Surgical Endoscopy
https://doi.org/10.1007/s00464-018-6052-0

A preclinical animal study of a novel, simple, and secure duct and vessel occluder for laparoscopic surgery

Amir Szold[1] · Arnold Miller[2] · Nir Lilach[3] · Ana-Maria Botero-Anug[4] · Raanan Miller[2] · Steven D. Schwaitzberg[5]

Received: 1 August 2017 / Accepted: 11 January 2018

Abstract

Background Secure occlusion of large blood vessels and ductal structures is critical to all surgeries and remains a challenge in many minimally invasive procedures. This study compares in vivo use of the Amsel Occluder (AO) for secure laparoscopic blood vessel and duct closure, with one of the many commercially available hemoclips (Ligaclip®), in the porcine model.

Methods Laparoscopic closure of vessels and ducts was performed on 12 swine to compare the ease of use, safety and efficacy of the AO with a hemoclip, as well as the tissue response at > 30 days (10 swine). All vessels and ducts were occluded and then transected between the occluding clips. Any bleeding or leakage was noted. In the chronic study, confirmation of satisfactory vessel occlusion post nephrectomy was determined by laparotomy as well as by contrast angiography and venography. The tissue response and healing was evaluated by a histopathological study for the effects of any biological incompatibilities.

Results In the acute laparoscopic study, a total of 24 occlusions between 2 and 10 mm were performed with the AO ($n = 19$) and hemoclip ($n = 5$). In the chronic study, 5 nephrectomies (AO $n = 3$, hemoclip $N = 2$) and 5 cholecystectomies (AO $n = 3$, hemoclip $n = 2$) were performed with survival ranging from 42 to 72 days. One pig who sustained a splenic injury at trocar insertion and suffered a delayed ruptured spleen with massive hemorrhage on postoperative day 22. Unlike occlusion with the AO, multiple hemoclips were used for each vessel occlusion. Histopathological examination showed no difference in the tissue response and healing of the AO and hemoclip.

Conclusions The Amsel Vessel occluder delivered laparoscopically provides an occlusion similar to a hand-sewn transfixion suture, is simple to use, and creates an occlusion which is not only more secure, but also as safe with respect to the health of the surrounding tissues, as that of the widely used hemoclip (Ligaclip®).

Keywords Secure mechanical closure of vessels and tubular structures · Hemostasis · Duct occlusion · Transfixion prevents dislodgement · Tissue adaption

There are multiple approaches to occlude of large blood vessels and ductal structures securely in minimally invasive procedures. The classical method for securing a ductal structure as used in open surgery is just a suture ligature, but this is time consuming and often technically demanding when attempted laparoscopically. Mechanical occlusion with the use of non-transfixing clips applied to the external surface of the vessels with a clip applier is currently the standard of care. The use of these clips is generally reliable and secure. These clips placed on larger vessels have been known to become dislodged with catastrophic consequences despite the use of multiple ligation clips for occlusion. As an example, the use of non-transfixion clips for renal artery and vein ligation during laparoscopic donor nephrectomy has been contraindicated by the FDA following fatal postoperative hemorrhage attributable to dislodgement of these non-transfixing clips [1–3]. Multiple adverse events have been reported to the FDA in various procedures including bleeding following harvest of the saphenous vein or mammary

✉ Arnold Miller
arnold@amseltech.com

1 Assuta Medical Center, Tel Aviv, Israel

2 Amsel Medical Corporation, 171 Hamilton Street, Cambridge, MA 02139, USA

3 Eliachar Technologies Development Ltd, Haifa, Israel

4 Pathovet, Rehovot, Israel

5 Jacobs School of Medicine, University at Buffalo, Buffalo, NY, USA

Published online: 16 January 2018

artery for coronary artery bypass, or bile leaks following occlusion of the cystic duct during cholecystectomy.

Alternative methods and techniques for occluding larger vessels or ducts include transfixing suture ligation, a stapler loaded with "vascular loads" or active energy blood vessel occluder (ultrasonic or radio-frequency). Laparoscopic linear stapling devices are effective, but they require wide exposure and sufficient length of the targeted vessel. In addition, there is often a problem with bleeding at the staple entry points. The active energy devices (electro-thermal (RF) or ultrasonic) work well on the smaller, less critical vessels [4, 5]. How secure they are on the larger vessels or large ducts has yet to be determined.

We have developed a novel technology providing a simple and cost-effective method for safely occluding vessels and ducts during laparoscopic surgery. This report presents the results of our preclinical in vivo laparoscopic studies in the porcine model where the Amsel Occluder (AO) was compared to the commercially available laparoscopically delivered hemoclip (Ligaclip®, Ethicon endo-surgery, LLC, Cincinnati, OH), for the occlusion of blood vessels and ducts ranging in external diameter from 2 to 10 mm.

