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1 **LASER USES IN NON-CORONARY ARTERIAL DISEASE**

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26

27 **ABSTRACT**

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29 **Objectives:** In the past decade, excimer laser angioplasty (ELA) has emerged in the field of peripheral  
30 atherosclerotic disease (PAD). Laser indications now extend to off-label uses, such as in situ fenestration of  
31 aortic endograft. The aim of this study was to review the different therapeutics applications of lasers in arterial  
32 disease treatment.

33 **Review Methods:** We reviewed the English-language literature using the Preferred Reporting Items for  
34 Systematic Reviews and Meta-Analysis (PRISMA) guidelines. We selected 106 relevant papers. We excluded  
35 unrelated papers (n= 67), letters and commentaries (n = 6) and review articles (n=7), leaving 26 articles to form  
36 the basis of this review.

37 **Results:** A total of 18 articles were included in the analysis of ELA applications in PAD. Nine articles were  
38 related to atherosclerotic plaques. With a mean follow-up of  $15\pm 7$  months, primary patency was  $65\%\pm 20\%$ .  
39 Mean distal embolism rate during the procedure was 5%. Eight more articles focused on in-stent restenosis. The  
40 mean technical success was 98%, and the rate of distal embolism during the procedure was 9%. With a mean  
41 follow-up of  $10\pm 4$  months, primary patency was  $68\%\pm 18\%$ . Eight articles described “off- label” excimer laser  
42 indications in endovascular therapy, including five papers regarding in situ fenestrations for complex aortic  
43 aneurysms.

44 **Conclusion:** Laser atherectomy and laser assisted techniques are an important part of a vascular surgeon and  
45 interventionalist's armamentarium.

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51 **Keywords:**

52 Excimer Laser, In stent restenosis, Atherosclerotic Plaques, In situ fenestration

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54 **MANUSCRIPT**

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56 **INTRODUCTION**

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58 Since 1960, light amplification by stimulated emission of radiation (laser) has appeared as an applicable energy  
59 source for medical use thanks to its unidirectional, pulsatile and monochromatic characteristics. The different  
60 physical mechanisms account for the many ways to exploit the capacity of laser technology in medical utilization  
61 [1–6]. In this last decade, laser technology has emerged as a new tool in endovascular therapy [7,8]. Lasers in  
62 endovascular therapy were applied in the endovenous laser ablation for treating saphenous insufficiency [9]. On-  
63 label indications of excimer laser angioplasty (ELA) in peripheral artery disease (PAD), specifically in-stent  
64 restenosis [10] and non-crossable chronic occlusions [11], have appeared. More recently, other off-label  
65 indications have emerged for material ablation and fabric welding to perform in situ fenestration of aortic  
66 endografts [12].

67 The main laser used in arterial surgery is the excimer laser using the photoablative laser's characteristics. An  
68 excimer laser is produced by a high-energy voltage associated with a dimeric solution of xenon and  
69 hydrochloride. The high-voltage energy excites the dimer XeCl and creates a photon. The laser is conducted by  
70 optic fibers, at a wavelength of 308 nm located in the blue spectrum. Whereas many other lasers deliver their  
71 energy in the warm red spectrum, the excimer laser is a cold laser. This last characteristic allows vascular  
72 surgeons and interventionalists to use excimer laser with a theoretical low risk of thrombus formation or  
73 deterioration of the arterial wall. The light penetration depth is around 0.05 mm, and each photon carries enough  
74 energy to break a single carbon-carbon bond. Intracellular lipids and proteins absorb this high energy and are  
75 quickly destroyed. Finally, all the intracellular liquid is vaporized. Microscopic subcellular debris are created  
76 and washed distally with a theoretical benefit in terms of clinic emboli.

77 Whereas the first lasers were continuous-wave lasers, the excimer laser delivers its energy by pulse to avoid the  
78 heat diffusion from the catheter tip and the damage of surrounding tissues.

79 Each catheter conducts its energy from a generator to the catheter tip, composed of multiple optic fibers arranged  
80 around a guidewire lumen. Different diameters of the catheter exist according to the surgical applications, from  
81 0.9 mm to 2.5 mm. Settings (Fluence (mJ/mm<sup>2</sup>) and rate (Hz)) can be modified per the power needed. In fact,  
82 for calcified lesions or occlusions, the average power should be increased to obtain a maximum debulking.

83 Two types of devices are commercially available. First, Turbo-Tandem (TT) (previous generation: Turbo-  
84 Booster (TB)/ CliRpath) (Spectranetics, Colorado Springs, CO, USA) is a laser-guided catheter combined with a  
85 laser atherectomy catheter, whereas Turbo-Elite (TE) (Spectranetics, Colorado Springs, CO, E-U) is just a laser  
86 atherectomy catheter. TT is preferred for diameters of target arteries over 5 mm or to obtain maximum  
87 debulking. Both devices progress on the wire after crossing the lesion or with a “step-by-step technique”. A  
88 speed progression of the catheter of 1 mm/s is advised to be more effective.

