, Bogaert G, Burgu B, et al. European Association of Urology Guidelines on Paediatric Urology. 2022:78. Accessed August 10, 2024 at: https://d56bochluxqnz.cloudfront.net/documents/full-guideline/EAU-Guidelines-on-Paediatric-Urology-2022.pdf
17 Clavica F, Zhao X, ElMahdy M, Drake MJ, Zhang X, Carugo D. Investigating the flow dynamics in the obstructed and stented ureter by means of a biomimetic artificial model. PLoS One 2014;9(02):e87433
18 Liu X, Huang C, Guo Y, Yue Y, Hong J. Comparison of DJ stented, external stented and stent-less procedures for pediatric pyeloplasty: a network meta-analysis. Int J Surg 2019;68:126–133
19 Wolf JS Jr, Humphrey PA, Rayala HJ, Gardner SM, Mackey RB, Clayman RV. Comparative ureteral microanatomy. J Endourol 1996;10(06):527–531
20 An Y, Zhang M, Xu S, et al. An experimental study of magnetic compression technique for ureterovesical anastomosis in rabbits. Sci Rep 2023;13(01):1708
21 Shlomovitz E, Copping R, Swanstrom LL. Magnetic compression anastomosis for recanalization of complete ureteric occlusion after radical cystoprostatectomy. J Vasc Interv Radiol 2023;34(09):1640–1641
22 Ünal E, Çiftçi TT, Akinci D. Magnetic compression anastomosis of benign short-segment ureteral obstruction. J Vasc Interv Radiol 2024;35(03):398–403
23 Parra I, Rivas JG, Gutíerrez B, et al. Pyeloureteral anastomosis as a reconstructive technique for post-renal transplant ureteral stenosis. Urol Res Pract 2023;49(06):406–412

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How I do it

Cheap and clean dry balloon training model for laparoscopic pyeloplasty

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Summary
Simulation-based training (SBT) has a significant role in training in complex procedure like laparoscopic pyeloplasty. We propose a new training model for laparoscopic pyeloplasty which has been compared to other models. Trainees (n = 22) evaluated our balloon model (BM) and three other models -glove finger model (GFM), chicken thigh model (ChTM) and chicken crop model (ChCrM)- subjectively, based on a 5-point Likert scale. The face validity mean score of our BM model was 3.58 ± 0.69. Our novel model can be a cost-effective, hygienic, and easy-access alternative to other laparoscopic pyeloplasty models.

Simulation-based training (SBT) has a very important role in surgical education, especially in minimally invasive pediatric surgery and urology [1,2].

Our aim was to compare our novel training model to other three, previously described laparoscopic pyeloplasty models in terms of face validity (Fig. 1).

BM is made from a spherical birthday balloon, representing the dilated renal pelvis and a sausage balloon, representing the proximal ureter. The spherical balloon was cut and sutured to a kidney-shaped sponge. The FGM is made from a latex glove: palm of the glove represented the dilated renal pelvis, finger of the glove represented the proximal ureter and a knot on it was considered as pyeloureteral junction obstruction [3]. The ChTM is made from reconfigured and sutured skin of a chicken thigh represented dilated renal pelvis and ureter [4]. The ChCrM is made from chicken crop stitched to pig kidney: crop filled with water simulated the dilated renal pelvis and chicken esophagus represented the proximal ureter [5]. All models were created by the same surgeon (ZH).

Twenty-two trainees (Table 1) attending a one-day laparoscopic skill training course were recruited in the study. They performed some intracorporeal knots and continuous suture on each model laparoscopically in random order and the models were assessed based on design, realism, similarity in size, tactile sensation, suturability, usability, and handling.

Thereafter they completed a 7 items Likert-based, non-validated questionnaire. The 5-point Likert scale is a type of psychometric response scale in which participants specify their level of agreement to a statement in five points: (1) very poor; (2) poor; (3) fair; (4) good; (5) excellent. A one-way ANOVA calculator was used to compare the models.

The study was conducted after the approval of the ethical committee and obtaining written informed consent. Semmelweis University's IRB number is IRB00013042.

All results are summarised in a table and a diagram (Fig. 2, Table 2).

In this study two low-fidelity, synthetic models and two high-fidelity animal-based models were compared.

The low-fidelity synthetic models (GFM, BM) have the advantages of being easy to replicate and available for domestic use, thus promoting repeated practice.

The animal-based high-fidelity models (ChTM, ChCrM) provide a more realistic experience, but they require special handling, including cold storage, a separate place or laboratory for practice, and thorough clean-up and disinfecting procedures after the practice to prevent infections. These models are not suitable and comfortable for domestic use.

The BM was found to be significantly superior to FGM and ChTM in design, realism and similarity in size. BM received generally high values, it scored below 4 only in tactile sensitivity and suturability.