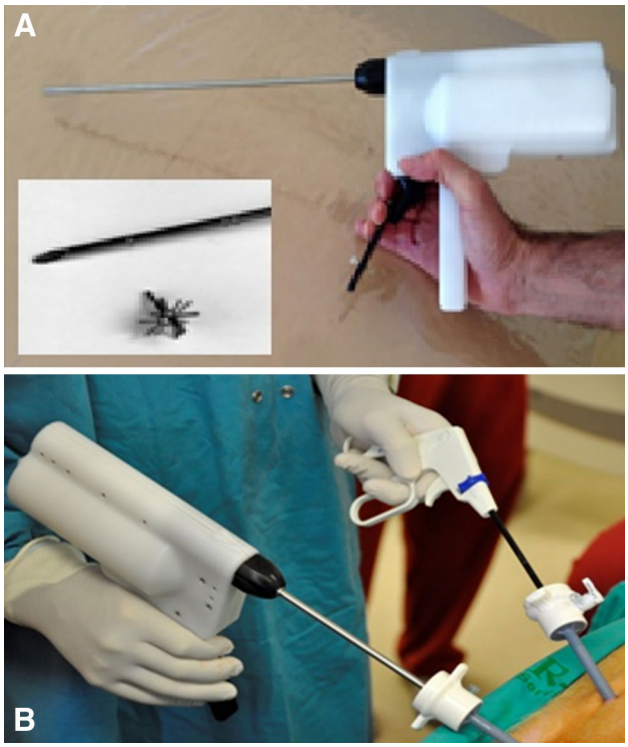

Fig. 1 **A**, **B** Amsel Occluder Laparoscopic Delivery Device and 18G needle with locked proximal and distal occluder elements. **A** Delivery device delivers 4 Amsel Occluders, each by 5 Trigger Actions as shown in (**B**). (i) Protrudes delivery needle (18G) for transfixion. (ii) Delivers distal occluder. (iii) Delivers proximal occluder. (iv) Locks proximal and distal occluders together and (v) disconnects delivery device

Materials and methods

Device description

The AVO consists of a multi-loader delivery device designed for laparoscopic use delivering 4 occluder clips by simple repeat trigger action (Fig. 1). The occluder clip which has been previously described for use in both open surgery [6] and percutaneous interventions [7] has received FDA 510 (k) clearance, similar to other metal clips (hemoclips) for the occlusion of vessels 2–7 mm in diameter, as well as for tubular structures, such as the cystic duct or ureter, for open surgery. Both the occluder device and the delivery device used in this study are of a prototypic design and can be easily modified to suite a particular application (Fig. 1).

The Amsel Occluder Clip is preloaded in the 18G needle of the AVO delivery device. The AVO is a mechanical occlusion clip that when deployed transfixes the target vessel while clamping it shut. The AVO consists of two "star"-shaped compression elements and a titanium fine strut which connects and locks the compression elements together (Fig. 1). The proximal element, which compresses the near wall of the vessel, and distal element, which compresses the far wall of the vessel, are made of shape memory metal (nitinol), which, once deployed, assumes its predetermined configuration closing off the vessel.

Once deployed and locked together the individual "arms" of the proximal occlusion component alternate with and interdigitate with the individual "arms" of the distal occlusion components. The "arms" pass below the plane of the distal occlusion component and vice versa. In effect, when fully deployed on a vessel or duct, there is a circular occlusion around the central rod by the "arms" of the two occlusion components and the proximal and distal wall of the occluded vessel are brought into apposition with one another regardless of vessel wall thickness [6, 7].

Hypothesis

The hypothesis being tested in this porcine model is that the use of the laparoscopically transfixion AO compared with the Ligaclip for both vessels and ducts would be as easily applicable while providing a more secure and safe vessel occlusion without injury to adjacent structures, and with no differences in the healing process, as evaluated by clinical and histopathological study.

Methods and surgical technique

The studies were approved by the Institute of National Animal Care and Use Committee, Israel, and performed at the

Lahav Institute of Animal Research, Lahav, Israel. A total of 12 female domestic pigs (Sus scrofa domestica), each weighing more than 60 kg at the time of implantation, underwent a laparoscopic surgical procedure where selected veins, arteries, and ducts between 2 and 10 mm in diameter were occluded. Two pigs in a non-survival acute study (Table 1) were subjected to occlusion of multiple vessels and ducts with either the AVO or the Ligaclip. In a chronic survival study, 10 pigs underwent either nephrectomy with occlusion of the renal vessels and ureter or cholecystectomy with occlusion of the cystic duct and artery. The AO was used in 6 pigs and the Ligaclip in 6 pigs (Table 2). All of the surgeries were laparoscopic and performed under general anesthesia by experienced laparoscopic surgeons (AS, SDS). Each animal was allowed to acclimate for at least 3 days prior to surgery. On the day of surgery, food was withdrawn and only water was allowed.

Prophylactic antibiotic (Cefazolin 20 mg IVI) was administered concomitantly with induction of anesthesia for those pigs in the chronic study. After occlusion with either the AVO or control hemoclips, the occluded vessel or duct was severed approximately midway between the occluding clips, examined for bleeding or leakage, and the results recorded (Fig. 2).

In the chronic study, after cholecystectomy was completed, the gall bladder was extracted through the camera port, and the kidney via a small flank incision by extension of the appropriate port. All wounds were closed in layers with absorbable sutures. The animals were then extubated and recovered. The pigs were then closely followed for between 22 and 72 days.

Prior to sacrifice, under general anesthesia, a plain AP X-ray of the abdomen was performed to visualize the occluding clips, either AO or hemoclip. In the post-nephrectomy pigs, a transfemoral aortic angiogram and IVC venogram were also performed to confirm occlusion of the renal vessels. Finally, through an abdominal incision, excision sites of the gall bladder and kidney, and their occluded vessels and ducts were identified and examined for signs of bleeding, infection, and healing. Excision of part of the occluded vessels and ducts with the occlusion clips was performed with a generous portion of the surrounding tissues and placed in formalin for histopathological examination of the tissue response and healing.