89 The aim of this study is to review the different therapeutics applications of excimer lasers in endovascular  
90 therapy.

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92

## 93 **METHODS**

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95 A literature's review was performed using of the Preferred Reporting Items for Systematic Reviews and Meta-  
96 Analysis (PRISMA) guidelines [13] **Figure.**

### 97 **Search Strategy**

98 We reviewed the English-language literature regarding the use of excimer laser on several medical databases:  
99 Medline databases using a PubMed interface, the Cochrane Database, Web of Science, and Scopus. The search  
100 period was from June 2005 to May 2017. We used the key words "Excimer Laser", "in stent restenosis," "in situ  
101 fenestration."

### 102 **Study Selection**

103 Studies were included if they met the following criterion: laser uses in arterial disease including PAD and aortic  
104 or visceral procedures.

105 Clinical and experimental papers were studied. Only published data were included in this study. Two  
106 independent analysts (J.J. and R.C.) selected and further analyzed 106 relevant papers. We excluded unrelated  
107 papers (n= 67), letters and commentaries (n = 6) and review articles (n=7). Finally, 26 articles were included in  
108 the qualitative synthesis.

### 109 **Data extraction**

110 Data were extracted regarding the type of paper (clinical or experimental and case report or case series) and  
111 summarized using data extraction sheets. Relevant data were considered: on-label or off-label indications,  
112 number of subjects, device used (TE, TT or TB, or both), demographics, technical success, in situ fenestration  
113 type (retrograde or anterograde), in situ fenestration technique (catheter's diameter, graft type), technical success  
114 rate, and early and late results (primary patency, target lesion revascularization). Data were managed using three  
115 independent analyses: atherosclerotic plaques, in-stent restenosis, and off-label indications.

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## 118 RESULTS

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120 In selected articles, TE catheters were used in 1,107 cases (79%) [14–28], whereas TT or TB  
121 [10,15,17,19,21,22,24,26,29] devices were used in 230 cases (16%), and CliRpath (first laser-guided catheter  
122 generation) was used in 51 cases (5%) [11].

123 A total of 18 articles were included in the analysis of the applications of ELA in PAD. The main objectives and  
124 results of treatment of atherosclerotic plaques and in-stent restenosis are respectively shown in **Tables 1 and 2**.  
125 Eight other articles described off-label” excimer laser indications in endovascular therapy, including five papers  
126 regarding in situ fenestrations for complex aortic aneurysms.

127

### 128 *Atherosclerotic plaques*

129 Nine articles [11,14,15,17,21,25,27–29] related to atherosclerotic plaques were found. A total of 847  
130 atherosclerotic plaques were treated, and 783 TE (88%) and 104 TT or TB (12%) devices were used. Rastan et  
131 al. and Wu et al. both included in stent restenosis and atherosclerotic plaques. CliRpath device was used for 51  
132 revascularizations. Among the nine articles, four included femoropopliteal lesions [15,21,27,29]. Sultan et al.  
133 included infra popliteal lesions, and the four last authors included femoropopliteal, infra popliteal, and combined  
134 lesions [11,14,17,28], respectively. Five articles specified the lesion length [14,15,21,25,27]. Mean lesion length  
135 treated was  $13.3\pm 4.6$  cm. ELA was associated with percutaneous transluminal angioplasty (PTA) in  $58\%\pm 37\%$  of  
136 cases. Stent implantation was performed in  $29\%\pm 28\%$  of cases. Wu et al. compared spot stenting versus  
137 systematic stenting after ELA, and stenting was performed in 91% of cases. They concluded that primary  
138 stenting resulted in a longer primary patency rates at one year. Sultan et al. described the ELA technique for  
139 lower-limb arteries, and only 35% of the patients were treated by combined treatment ELA and stenting. No  
140 drug-eluting balloons were used for de novo arteries lesions.

141 Primary patency rates were available in five articles [14,15,17,21,27]. At  $15\pm 7$  months, mean primary patency  
142 rate was  $65\%\pm 20\%$ .

143 Mean distal embolism rate of four articles during the procedure was 5% [15,21,25,29].

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### 145 *In-stent restenosis*

146 Regarding in-stent restenosis, inclusions criteria were met in eight articles [10,18–20,22–24,26]. A total of 427  
147 femoropopliteal lesions were treated, and 316 TE (42%) devices and 123 TB or TT (58%) were used. Mean

148 lesion length treated was  $17.5\pm 4.1$  cm. The mean technical success was 98%, and mean rate of distal embolism  
149 during the procedure was 9%. ELA was systematically evaluated in combination with another treatment. Three  
150 studies combined ELA technique with drug-eluting balloons [18,20,23], four associated ELA with PTA  
151 [19,22,24,26], and the SALVAGE study [19] describe results of ELA followed by covered stenting.  
152 Primary patency rates were available in six articles [10,18,20,22-24]. At  $10\pm 4$  months, mean primary patency  
153 rate was  $68\pm 18$  %.

