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Pyeloureteric magnetic anastomosis device to simplify laparoscopic pyeloplasty: a proof-of-concept study

Laparoscopic pyeloplasty is a standard, but demanding operation. According to the European Association of Urology guidelines this procedure scores 13 out of 18 on the difficulty scale [1]. Articulating instruments, three-dimensional video systems and robots may facilitate complex suturing of the ureteropelvic anastomosis at higher financial costs [2,3]. Magnetic compression anastomosis (magnamosis) has been used safely and effectively in the gastrointestinal tract [4,5]; however, it has not been applied in the urinary tract.

The aim of the present study was to prove the concept of magnamosis in the urinary system and to develop a pyeloureteric magnetic anastomosis (PUMA) device in order to simplify laparoscopic pyeloplasty.

The study was conducted using a stepwise approach [6] in six female Vietnamese minipigs, in accordance with the National Institutes of Health guidelines and European Union directive 2010/63 for the protection of animals used for scientific purposes, and was approved by the National Scientific Ethical Committee (V.2480/2017). In order to perform the procedure laparoscopically throughout, a hydronephrosis model [7] was finally applied in animals 5 and 6 (Table 1).

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 or a 4.7-Fr, 12- to 18-cm pyeloureteric stent (Salle stent). The 'ureteric' magnet was fixed to the stent. The 'pelvic' magnets were left unattached in animals 1 and 2, but inserted/fixed into a 10-Fr 'nephrostomy' tube (animals 3 and 4) or into a Malecot catheter tip (animals 5 and 6), respectively. A surgical needle (31 mm ½ c tapered) was integrated into the proximal end of the stents using cyanoacrylate glue.

The stents with the 'ureteric' magnet were threaded into the ureter and/or the bladder. The proximal part of the stents with the integrated needle was stitched inside-out from the ureter 10 mm below the free end, which was closed with a 5-mm titanium clip (Video S1).

The stents were stitched into the 'pelvis' in an outside-inside fashion. The 'pelvic' magnet was threaded onto the stents. In animals 1, 5 and 6, JJ stents, and in animals 2 to 4, Salle stents were applied, with the proximal tip being brought out as a 'nephrostomy' via a 10-Fr suction catheter in the latter. The 'pelvis' was closed with a 4/0 barbed suture (Polydioxanone, synthetic monofilament absorbable barbed suture) without the need for knot tying (Video S1).

Because each intervention required another anaesthesia, postoperative imaging was kept to a minimum. The animals were killed between 2 (animal 1) and 10 weeks (animal 6) after the procedure, and the anastomoses were assessed macroscopically and/or microscopically, using haematoxylin and eosin staining. The magnets were removed via the vesico-ureteric junction in animals 1 and 5 at autopsy. In animal 6 the PUMA was removed via cystoscopy *in vivo* 4 weeks prior to termination (Table 1).

A PUJ obstruction model, made from a spherical birthday balloon (40 mm, representing the dilated pelvis) and a sausage balloon (5 mm, representing the proximal ureter), was placed on a laparoscopic simulator (Eosurgical Ltd, Edinburgh, UK). Eleven surgeons, experienced in laparoscopy, were asked to perform a laparoscopic ureteropelvic anastomosis using the standard approach followed by using the PUMA device. The time required for the procedures was recorded. The quality of the performance was assessed by the instructor (T.C.) as well as the candidates, and rated with scores ranging from 1 (poor) to 5 (excellent). Subsequently, a time–quality score was calculated using the formula: time–quality score = time × 5/quality score.

After initial failure in animals 1 and 2, a widely patent anastomosis was achieved in animals 3 to 6. After having switched to the hydronephrotic animal model, the procedure was carried out laparoscopically throughout. The need for laparoscopic suturing and knot-tying was eliminated. Removal of the magnetic JJ stent was possible via the vesico-ureteric junction (Table 1). The anastomosis remained widely patent after removal of the device.

In the simulation, the mean time required for the anastomosis dropped from 39.91 $\pm$ 14.08 to 8.18 $\pm$ 2.75 min ($P < 0.0001$) and the quality increased from a median (range) of 3 (2–5) to a median (range) of 5 (3–5) with the PUMA device ($P = 0.0156$). The mean time–quality score was significantly higher (i.e. less favourable) with the standard technique (67.79 $\pm$ 34.42) compared with the PUMA method (9.45 $\pm$ 5.14; $P = 0.0003$). Of note, in each case the time taken for the procedure was shorter and the estimated quality either better or equivalent with the PUMA device.

The ideal magnetic compression force to create a ureteric anastomosis is unknown. A recent experimental study estimated the optimal pressure to be between 79.8 and 169 kPa for an intestinal anastomosis in dogs [8]. The maximal magnetic compression force of the magnets that

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Table 1 Summary of the animal series.