Table 1 Acute occlusions

Pig #	Vessel/duct occluded	Proximal # of AVO	Distal # of AVO	Estimated size (mm)	Proximal # of Ligaclip	Distal # of Ligaclip	Result
4373-00							
	Uterine horn	1	2	10			Occluded
	Uterine artery	2	1	3			Occluded
	R iliac artery	2	1	8			Occluded
	L Iliac artery	1	1	7			Occluded
	L Iliac vein	1	1	10			Occluded
	L ureter	1	1	10			Occluded
	L renal artery	1		4			Occluded
	L Renal vein (branch)	1	1	8			Occluded
	L renal vein (branch)			5	1	1	Occluded
	L renal artery (branch)			2	1	1	Occluded
	L renal artery (branch)			5	1	1	Occluded
4374-01							
	Cystic artery	1		2		1	Occluded
	Cystic duct	1		2		1	Occluded
	L uterine artery	1	1	4			Occluded
	Gasto-epiploic Artery	1	1	5			Occluded
	L Iliac artery	1	1	8			Occluded
	L iliac vein	1	1	8			Occluded
4707-9[a]							
	Mesenteric vessels	1	1	2			Occluded
	Mesenteric vessels	1	1	2			Occluded

[a]At sacrifice

Table 2 Chronic occlusions

Pig #	Procedure	Vessel/duct occluded	# of AVO proximal	Distal	# of Ligaclip proximal	Distal	Estimated size (mm)	Survival days	Result
4556-1									
	Nephrectomy	Ureter	1	1			10	72	Occluded
		L renal artery	2	1			8		Occluded
		L renal vein i	1	1			8		Occluded
		L renal vein ii	1	1			4		Occluded
4557-2									
	Nephrectomy	Ureter	1	1			10	72	Occluded
		L renal artery					8		Occluded
		L renal veins	1	1			8		Occluded
4558-3									
	Nephrectomy	Ureter	1	1			9	22	Occluded
		L renal artery	1			2	8		Occluded
		L renal vein i			3	2	7		Occluded
		L renal vein ii			2	2	4		Occluded
4559-4									
	Cholecystectomy	Cystic duct			1	1		72	Occluded
		Cystic artery			1	1			Occluded
4641-5									
	Cholecystectomy	Cystic duct	1	1			2	56	Occluded
		Cystic artery	1	1			2		Occluded
4642-6									
	Cholecystectomy	Cystic duct	1	1			2	56	Occluded
		Cystic artery					< 1		Occluded (Bovie)
		Liver bed (bleeding)	1						Occluded
4643-7									
	Cholecystectomy	Cystic duct	1	1			2	56	Occluded
		Cystic artery	1	1			2		Occluded
4644-8									
	Nephrectomy	Ureter			2	1	10	56	Occluded
		L renal artery			Multiple	Multiple	8		Occluded
		L renal vein i			Multiple	Multiple	8		Occluded
		L renal vein ii			Multiple	Multiple	3		Occluded
4707-9									
	Cholecystectomy	Cystic duct			2	1	3	42	Occluded
		Cystic artery			2	1	3		Occluded
4709-10									
	Nephrectomy	Ureter			Multiple	Multiple	10	42	Occluded
		L renal vein i			Multiple	Multiple	8		Occluded
		L renal vein ii			Multiple	Multiple	3		Occluded

Results

Acute study (Table 1)

Three pigs (2 acute and 1 chronic at time of sacrifice) underwent a total of 19 acute occlusions (2 clips per vessel or duct) of both arteries and veins ($n = 16$) and ducts ($n = 3$) ranging in size from 2 to 10 mm. Occlusion was confirmed when no bleeding or leakage occurred after transecting the occluded vessels or ducts between the two occluders (Fig. 2). Ten arteries, 3 veins, and 3 ducts were occluded with the AO and 2 arteries and 1 vein with the hemoclip. One cystic duct was occluded with a proximal AO and a distal hemoclip. Of the 19 occlusions, 17 occlusions were achieved with a single

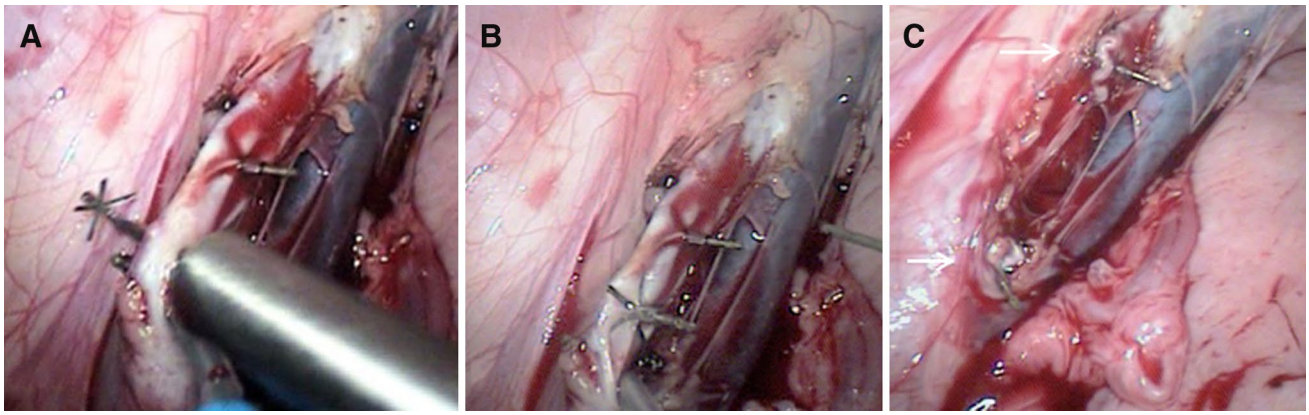

Fig. 2 **A**–**C** Occlusion of left iliac artery (7 mm) with Amsel Occluder (Table 1, Pig 4373-00). **A**, **B** Transfixion and occlusion of iliac artery with proximal and distal Amsel Occluders. **C** Division of iliac artery between the two Amsel Occluders with no bleeding. Note the inter-digitation of the "arms" folding in the walls of the iliac artery providing secure occlusion without pressure necrosis (arrows)