This study gathered only on non-expert' feedback. Objective parameters, such as anastomotic construction time and reliability were not tested, and the sample size was small. The trainees assessed the models in

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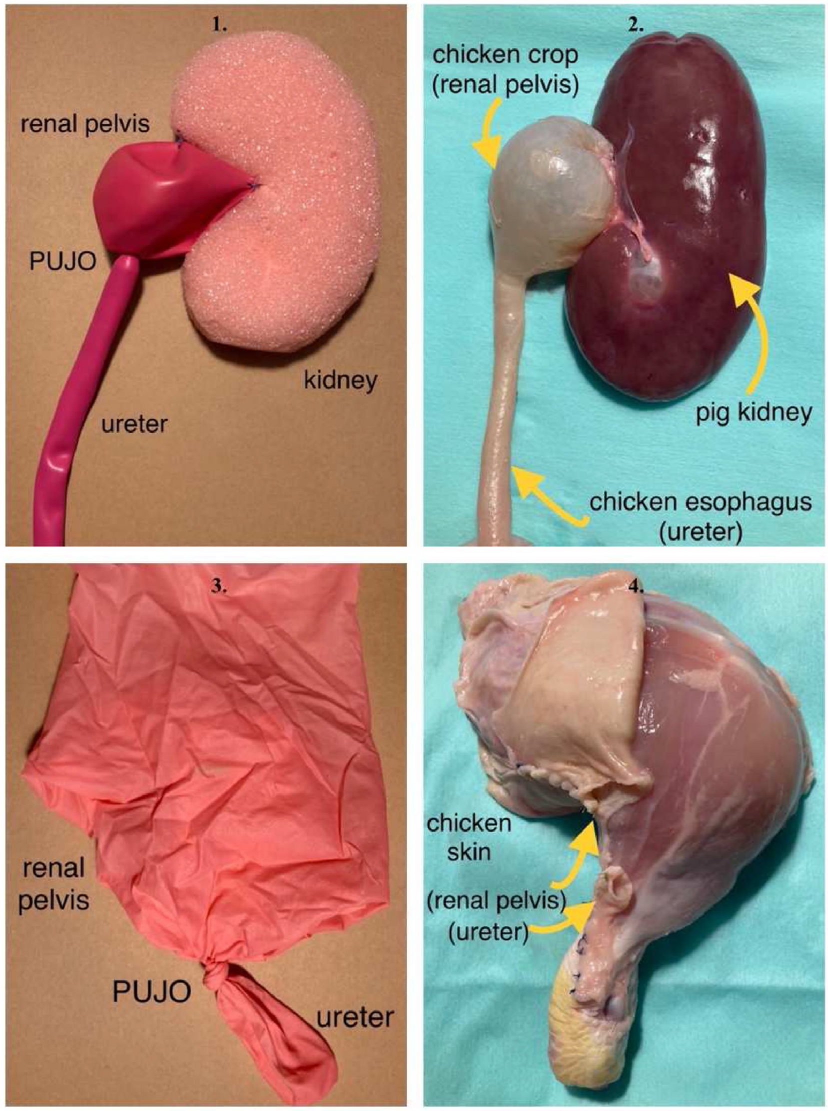

Fig. 1 1. Balloon model (BM), 2. Chicken crop model (ChCrM), 3. Finger glove model (FGM), 4. Chicken thigh model (ChTM).

Table 1 Demographic data of trainees.

Surgical specialities	Number of trainees (%)
general surgery	10 (45%)
pediatric surgery	4 (18%)
gynecology	4 (18%)
urology	3 (14%)
neurosurgery	1 (5%)
Operative experience	
1 year	1 (5%)
2 years	14 (64%)
3 years	5 (23%)
4 years	0
5 years	1 (5%)
6 years	1 (5%)
Laparoscopic experience	
yes	16 (73%)
no	6 (27%)

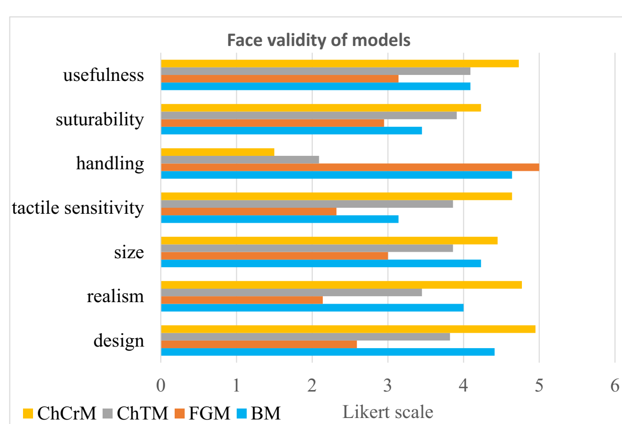

Fig. 2 Analysis of the survey results.

Table 2 Trainees subjective scores (mean ± SD) on the models, based on a 5-point Likert scale. The differences between face validity mean scores were statistically significant ($p = 0.00001$).

	BM	FGM	ChTM	ChCrM
design	4.41 ± *0.59*	2.59 ± *1.05*	3.82 ± *0.91*	4.82 ± *0.50*
realism	4.00 ± *0.76*	2.14 ± *0.99*	3.45 ± *1.06*	4.77 ± *0.43*
size	4.23 ± *0.75*	3.00 ± *0.69*	3.86 ± *0.56*	4.45 ± *0.74*
tactile sensitivity	3.14 ± *0.83*	2.32 ± *0.72*	3.86 ± *0.64*	4.64 ± *0.49*
handling	4.64 ± *0.49*	5.00 ± *0*	2.09 ± *0.61*	1.50 ± *0.51*
suturability	3.45 ± *0.96*	2.95 ± *0.95*	3.91 ± *0.68*	4.23 ± *0.61*
usefulness	4.09 ± *0.87*	3.14 ± *0.89*	4.09 ± *0.75*	4.73 ± *0.46*
MEAN SCORE	**3.99 ± *0.53***	**3.02 ± *0.95***	**3.58 ± *0.69***	**4.16 ± *1.19***

random order, which could potentially affect the outcomesof our study.