154 Finally, a clinical investigation focused on distal embolic events using ELA in 28 peripheral vascular lesions. A  
155 distal protection filter was deployed before laser therapy to recover debris produced by laser atherectomy. They  
156 highlighted 20% rate of clinically significant macrodebris [16].

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### 158 *Off-label indications*

159 Among the eight selected articles regarding off-label indications, five were related to in situ fenestration of aortic  
160 endografts [12,30-33].

161 Seventy in situ laser fenestrations were performed, and results are described in **Table 3**. The main objective was  
162 to perform a retrograde fenestration from the left subclavian artery to a thoracic aortic endograft during  
163 emergency endovascular treatment of a thoracic aortic aneurysm. A total of 35 Talent endograft, 8 Gore TAG, 3  
164 Cook TX2 and 2 LifeTech Scientific Corp. were fenestrated using the TE catheter or Lasemar catheter. Laser  
165 catheter diameter varied between 2.0 and 2.5 mm. Three authors specified that the contact between the endograft  
166 and the catheter tip was around 3 to 5s [30,31,33]. Two type II endoleak from the left subclavian artery, which  
167 was successfully treated by coil embolization were reported. Concerning the four clinical evaluations, the  
168 primary patency rate was 100% after  $9\pm 1$ -month follow-up. In the largest clinical study, technical success was  
169 achieved in 95.8% of cases [33]. An experimental study on pigs regarding embolism after antegrade  
170 fenestration of textile polyester stent grafts using a 2 mm TE catheter was performed. They concluded that the  
171 technique does not produce macroscopically visible emboli or clot.

172 Three articles described other off-label excimer laser indications in endovascular therapy. First, Chander et al.  
173 [34] reported a case series of 4 recanalizations of failed autogenous saphenous vein graft using laser  
174 revascularization. A 0.9 to 1.7 TE laser catheter was used with 100% technical success. Second, Topaz et al. [35]  
175 described a retrospective review of excimer laser debulking of 12 lesions unsuitable for standard renal  
176 angioplasty. The laser debulking using a 0.9 to 2 mm TE catheter was followed by renal artery stenting. No  
177 laser-induced complications and no controlled angiographic renal artery stenosis occurred. Finally, a case of

178 excimer laser use to treat a severe central venous lesion downstream to an arterio-venous access was reported  
179 [36]. A 2 mm TE catheter was introduced in the right subclavian vein followed by an 8 mm high pressure  
180 balloon angioplasty.  
181

## 182 DISCUSSION

183

184 This work aimed to review the use of excimer laser in PAD and in other off-label indications such as in situ  
185 fenestration of aortic endografts.

186

187 The excimer Laser was first used for coronary revascularization specifically for treating in-stent restenosis and  
188 atherectomy [37,38]. Other cardiologic applications such as transvenous extraction of implanted pacemakers and  
189 implantable cardioverter-defibrillator leads have emerged [39]. Neurosurgeons and neuroradiologists have also  
190 used this technology and developed a new technique called excimer laser-assisted non-occlusive anastomosis to  
191 perform anastomosis on intracerebral arteries and have reported encouraging results [40]. The large size of the  
192 devices and difficulty implementing them limited laser use for medical indications; miniaturization has allowed  
193 laser technology to develop and for the number of applications in medical and surgical use to increase.

194 The ELA procedure represents an alternative for treating in-stent restenosis and atherosclerotic plaques [16].  
195 Neither significant arterial perforation nor saphenous nerve injury were reported. However, short and mid-term  
196 primary patency rates were available for only 11 articles among the 18 articles included in the analysis of ELA  
197 in PAD. Besides, bail out stenting was frequently needed in the treatment of atherosclerotic plaques because of  
198 local dissections following catheter crossing.

199 Embolization rates were substantial following an ELA procedure. Our analysis highlights a 5% and 9%  
200 embolization rate following ELA in atherosclerotic plaques and in stent restenosis treatment, respectively.  
201 Specifically, the DEEPEMBOLI registry assessed the presence of embolic debris following ELA using  
202 systematic distal filter [16]. A concerning rate of 20% of macrodebris was found. The authors suspected ELA  
203 treatment of complex atherosclerotic lesions and suboptimal debulking as risk factors for distal embolization  
204 [16]. This raises the question of systematic distal filter protection during ELA procedure.