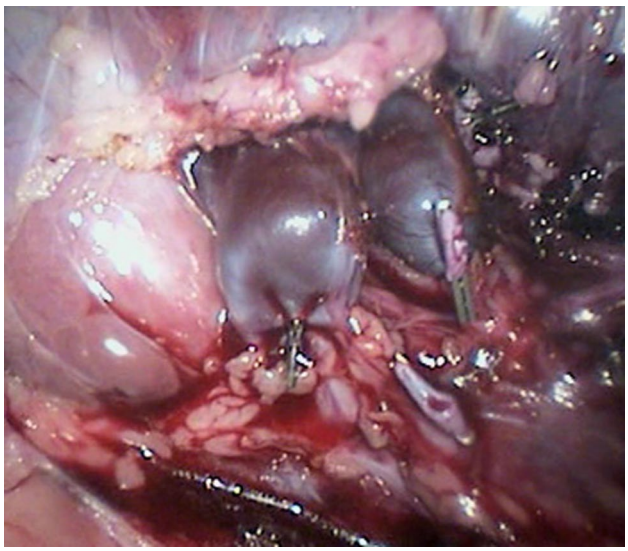

Fig. 3 Main left renal vein (8 mm) securely occluded with the Amsel Occluder and tributaries of renal vein (5 mm) occluded with hemoclips. Note how the hemoclips appear to have slipped to the edge of the divided vessels

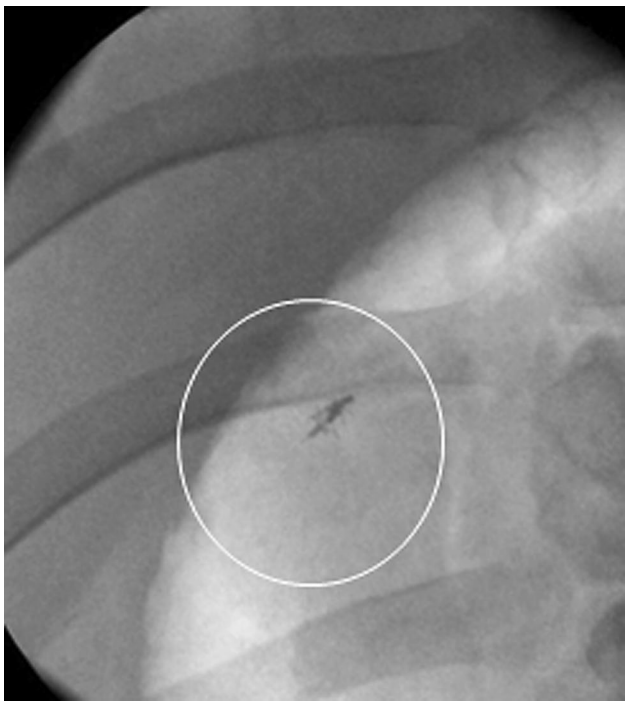

Fig. 4 X-ray of upper abdomen (Table 2, Pig 4641-5) showing two Amsel Occluders, one on the cystic duct and one on the cystic artery

AO. In 2 occlusions where the first AO was placed on the edge of the vessel and did not completely occlude the vessel, a 2nd AO was necessary to achieve complete occlusion.

In this acute study, the laparoscopically delivered hemoclips were used on smaller vessels ranging in size from 2 to 5 mm as the hemoclips appeared to be insecure, slipping to the edge of the divided vessel segments (Fig. 3).

Chronic study (Table 2)

For the chronic study, 5 laparoscopic nephrectomies (3 with the AO and 2 with the hemoclip) and 5 cholecystectomies (3 with the AO and 2 with the hemoclip) were performed. The vessels and ducts for the nephrectomies ranged in size from 4 to 10 mm and for the cholecystectomies from 2 to 3 mm. All the renal vessels and ureters were securely occluded with single AO (Figs. 4, 5) except for 1 renal artery where the proximal AO was placed at the edge of the vessel and a 2nd AO was necessary for complete occlusion. For vessel occlusion with the hemoclips, to ensure secure occlusion, multiple clips were used (Table 1; Fig. 6).

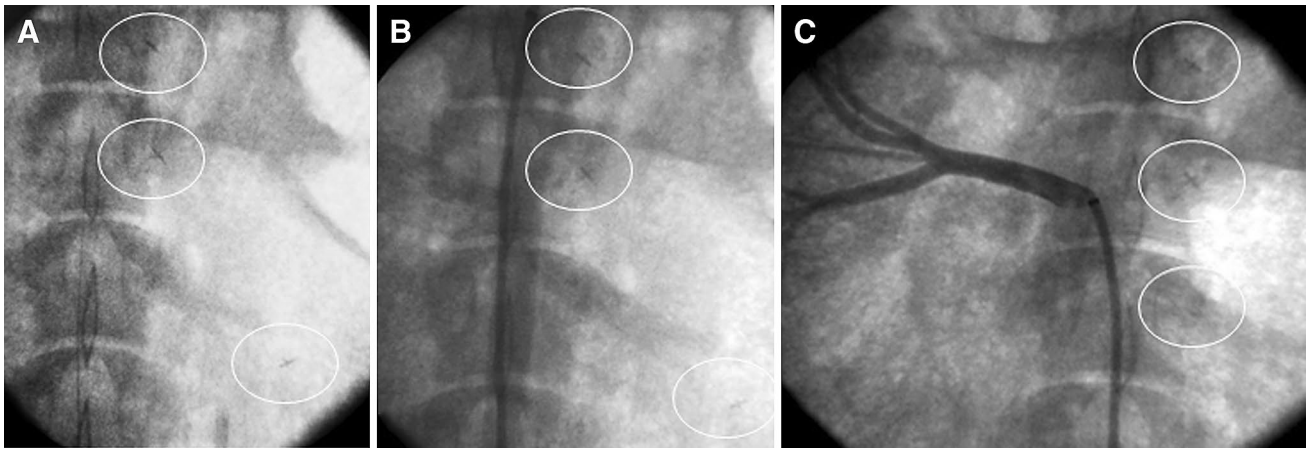

Fig. 5 **A**–**C** Abdominal X-ray prior to sacrifice at 72 days after nephrectomy shows single Amsel Occluders each occluding the renal artery, vein, and ureter (Table 3, Pig 4557-), **B** aortogram showing widely patent right renal artery and occluded left renal artery confirmed on (**C**) selective right renal angiography