BM can be considered as a useful high-fidelity, easy access, cheap, hygienic, domestic-use training tool for suturing and hand-eye coordination which are prerequisite for successful laparoscopic pyeloplasty.

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Conflicts of interest

The authors have no conflict of interests.

References

[1] Barsness K. Simulation-based education and performance assessments for pediatric surgeons. Eur J Pediatr Surg 2014;24(4): 303–7. https://doi.org/10.1055/s-0034-1386650.

[2] Mei H, Pu J, Yang C, Zhang H, Zheng L, Tong Q. Laparoscopic versus open pyeloplasty for ureteropelvic junction obstruction in children: a systematic review and meta-analysis. J Endourol 2011;25(5):727–36. https://doi.org/10.1089/end.2010.0544.

[3] Raza SJ, Soomroo KQ, Ather MH. "Latex glove" laparoscopic pyeloplasty model: a novel method for simulated training. Urol J 2011;8(4):283–6. PMID: 22090046.

[4] Ooi J, Lawrentschuk N, Murphy DL. Training model for open or laparoscopic pyeloplasty. J Endourol 2006;20(2):149–52. https://doi.org/10.1089/end.2006.20.149.

[5] Jhala T, Zundel S, Szavay P. Surgical simulation of pediatric laparoscopic dismembered pyeloplasty: reproducible high-fidelity animal-tissue model. J Pediatr Urol 2021;17(6): 833.e1–4. https://doi.org/10.1016/j.jpurol.2021.09.015.

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Esophageal Magnetic Anastomosis Device (EMAD) to simplify and improve outcome of thoracoscopic repair for esophageal atresia with tracheoesophageal fistula: A proof of concept study

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ABSTRACT

Background: We designed a new Esophageal Magnetic Anastomosis Device (EMAD) for thoracoscopic repair of esophageal atresia (EA) with tracheoesophageal fistula (TEF) without the need of handheld suturing or additional gastrostomy.
Methods: *Synthetic EA-TEF model:* Spherical and tubular shaped rubber balloons and a term infant sized plastic doll were used. Medical students ($n = 10$) and surgical trainees ($n = 10$) were asked to perform thoracoscopic repair of an "EA" with a hand sutured anastomosis (HA) and with the EMAD. *Euthanized animal model:* The esophagus in 5 piglets (3–4 kg) was dissected and a thoracoscopic esophageal magnetic anastomosis (EMA) was performed. *Bursting pressure (BP) and pulling force (PF):* HA and EMA were created on ex vivo New Zealand white rabbit (2.5–3 kg) esophagi ($n = 25$ in each test series). BP and PF were measured and compared against each other.
Results: Medical students were unable to complete HA, but were successful with the EMAD in 11.1 ± 2.78 min. Surgical trainees completed EMA in 4.6 ± 2.06 min vs. HA 30.8 ± 4.29 min ($p<0.001$). The BP following a HA (14.1 ± 3.32 cmH_2O) was close to the physiological intraluminal pressure reported in a neonatal esophagus (around 20 cmH_2O), whereas the BP with the EMAD was extremely high (>90 cmH_2O) ($p<0.001$). The PF of an EMA (1.8 ± 0.30 N) was closer to the safety limits of anastomotic tension reported in the literature (i.e. 0.75 N) compared with the HA (3.6 ± 0.43 N) ($p<0.0001$).
Conclusion: The EMAD could simplify, shorten, and potentially improve the outcome of thoracoscopic repair for EA with TEF in the future. A high BS and a relative low PF following EMAD application may lower the risk of postoperative complications such as esophageal leakage and stricture formation.

1. Introduction

Thoracoscopy in children is well established. However, the requirement of high level endoscopic suturing skills and a long procedural time in complex operations such as esophageal atresia (EA) repair reduces the acceptability of MIS in neonates [1]. Additionally, thoracoscopic repair of EA has not been proven to be superior in terms of postoperative complications compared with an open repair [2].

Magnetic compression anastomosis (MCA) was originally designed to simplify and shorten surgical procedures by eliminating the need for suturing and to reduce the risk of anastomotic leakage by providing equal and continuous tissue compression (i.e. better seal compared with a conventional hand held suture) [3]. The Harrison ring has been approved by the U.S. Food and Drug Administration (FDA) for intestinal anastomoses [4]; the Flourish device was designed to repair long gap EA without tracheoesophageal fistula (TEF) and has been reported to eliminate anastomotic leakage completely [5]; the Connect-EA has been successfully used for EA repair in neonates [6]. However, in both of the latter devices a two-staged procedure is required - 1) thoracoscopy (or thoracotomy) in order to ligate the fistula and/or insert a gastrostomy followed by 2) insertion of magnets [5,6].