Animal no.	Kidney anatomy	Surgery	PUMA prototype	Postoperative X-ray, day	Position of magnets on day 14	Stent diameter at level of anastomosis*	Removal of stent (day)	Observation/ complications	Appearance of anastomosis
1	Normal	Open	JJ stent with 'pelvic' magnet unattached	0/7/14†	Below anastomosis	4.7 Fr	At autopsy (14), via vesico-ureteric junction	Hydronephrosis	Narrow
2	Normal	Laparoscopy/open‡	Salle stent with 'pelvic' magnet unattached	0/7/14§/28¶	Below anastomosis	4.7 Fr	At autopsy (28)	Hydronephrosis	Narrow
3	Normal	Laparoscopy/open‡	**Salle stent with 'pelvic' magnet fixed in a 10-Fr nephrostomy**	0/7/14	**At level of anastomosis**	**10 Fr**	At autopsy (42)	Normal anatomy	**Good calibre**
4	Normal	Laparoscopy/open‡	**Salle stent with 'pelvic' magnet fixed in a 10-Fr nephrostomy**	14	**At level of anastomosis**	**10 Fr**	At autopsy (42)	Normal anatomy; infection	**Good calibre**
5	Induced hydronephrosis**	Laparoscopy	**JJ stent with 'pelvic' magnet fixed in Malecot tip**	–	n.a.	**12 Fr**	At autopsy (42)	Normal anatomy; infection	**Good calibre**
6	Induced hydronephrosis**	Laparoscopy	**JJ stent with 'pelvic' magnet fixed in Malecot tip**	–	n.a.	n.a.††	Cystoscopy (42) (via vesico-ureteric junction)††	Normal anatomy	**Good calibre**

*n.a., not assessed; PUMA, pyeloureteric magnetic anastomosis. Bold values in table suggest: large caliber stent or the magnets found at the level of the anastomosis after 14 days is associated with good outcome i.e. good caliber anastomosis. *At autopsy. †Retrograde contrast study performed on day 14 prior to termination. ‡Conversion to open surgery required in order to bring Salle stent out as nephrostomy and to insert the (second) 'pelvic' magnet into the non-hydronephrotic (normal) proximal ureter. §Intravenous pyelogram performed on day 14. ¶Nephrostogram performed on day 28 prior to termination. **Loose ligation of the ureter (laparoscopic approach) was performed with a 15-cm long rubber vascular loop [7] 4 weeks prior to pyeloplasty in animals 5 and 6. ††No stent in situ at autopsy; the stent was removed via cystoscopy on day 42, 4 weeks prior to termination.*

were applied in this study lies between 3 and 4 N, as stated by the manufacturer (Euromagnet KFT, Budapest, Hungary). It is well known that the magnetic force is inversely proportional to the square of the distance between the magnets. In order to calculate the magnetic pressure, we considered a 2-mm separation (i.e. two times the ureteric wall thickness) of the magnets since the normal ureteric wall thickness has been estimated to be approximately 1 mm. Subsequently, the area of the magnets was calculated using the equation:

$$\text{Area}_{(\text{surface})} = \text{Area}_{\text{outside}} - \text{Area}_{\text{inside}} = \left(\frac{\text{diameter}_{\text{outside}}}{2}\right)^2 * \pi - \left(\frac{\text{diameter}_{\text{inside}}}{2}\right)^2 * \pi.$$

Therefore, the magnetic pressure in our study ranged between 79.6 and 106.1 kPa, calculated by: $\text{Pressure} = 0.25 * \frac{\text{Force}}{\text{Area}(\text{surface})}$. These numbers were in accordance with the above-mentioned study [8].

In the present series, postoperative X-rays revealed that the magnets did not cut through very rapidly, providing a reasonable time (i.e. 7 days) for the ureteric wall to remodel and heal. Moreover, no extravasation of contrast was seen on intravenous urography. We observed a narrowing of the anastomosis only in animals 1 and 2, in which the magnets passed below and only a small-calibre stent was present at the PUJ 14 days after the procedure. However, good-sized anastomosis was achieved in those animals in which the magnets or large-calibre stent remained at the level of the PUJ for at least 14 days. This may indicate that the anastomosis has to be kept open at a full calibre for a few weeks to prevent stricture. Of note, in animal 6 no narrowing was observed 4 weeks after stent removal.

The simulation revealed a significantly shorter operating time with the PUMA device compared with the standard method. The quality of the new operation (i.e. position and adherence of the magnets) was rated as being equivalent or superior in each case. Moreover, all participants found the new technique less demanding. In addition, although not in accordance with our original study protocol, we asked five paediatric nurses, who had never received training in laparoscopic instrumentation, to perform an anastomosis with the PUMA device in the simulator after watching a short tutorial video. Interestingly, their average time to complete the task was only slightly longer compared with that of the surgeons (10.60 ± 1.67 vs 8.18 ± 2.75 min).

This was a proof-of-concept study and has its limitations. A limited number of animals were used, and only short-term follow-up was applied to prove a patent anastomosis.

In summary, magnamosis has great potential in creating a purpose-built anastomosis device in order to simplify laparoscopic pyeloplasty.

Conflicts of Interest

Tamas Cserni reports a UK patent application filed pending. Daniel Urban, Daniel Hajnal, Daniel Erces, Gabriella Varga, Andras Nagy, Marton Cserni, Mahmoud Marei, Supul Hennayake, and Rainer Kubiak have nothing to disclose.

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Abbreviation: PUMA, pyeloureteric magnetic anastomosis.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Video S1. Pyeloplasty wth the PUMA device (https://www.dropbox.com/s/wf70aknoh561v9u/Video-Puma2.mp4?dl=0).