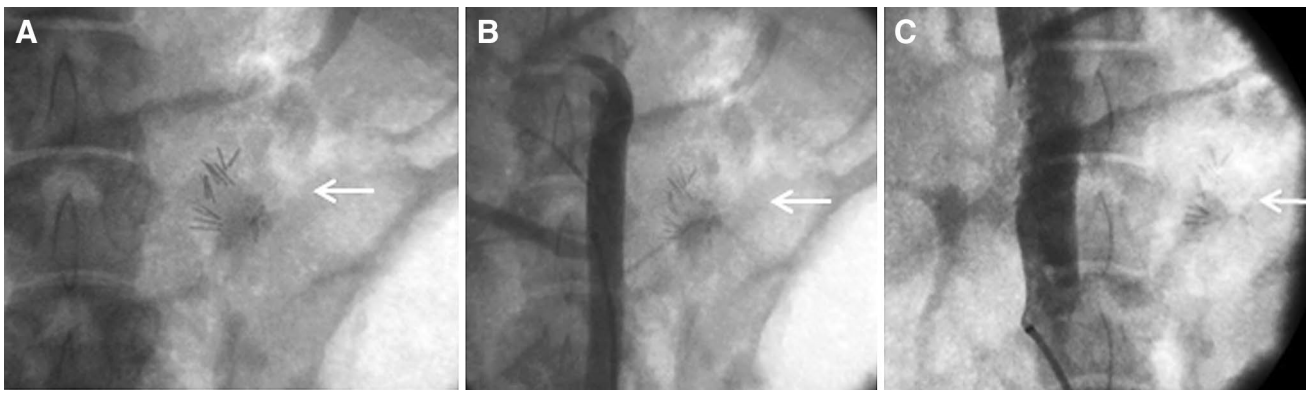

Fig. 6 **A**–**C** X-ray of left upper quadrant at site of nephrectomy 56 days previously. Note multiple hemoclips occluding the renal vein, artery, and ureter. **B** Angiography confirms left renal artery occlusion. **C** Venography shows normal IVC with no filling of either renal vein or contrast filling of L ureter (Table 2, Pig #: 4644-8)

Survival for the chronic study was more than 30 days (range 42–72 days) except for one pig (Table 2, Pig #4558-3) who post nephrectomy suffered a massive hemorrhage from a spontaneous delayed splenic rupture on day 22, after sustaining a splenic injury with the introduction of a laparoscopic port insertion at the time of nephrectomy. Postmortem confirmed the renal artery, vein, and duct occlusion with the AO to be intact.

In the remaining survivors, an AP abdominal X-ray was performed prior to sacrifice to confirm the position and number of the ligation clips used (Table 2; Figs. 4, 5, 6). Transfemoral angiography after catheter placement in the aorta confirmed occlusion of the previously occluded renal arteries (Figs. 4, 5, 6). IVC venography was performed but retrograde flow into the renal veins to confirm occlusion could not be achieved and occlusion of the renal veins was confirmed only on direct open and histopathological examination. Surgical examination of the occlusions sites showed good healing and tissue incorporation for both the AO and hemoclip (Ligaclip®) without any evidence of hemorrhage or leakage, or infection.

Histopathology (Table 3)

For preparation of the pathological specimens of the occluding clips, the hemoclip and the AO were removed from the specimen prior to embedding and staining. This caused some fragmentation artifact for histological evaluation which was especially noticeable with the AO, as removal of the "arms" before processing caused some tearing of the tissues. The tissue reaction to both the Ligaclip and the AO, subjected to a comparative histopathological study [8], was very similar and typical of a chronic foreign body reaction, with minimal mononuclear cell infiltration, occasional granulomas, and

Table 3 Average of score per parameter and tests, and comparison between tests

Treatment name	GB-AO	GB-clip	U-AO	U-clip	Art-AO	Art-clip	Vein-AO	Vein-clip
Number samples evaluated	4	1	3	2	3	3	2	2
Polymorphonuclear	0.3	0	0.3	0	0.0	0.0	0	0
Lymphocytes	2.5	1	1.7	0.5	1.7	1.0	1	0.5
Macrophages	1.5	0	0.0	1	0.3	0.3	0	1
Giant cells	2.0	2	0.3	2.5	0.3	0.7	1.5	0.5
Necrosis, extent	0.3	0	0.0	0	0.0	1.0	0	0
Neovascularization	1.3	2	1.0	1.5	2.0	1.3	0.5	1
Fibrosis	0.7	1	1.0	1.5	3.0	2.3	0.5	1
Fatty infiltrate	0.0	0	0.0	0	0.0	0.0	0	0
Total	8.7	6	4.3	7	7.3	6.7	3.5	4
Test-control	8.7–6		4.3–7		7.3–6.7		3.5–4	
Results	2.7		0		0.6		0.5	

Results key

Non-irritant 0.0–2.9

Slight irritant 3–8.9

Moderate irritant 9–15

Severe irritant > 15

Negative difference is recorded as 0

variable amounts of focal fibrosis. More necrosis was noted in the Ligaclip specimens where the 2 arms of the Ligaclip compressed the tissues along the length of the occlusion (Fig. 7). The AO also caused some necrosis at the central area of the locking of the occluder elements but not where the "arms" of the occluder extended over the tissues. These findings appear to be very similar in all samples with mild variations in intensity of fibrosis and mononuclear cell infiltration. The histological findings in the present study are very similar to those observed in the previous preclinical animal studies performed for "open" surgery [6] and percutaneous interventions [7].