Most recently, our group reported on the pyeloureteral magnetic anastomosis (PUMA) device with a unique delivery system, which significantly simplifies laparoscopic pyeloplasty in an experimental setting [7]. Based on the PUMA concept, this paper reports our technique of performing a one-stage procedure - thoracoscopy for ligation of fistula and simultaneous insertion

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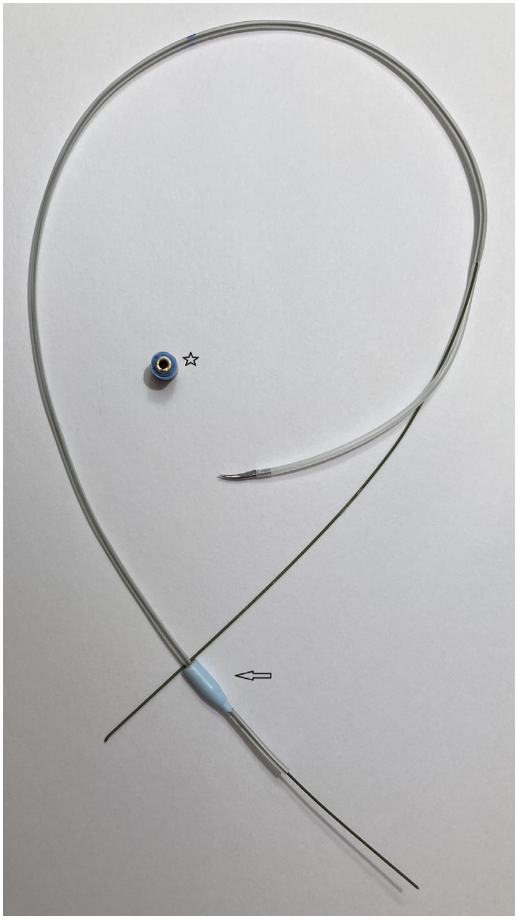

Fig. 1. Esophageal Magnetic Anastomosis Device (EMAD) with fixed "lower pouch magnet" (arrow) and free "upper pouch magnet" (star).

of magnets together with a transanastomotic feeding tube. Of note, our primary objective is not to review the validity of using magnets for creating an esophageal anastomosis since this has been reported previously [5,6]. Our aim is rather to assess a new method of delivering the magnets thoracoscopically for simultaneous EA and TEF repair. Crucially, there is no need for gastrostomy and mini-laparotomy, there is no need for endoscopy, and there is no need for image-intensifier.

2. Material and methods

2.1. Device

The Esophageal Magnetic Anastomosis Device (EMAD) was built with two N35 neodymium nickel coated magnetic cylinders with 4 mm outer diameter, 2 mm inner diameter and 8 mm length. The first magnet ("lower pouch magnet") is fixed to a 6 Fr soft feeding tube and a 3/8 circle, custom-made needle (Meditű KFT, Makó, Hungary). A second magnet is "free" in order to be administered orally into the upper pouch (Fig. 1).

2.2. Assessment of ease, speed and feasibility of using EMAD

2.2.1. Anastomotic construction time in a synthetic EA-TEF model

An EA-TEF model was made out of spherical and tubular shaped rubber balloons fixed in a term infant sized baby doll. It was cut in half in the sagittal plane and placed in the left hemidecubitus position in order to simulate a realistic surgical position. Plastic tubes were used to represent authentic anatomical structures such as trachea, azygos vein and vagal nerve. A 5 mm port was inserted in the "fifth intercostal space" at the lower edge of the scapula for a USB camera that was connected to a personal computer. For instrumentation, a 3 mm port was placed into the right thoracic cavity in the "third intercostal space" in the mid-axillary line, and another 5 mm port at the level of the "fifth intercostal space" further posteriorly (Fig. 2).

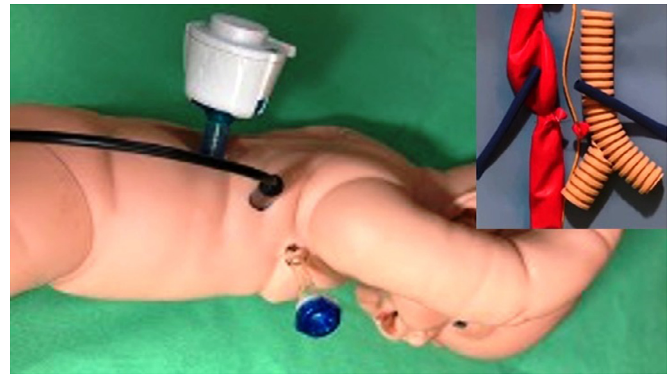

Fig. 2. Synthetic EA-TEF model.

Two groups were studied: ten ($n = 10$) medical students with no previous experience in laparoscopic surgery and ten ($n = 10$) general surgical trainees, who had been enrolled into a laparoscopic skills training program. They were asked to perform an anastomosis within the model by using both methods, a conventional laparoscopic single layer hand sutured end-to-end anastomosis (HA) with 6 knots and the EMAD. Prior to the procedure all participants viewed a short instructional video.

The operating time (t) for each method (HA versus EMAD) was measured from the moment the instruments were touched until removal of all instruments.

2.2.2. Euthanized animal model

Five euthanized piglets (weighing 3–4 kg) were used to perform the new EMAD method. All operations were carried out by the same surgeon (ZH). The piglets were placed in the left recumbent position. A 5 mm optical Visiport trocar was inserted under video guidance just below the tip of the right scapula. A 5 mm port was placed in the fourth intercostal space close to the spine and another 3 mm port at the same level with projection to the anterior axillary line. A pneumoperitoneum with 10 mmHg CO_2 was established. The azygos vein, trachea, and esophagus were identified. Following mobilization, the esophagus was transected. The upper end was ligated with either an Endoloop or a 5 mm clip. The first magnet of the EMAD was introduced via the 5 mm port and directed into the lower pouch. The needle of the device was then pulled into the chest and stitched in an inside-out fashion into the lower pouch. Following removal of the needle, the lower pouch of the esophagus was closed with a clip. Subsequently, a semi flexible endoscopic forceps was introduced from orally and pushed through the wall of the upper pouch. The end of the stent was grasped and pulled out through the mouth. Finally, the second magnet was introduced and pushed down on the stent into the upper pouch while the stent was simultaneously pulled towards cranial until the two pouches with magnets met head on (Video).

2.3. Validation of anastomotic integrity

2.3.1. Bursting pressure

Fifty esophagi with an equal length of 10 cm were taken from on-farm sacrificed adult New Zealand white rabbits (weighing 2.5 to 3 kg). In order to assess the bursting pressure (BP) they were

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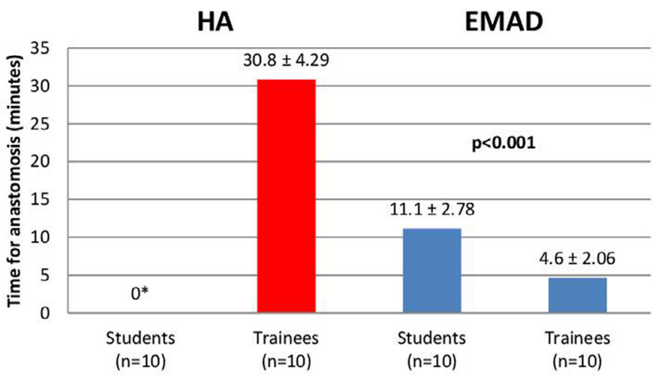

Fig. 3. Comparison of time for hand sutured end-to-end anastomosis (HA) and use of EMAD performed by medical students and surgical trainees. *, medical students were unable to complete HA.

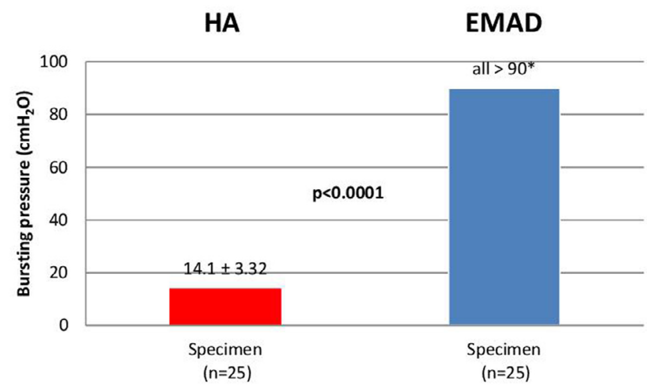

Fig. 4. Comparison of bursting pressure (cmH_2O) following HA and application of the EMAD in rabbit esophagi. *, the maximum of 90 cm hydrostatic head in our experimental setting was exceeded in all specimen following the EMAD technique.

transected transversely and randomly divided into two groups: end-to-end HA in group A ($n = 25$) and end-to-side esophageal magnetic anastomosis (EMA) in group B ($n = 25$). For the HA interrupted suture were performed with two corner stitches followed by two stitches each in the anterior and posterior esophageal wall using USP 4–0 polydioxanone. All preparations were carried out by the same surgeon (ZH). The hydrostatic pressure was measured in both groups in compliance with the principle of communicating vessels. A clamp was placed on the distal end of the esophagus and the proximal end was filled with water stained with methylene blue at a steady rate. The pressure when the anastomosis began to leak was defined as “bursting pressure”.

2.3.2. Pulling force

Fifty esophagi with an equal length of 10 cm were taken from on-farm sacrificed adult New Zealand white rabbits (weighing 2.5 to 3 kg). Subsequently, the pulling force (PF) was measured in $n = 25$ for each group (i.e. HA versus EMDA). For this purpose, one end of the resected esophagus was mounted on a table and the other end was attached by traction sutures to a dynamometer. The ends were then stretched at a constant speed. The pulling force was defined as the pressure applied when the ends of the anastomosis started to come apart.

2.4. Statistical analysis

Data were expressed as mean (± SEM) as stated. The Student's *t*-test was applied for comparison of the results. P-values ≤ 0.05 were considered statistically significant.

3. Results

3.1. Assessment of ease, speed and feasibility of using EMAD

3.1.1. Anastomotic construction time in the EA-TEF synthetic model

The results are presented in Fig. 2. Medical students were unable to complete the conventional hand sutured anastomosis (HA) at all. Surgical trainees were able to cope with either method. In the latter subgroup ($n = 10$) the time for the esophageal magnetic anastomosis (tEMA) was significantly shorter (4.6 ± 2.06 min) compared with tHA (30.8 ± 4.29 min) ($p<0.001$) (Fig. 3).