Discussion

This study shows that the AO clip can be effectively delivered laparoscopically to achieve the same secure permanent occlusion of vessels and ducts ranging in size from 2 to 10 mm, similar to our previous studies on the use of the AO in open surgical procedures and percutaneous interventional procedures [6, 7]. The advantages of the transfixing AO over the externally placed hemoclip laparoscopically delivered are clearly demonstrated by the difference in the number and the multiplicity of clips used when

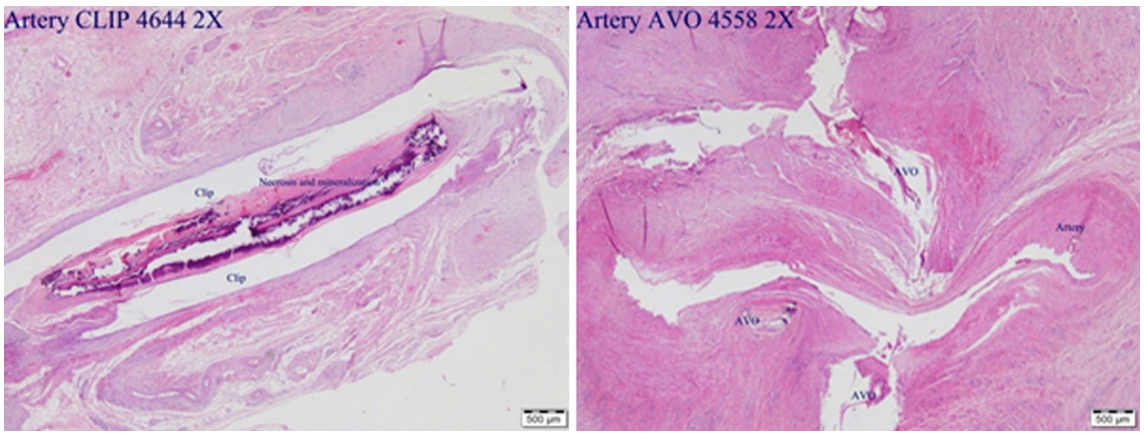

Fig. 7 Pig 4644 (Table 2): Hemoclip (Ligaclip®) occlusion of the artery. The compressed artery is necrotic with extensive mineralization. The hemoclip is surrounded by mature fibrous tissue with minimal leukocytic infiltration; Pig 4558 (Table 2): the Amsel Occluder (AVO) is surrounded by extensive fibrosis with minimal mononuclear infiltration. There is a single focus of mineralization around one of the arms of the device

larger critical vessels such as the renal artery and veins were occluded. The multiple hemoclips used for occlusion of the renal vessels as compared to the single AO in this study are a reflection of the surgeon's perspective on the insecurity of the non-transfixion clips, where the use multiple clips for critical occlusions are the current standard of practice. The security of the AO in a large range of sizes and types of vessels and ducts was demonstrated in this study and validates the unique design advantages of the AO. The transfixion by the AO secures the occluder in place eliminating any slippage. The interdigitating or interweaving of the occluding arms allows for occlusion of the arteries, veins, and ducts of various thicknesses and sizes without causing pressure necrosis on the walls of the occluded structure. Made of Nitinol, these arms apply a variable differential pressure on the tissues depending on the thickness of the tissues being occluded. In addition, this study confirms that the tissue response to the laparoscopically delivered AO and hemoclip (Ligaclip®) is similar (Table 3) and no different to the findings of tissue response to the previous open surgical and percutaneous studies [6, 7].

The AO and multi-loader delivery device used in this study is of prototypic design and can be modified to optimize performance and size, allowing different matching size clips for smaller or larger vessels. The single sized AO used in this study securely occluded vessels and ducts from 2 to 10 mm. It was designed with 2 locking stations to allow for occlusion of the larger vessels and ducts. However, in this and our previous studies, locking has been achieved in all occluded vessels and ducts at the first locking station.

Removal of the second locking station shortens the size of the rod connecting the two occluder elements (Fig. 8). The delivery system in this study delivers 4 consecutive occluders by a simple trigger action (Fig. 1). Automation of the delivery system and increasing the number of occlusion clips is easily achievable and would be similar to the current Laparoscopic delivery devices such as those used in our study which have the potential to deliver 12–15 hemoclips per delivery device. In practice, 2 or more hemoclips are generally applied to critical structures to minimize and prevent inadvertent clip dislodgement.