Medical students were able to successfully complete an anastomosis with the EMAD. Although it took them considerably longer than their experienced colleagues (11.1 ± 2.78 min vs. 4.6 ± 2.06 min; $p<0.001$), the time was still significantly shorter in relation to tHA (11.1 ± 2.78 min vs. 30.8 ± 4.29 min) ($p<0.001$).

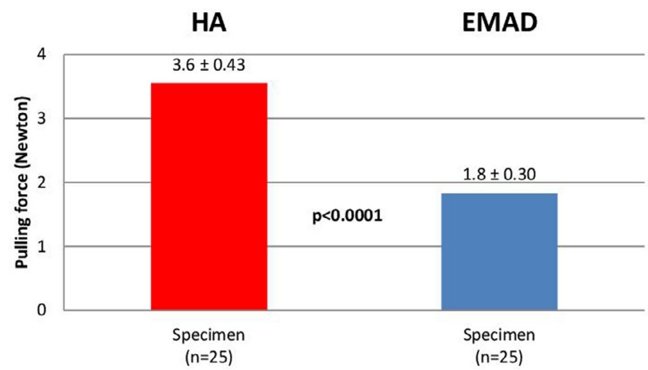

Fig. 5. Comparison of pulling force (Newton) following HA and application of the EMAD technique in rabbit esophagi.

3.1.2. Procedure in euthanized piglets

The application of the new EMAD was feasible in 5 euthanized piglets. No hand held anastomotic suturing was necessary.

3.2. Validation of anastomotic integrity

3.2.1. Bursting pressure

The results are presented in Fig. 4. The mean BP of the EMA ($n = 25$) was significantly higher (>90 cmH_2O) compared with the HA ($n = 25$) (14.1 ± 3.32 cmH_2O) ($p<0.0001$). Of note, BP was above 90 cmH_2O in all cases following magnamosis.

3.2.2. Pulling force

The mean maximum PF of the HA ($n = 25$) (3.6 ± 0.43 N) was significantly higher than the anastomosis using the EMAD ($n = 25$) (1.8 ± 0.30 N) ($p<0.0001$) (Fig. 5).

4. Discussion

A thorascoscopic repair of an EA is a difficult procedure which requires extensive training and expertise. The surgery takes place in a small body cavity (which restricts the ergonomics) and traditionally requires 8–12 hand sutured stitches. This can take place under suboptimal conditions (e.g. the anesthetist may struggle with one lung collapsed, and there may be escape of ventilation through a large fistula). While speed should never be a major criterion for performing complex surgery, in the context of thoracoscopic repair of EA, speed (not haste) is important.

At present, magnetic anastomotic techniques are mainly applied for the treatment of long gap EA without TEF [5,6]. We speculate that, if magnamosis was successful in cases with long gap EA, it could have been even useful for the most common cases of EA with TEF. The benefits with our EMAD would be that the procedure becomes more simple and easy to perform, with a reduced operative time, and potentially less complications (i.e. leakage and stricture formation) compared with the open and/or thoracoscopic standard procedures, after which postoperative sequelae are still reported. This paper describes a technique which effectively shortens the time taken to perform the most difficult technical part of the procedure while still achieving a secure anastomosis. It also obviates the need for a second procedure (i.e. to insert magnets).

The presented technique was modified from a previously described method for performing a pyeloplasty using magnamosis (PUMA) [7]. In both, a smaller caliber tube (i.e. lower esophageal pouch or distal ureter) requires connection to a larger caliber tube/structure (i.e. upper esophageal pouch or renal pelvis) and meticulous surgical skills are mandatory in order to avoid postoperative complications including leakage and stricture formation. This similarity inspired us to develop an EMAD based on the PUMA concept [7].

Our EA-TEF model that was developed to assess the EMAD was built from similar materials used previously for the PUMA simulator. In fact, the size of the balloons (with a diameter of 15 mm) resembles the esophagus even more realistically than the ureter [7]. Overall, our experience with the EMAD was very similar to the PUMA device. The application of either method seemed to require no specific previous MIS skills, but only a short video tutorial and some verbal advice.

Laparoscopic suturing requires practice and skill. Not surprisingly the medical students were unable to perform a hand sutured anastomosis without basic training. However, they all completed the EMA with relative ease. They took a mean of 11.1 min to perform an anastomosis using the EMAD. Although they required longer than the surgical trainees their performance with the new device was still remarkable and still significantly faster compared with the time taken for a HA by their senior colleagues. We feel this provides clear evidence that the EMAD simplifies and shortens the procedure without the burden of a learning curve as described for thoracoscopic EA repair performed with a standard technique [8].

Rabbit esophagi have been previously used as a model for thoracoscopic EA repair and research regarding the quality of esophageal anastomoses [9–11]. The size of the adult rabbit esophagus is comparable with that of a human newborn (on average 5 mm in diameter and 8–10 cm in length). The rationale behind testing mechanical stability in euthanized animals was to demonstrate the stability of the device in the „acute postoperative phase". Since feeding is commenced normally early via the NG tube and associated gastroesophageal reflux and/or esophageal dysmotility are always present to a certain extent, a mechanically more stable „junction" or "anastomosis" is a clear advantage after EA repair. We observed that the anastomotic leak point following a hand sutured anastomosis was much closer to the physiological intraluminal pressure (around 20 mmH_2O) reported in neonates [12] compared with that of the EMA. This suggests a better seal and may explain the lower rate of postoperative anastomotic leakage after EMA in clinical studies [4–6]. Moreover, we speculate that EMA may reduce human errors that occur with hand-held suturing.