Technically, for the application of both the hemoclip and AO, the vessel or duct is dissected free from the surrounding tissues prior to occlusion. For the AO, tension is applied to the targeted vessel or duct to allow through and through transfixion of the vessel or duct prior to delivery of the occluding clips. Although there was some initial concern of possible unintentional injury to underlying or adjacent structures, none occurred during > 60 AO deliveries in 30 vessels and ducts occluded in this study (Tables 1, 2). Modifications to the delivery device to provide for a protective shield in critical areas can easily be made, but with an experienced

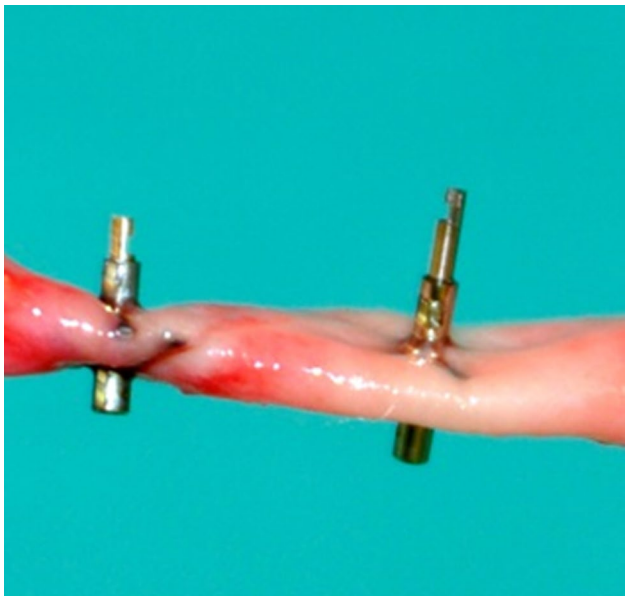

Fig. 8 Comparison of low-profile and standard Amsel Occluders. Occlusion of an 8-mm carotid artery with the short (5.45 mm), one locking station Amsel Occluder, and the long (7.95 mm), two locking stations occluder used in this preclinical study (Pig 4709-10). Both versions of the Amsel Occluder have received FDA 510(k) preclinical clearance

operator, good visualization of the penetrating needle, and careful technique this may not always be necessary. In the few instances when the first AO did not achieve complete occlusion, a second AO was placed and the vessel securely occluded (Tables 1, 2).

Unlike the current hemoclips, the prototypic AO used in this preclinical study is not easily removed once locked in place. However, there are a number of steps required prior to the locking of the device. These steps include needle transfixion of the vessel or duct and delivery of the proximal and distal occluders prior to the locking together of the occluder elements. At any of these steps, the procedure may be aborted and the AO removed without locking of the occluder elements together. This leaves an 18G needle hole in the vessel or duct with which can easily be addressed. In more than 60 deployments of the AO in this study, removal of the AO or Ligaclip was not required. However, providing locking reversal and removability will be addressed in future iterations of the Amsel device. It should be noted that there is much less injury to the vessel or duct from the AO as compared to the Ligaclip following application and removal (Fig. 7), thus reducing the possibility of late complications such as healing with stenosis/stricture.

For procedures such as in laparoscopic organ harvest in living donors, particularly for kidney transplantation the AO has a number of advantages over the vessel stapler. The AO provides secure occlusion with a minimal footprint on the

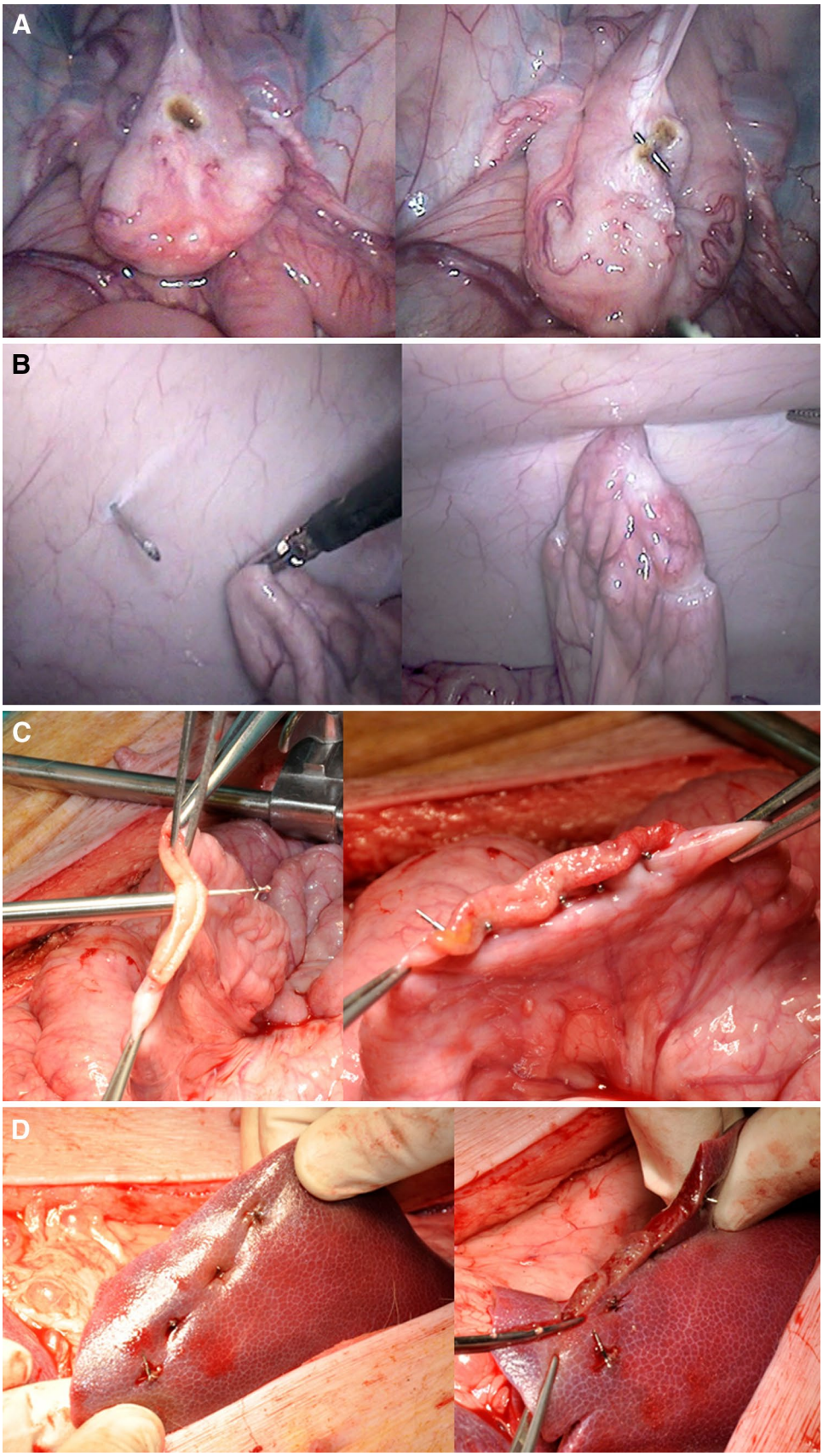

Fig. 9 **A**–**D** Tissue adaption procedures with the Amsel Occluder. **A** Laparoscopic closure of cystostomy, **B** laparoscopic attachment of bowel to the abdominal wall for enterostomy: the Amsel Occluder is introduced percutaneously; the distal occluder delivered within bowel brought up to site of needle entry; and the 2 occluders are locked together, attaching the bowel to the abdominal wall. (**C**) "Open" surgical closure of enterotomy with the Amsel Occluder and **D** "open" surgical partial liver resection with the Amsel Occluder for hemostasis. Both (**C**) and (**D**) could be performed laparoscopically

renal vessels, preserving the maximal length of the donor vessel or duct which is critical for transplantation. It is similar in security to a hand-sewn transfixion suture but much simpler, and quicker to perform in the laparoscopic setting.

Finally, because of the unique properties of the AO, where the arms of the occluder are spring-like in that they provide a variable and adjustable pressure without causing through and through compression necrosis except at the central locking point of approximately 1 mm diameter, the AOs may be useful in other surgical applications where tissue compression rather than hollow structure occlusion is required. Examples of possible applications may include a simple tissue approximation technique for securing bowel to the abdominal wall for gastrostomy or enterostomy, closure of an enterotomy following the use of a stapler for bowel anastomosis, or closure of a cystostomy and hemostasis for solid organ trauma or resection (Fig. 9a–d). The use of a simple, rapidly applied mechanical device avoids the often tedious laparoscopic manual suturing required for these procedures.

Conclusions

In this porcine model, we demonstrated that the Amsel Vessel occluder delivers laparoscopic mechanical occlusion similar to a hand-sewn transfixion suture for blood vessels and ducts with minimal to no risk of dislodgment associated with the conventional clip application.

Compliance with ethical standards

Disclosures This study is fully funded by Amsel Medical Corporation, a private company registered in Delaware, USA. Amir Szold, MD, Medical Director, Assia Medical Group, Assuta Medical Center, Tel Aviv, Israel—consultant surgeon to Amsel Medical and advisor to LifeBond, Asymmetric Medical, Augmedix Medical, Virtual Ports, MST Medical, and CMO of Human Extensions. Arnold Miller, M.D.—vascular surgeon, founder, and president of Amsel Medical Corporation. Nir Lilach, I.E.D.—consultant engineer (Eliachar Technologies Development Ltd, Haifa, Israel). Ana-Maria Botero-Anug, D.V.M., D.V.Sc—consultant pathologist (Pathovet, Rechovot, Israel). Raanan Miller Ph.D.—founder and C.E.O. of Amsel Medical Corporation. Steven Schwaitzberg—Chairman, Department of Surgery, University at Buffalo. Dr Schwaitzberg is on the medical advisory panels for Amsel Medical Corporation, Acuity Bio, Arch Therapeutics, Gordian, and Human Extensions.

References

1. Maartense S, Heintjes RJ, Idu M, Bemelman FJ, Bemelman WA (2003) Renal artery clip dislodgement during hand-assisted laparoscopic living donor nephrectomy. Surg Endosc 17(11):1851
2. Hsi Ryan SA, Ojogho Okechukwu NA, Baldwin D, Duane A. Analysis of techniques to secure the renal hilum during laparoscopic donor nephrectomy: review of the FDA database. Urology 2009:74(1):142–474
3. U.S. Food and Drug Administration [internet]. FDA and HRSA Joint Safety Communication: Weck Hem-o-Lok Ligating Clips Contraindicated for Ligation of Renal Artery during Laparoscopic Living-Donor Nephrectomy (issued 5 May 2011). http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm253237.htm
4. Newcomb WL, Hope WW, Schmelzer TM, Heath JJ, Norton HJ, Lincourt AE, Heniford BT, Iannitti DA (2009) Comparison of blood vessel sealing among new electrosurgical and ultrasonic devices. Surg Endosc 23(1):90 – 6
5. Hruby GW, Marruffo FC, Durak E, Collins SM, Pierorazio P, Humphrey PA, Mansukhani MM (2007) Evaluation of surgical energy devices for vessel sealing and peripheral energy spread in a porcine model. J Urol 178(6):2689–2693
6. Miller A, Lilach N, Botero-Anug A, Willenz U, Miller R (2017) Comparison of a novel secure transfixing blood vessel occluder with the hemoclip in the porcine model. J Surg Res 209:211–219
7. Miller A, Lilach N, Miller R, Kabnick L (2017) A novel, simple, and secure, percutaneous vessel occluder for the treatment of varicose veins. J Vasc Surg 5:114–120
8. I.S. EN ISO 10993-6 (2009) (English): biological evaluation of medical devices—part 6: tests for local effects after implantation [Authority: The European Union Per Directive 90/385/EEC]., Annex E, pp 17–18