Increased tension between the two ends of the anastomosis is a significant problem following EA-TEF repair, particularly in those cases with a longer distance between both ends (i.e. long gap EA). Most recently a Canadian group reported on a higher incidence of stricture formation and the need for numerous dilatations following magnetic repair of EA. [13]. However, in their study only two complicated cases were included, both of which underwent magnamosis after primary repair had failed [13].

It remains vague to define the exact amount of tension in individual patients that is still within tolerable limits in order to minimize the risk of postoperative sequelae, including leakage and/or stricture formation: To the best of our knowledge there is no standard tool available for this except the surgeon's experience. In one study the estimated tension that was considered to be "safe" should not exceed 0.75 N [14].

The maximum pulling force of the magnets used for the EMAD lay between 3 and 4N according the manufacturer's manual (Euromagnet KFT, Budapest, Hungary). As a consequence, if the magnets are not correctly aligned (i.e. magnets are not remaining together) or are easy to separate, the tension between the pouches is probably beyond the safety limit. In this study, the mean pulling force in an ex vivo model using rabbit esophagi was significantly lower with the EMAD compared with a hand sutured anastomosis (1.8 versus 3.6 N). Therefore, we believe that an EMAD rather may help the surgeon to assess whether an esophageal anastomosis is still safe or possibly necessitates a change of strategy, such as extended mobilization of the upper and/or lower pouch or a staged repair [15,16]. Ideally, if we knew the minimal force required for the anastomosis and add the safe tension limit, we could have then created the optimal magnetic strength for our device.

The application of our EMAD results in an end-to-side anastomosis. Previous studies have described end-to-side repair of esophageal atresia with ligation of the fistula as a possible alternative to an end-to-end anastomosis with no significant difference in the postoperative leakage rate [17,18].

The use of endoclips for TEF closure is debatable, however, there are no reported long-term complications with this method and the use of clips simplifies and shortens the procedure [19,20]. For practical reasons we used simple titanium clips in our model on five euthanized piglets for closure of the distal esophageal end. Since a certain amount of tension towards the (clipped) distal esophageal pouch can be expected this approach could be associated with an increased risk (i.e. dislodgement of the clip) in vivo. We would therefore recommend the application of special endoclips ideally with a chevron shape and/or a locking system in order to provide a tip-to-tip closure and ensuring more secure containment of the tissue. During the insertion of the EMAD it is also important to keep an appropriate distance from the esophageal end of the dissected fistula when the device is being stitched in. This is in order to further reduce the tension towards the clip by providing an adequately sized stump. In this context we would like to stress the point that significant tension of the anastomosis should be generally avoided. In those cases in which the magnets are not coming together smoothly, a different technique should be considered.

This study is limited because it focuses on a new surgical method with a new delivery system that was only tested in a simulator (i.e. plastic doll) and ex vivo tissue, but not within an in vivo animal model. Survival of the animals (i.e. keeping the animals alive after esophageal dissection and anastomosis with the EMAD) would have been very difficult. Moreover, the safety and benefits of magnetic anastomoses have been already shown in animal and human studies [6,21,22].

The guide wire that is passed via the trocar into the lower stump to facilitate the insertion of the stent with the needle and the first magnet attached is considered as being sterile. However, the grasper which is introduced trough the upper pouch into the mediastinum in order to pull the stent out into the mouth will create a small caliber hole; hence this maneuver may be associated with an increased risk of infection. Nevertheless, this "iatrogenic lesion" is significantly smaller (i.e. less than 2 mm) than the outer diameter of the magnet applied (5 mm). Unless there was no exceeding tension (e.g. long gap EA), in which case a primary anastomosis with the EMAD is usually not recommended and would have been swapped to another approach/technique, the (second) magnet will not pass through this hole and should provide an adequate seal. In this context, as part of the "gold standard" (open and/or thoracoscopic) EA-TEF repair the upper pouch is opened routinely to advance an NG tube further into the lower pouch. This is also a potential source of contamination to the mediastinum, but not considered as a major risk, particularly since the patients are normally commenced on prophylactic antibiotics.

With regard to the analysis of the bursting pressure in rabbit esophagi all EMDA samples exceeded 90 cmH_2O. Because of our experimental setting with a maximum of 90 cm hydrostatic head exact numbers are missing. Nevertheless, a significant difference compared with the bursting pressure following a HA could be detected.

Overall, we feel that the presented investigations provide sufficient evidence for proof of concept and possible benefits of an EMAD.

5. Conclusion

In conclusion, the EMAD based on the PUMA concept may simplify and improve outcome for thoracoscopic repair of EA with TEF in the future.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jpedsurg.2022.09.040.

References

[1] Bishay M, Giacomello L, Retrosi G, et al. Hypercapnia and acidosis during open and thoracoscopic repair of congenital diaphragmatic hernia and esophageal atresia: results of a pilot randomized controlled trial. Ann Surg 2013;258:895–900. doi:10.1097/SLA.0b013e31828fab55.
[2] Pinheiro PF, Simões e Silva AC, Pereira RM. Current knowledge on esophageal atresia. World J Gastroenterol 2012;18:3662–72. doi:10.3748/wjg.v18.i28.3662.
[3] Obora Y, Tamaki N, Matsumoto S. Nonsuture microvascular anastomosis using magnetic rings: preliminary report. Surg Neurol 1978;9:117–20.
[4] Graves CE, Co C, Hsi RS, et al. Magnetic compression anastomosis (magnamosis): first-in-human trial. J Am Coll Surg 2017;225:676–81 e1. doi:10.1016/j.jamcollsurg.2017.07.1062.
[5] Zaritzky M, Ben R, Zylberg GI, et al. Magnetic compression anastomosis as a nonsurgical treatment for esophageal atresia. Pediatr Radiol 2009;39:945–9. doi:10.1007/s00247-009-1305-7.
[6] Muensterer OJ, Evans LL, Sterlin A, et al. Novel device for endoluminal esophageal atresia repair: first-in-human experience. Pediatrics 2021;148:e202004962. doi:10.1542/peda.2020-049627.
[7] Cserni T, Urban D, Hajnal D, et al. Pyeloureteric magnetic anastomosis device to simplify laparoscopic pyeloplasty: a proof-of-concept study. BJU Int 2021;127:409–11. doi:10.1111/bju.15301.
[8] Van der Zee DC, Tytgat SH, Zwaveling S, et al. Learning curve of thoracoscopic repair of esophageal atresia. Word J Surg 2012;36:2093–7. doi:10.1007/s00268-012-1651-8.
[9] Till H, Kirlum HJ, Boehm R, et al. Thoracoscopic correction of esophageal atresia: training in rabbits provides valuable surgical expertise and shortens the learning curve. Pediatr Endosurg Innov Tech 2001;5:235–9. doi:10.1089/10926410152634330.
[10] Crelin ES. Functional anatomy of the newborn. Yale University Press; 1973.
[11] Villegas-Alvarez F, Olvera-Durán J, Rodríguez-Aranda E, et al. Esophageal anastomotic failure: an experimental study. Arch Med Res 2003;34:171–5. doi:10.1016/S0188-4409(03)00028-6.
[12] Pokora TJ, Mammel MC, Thompson TR, et al. Measurement of esophageal pressure in newborn infants using an esophageal balloon gastric catheter. Crit Care Med 1982;10:522–4. doi:10.1097/00003246-198208000-00008.
[13] Wolfe E, Zidane M, Hancock BJ, et al. Magnamosis for esophageal atresia is associated with anastomotic strictures requiring an increased number of dilatations. J Pediatr Surg 2020;55:821–3. doi:10.1016/j.jpedsurg.2020.01.022.
[14] Takada Y, Kent G, Filler RM. Circular myotomy and esophageal length and safe esophageal anastomosis: an experimental study. J Pediatr Surg 1981;16:343–8. doi:10.1016/s0022-3468(81)80692-6.
[15] Bairdain S, Hamilton TE, Smithers CJ, et al. Foker process for the correction of long gap esophageal atresia: primary treatment versus secondary treatment after prior esophageal surgery. J Pediatr Surg 2015;50:933–7. doi:10.1016/j.jpedsurg.2015.03.010.
[16] Bogusz B, Patkowski D, Gerus S, et al. Staged thoracoscopic repair of long gap esophageal atresia without temporary gastrostomy. J Laparoendosc Adv Surg Tech A 2018;28:1510–12. doi:10.1089/lap.2018.0188.
[17] Askarpour S, Ostadian N, Peyvasteh M, et al. End-to-end versus end-to-side anastomosis in the treatment of esophageal atresia or tracheo-esophageal fistula. Arq Bras Cir Dig 2016;29:48–9. doi:10.1590/0102-6720201600010012.
[18] Touloukian RJ, Seashore JH. Thirty-five-year institutional experience with end-to-side repair for esophageal atresia. Arch Surg 2004;139:371–4. doi:10.1001/archsurg.139.4.371.
[19] Chiarenza SF, Bleve C, Zolpi E, et al. The use of endoclips in thoracoscopic correction of esophageal atresia: advantages or complications? J Laparoendosc Adv Surg Tech A 2019;29:976–80. doi:10.1089/lap.2018.0388.
[20] Rothenberg SS. Thorascopic repair of esophageal atresia and tracheoesophageal fistula in neonates, first decadeś experience. Dis Esophagus 2013;26:359–64. doi:10.1111/dote.12054.
[21] Bruns NE, Glenn IC, Craner DR, et al. Magnetic compression anastomosis (magnamosis) in a porcine esophagus: proof of concept for potential application in esophageal atresia. J Pediatr Surg 2019;54:429–33. doi:10.1016/j.jpedsurg.2018.09.014.
[22] Muensterer OJ, Sterlin A, Oetzmann von Sochaczewski C, et al. An experimental study on magnetic esophageal compression anastomosis in piglets. J Pediatr Surg 2020;55:425–32. doi:10.1016/j.jpedsurg.2019.04.029.

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