205 In-stent restenosis rates due to myointimal hyperplasia reach up to 50% [41,42]. Several treatments, such as  
206 cutting balloons, directional atherectomy, and drug-eluting balloons, have been evaluated to cure myointimal  
207 hyperplasia. Some authors have prospectively studied, the treatment of in-stent restenosis using paclitaxel-  
208 eluting balloon angioplasty. After 1 year, the primary patency rate was 83.7% with a reintervention rate of 9.8%  
209 [43]. The excimer laser allows recalibrating the vessel lumen in the stent by destroying fibrous material. ELA  
210 was associated with adjunctive therapy, such as drug-eluting balloons, provides satisfactory results [20], but this  
211 treatment should be evaluated by large and randomized series [45]. In the last decade, several off-label

212 indications of ELA have emerged, mainly laser in situ fenestration of aortic endografts. Laser technology is an  
213 alternative to mechanical technique using transseptal needles or stiff guidewires [46]. Recently, it was stressed  
214 that needles compared to laser catheters were not flexible enough to enter a directional sheath, thereby limiting  
215 their use for antegrade in situ fenestrations [47]. Laser in situ fenestration consists of puncturing the endograft  
216 with the laser catheter angled by steerable sheath, enlarging the hole created if necessary and stabilizing the  
217 fenestration by covered or uncovered stent. The successful treatment of a proximal type 1 Endoleak using an  
218 Endurant aortic cuff with triple antegrade in situ fenestration was recently reported [48]. However, the choice of  
219 the best graft and the impact of laser fenestration on textile remain unknown. More experimental studies must be  
220 conducted to assess biomechanical textile modification and long-term effects following laser fenestration, for the  
221 latter to become an “on-label technique.”

222 ELA’s cost-effectiveness is yet to be demonstrated and remains a global concern. In our country, TE’s price  
223 reaches 1 900€ (approx. 2,200US\$) for the catheter and 175 000€ (approx. 204,000US\$) for the CVX 300  
224 generator (taxes not included). Combined with adjunctive therapy such, as drug-eluting balloons, stenting, and  
225 perclose systems, the cost of ELA procedures can become extremely high. This may limit ELA diffusion [49].

226 Finally, reported results of the excimer laser open prospects for new applications such as arteriovenous accesses  
227 management. Venous stenosis caused by myointimal hyperplasia lead to high rates of reinterventions that could  
228 be simplified by laser use. Similarly, in situ fenestration was frequently performed using textile polyester  
229 endograft, but polytetrafluoroethylene (PTFE) endograft testing could be relevant to get away the fenestration  
230 from filament textile deterioration and extend the indication to the endovascular treatment of femoral bifurcation  
231 and popliteal occlusive disease.

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## CONCLUSION

The number of excimer laser applications is increasing. Laser technology represents a physical alternative to current mechanical means to treat various arterial diseases. Limitations include a concerning intra-operative embolism rate when treating PAD and a high cost. Long-term results and prospective comparative studies are lacking to validate the excimer laser as standard use in endovascular therapy.

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402 **LEGENDS :**

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404 **Table 1:** Tabular review of paper regarding de novo lesions treatment using ELA

405 PP: Primary patency, TLR: Target lesion revascularization, CLI: critical limb ischemia, FP: Femoropopliteal,

406 ABI: Ankle brachial index, DEB: Drug eluted balloon, TBA: Tibial balloon angioplasty, NA: Not available,

407 applicable

408

409 **Table 2:** Tabular review of paper regarding in stent restenosis treatment using ELA

410 PP: Primary patency, TLR: Target lesion revascularization, TVR: Target vessel revascularization, FPISR:

411 Femoropopliteal in stent restenosis, ABI: Ankle brachial index, DEB: Drug eluted balloon, PTA: Percutaneous

412 transluminal angioplasty, NA: Not available, applicable

413

414 **Table 3:** Tabular review of paper regarding laser in situ fenestration

415 LSCA: Left Subclavian artery, TEVAR: Thoracic endovascular aneurysm repair, ISF: in situ fenestration, PP:

416 Primary Patency, NA: Not available, applicable

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418 **Figure :** Flow chart depicting articles selection for the current review according to the PRISMA (Reporting

419 Items for Systematic Reviews and Meta-Analysis) guidelines.

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Identification

Records identified through  
database searching  
(n=106)

Screening

Records screening (n=106)

Records excluded  
(n=67)

Eligibility

Full-text articles assessed  
for eligibility (n=39)

Articles excluded  
(n=13)

Included

Studies included in  
qualitative synthesis  
(n=26)

Reference	Main objective	Study Design	Results					
			N (Lesions)	Technical success (%)	Follow-up (months)	PP (%)	TLR (%)	Others relevant results
<b>Bosiers 2005</b>	Efficacy of Laser angioplasty in CLI	Prospective multicentric	51	NA	6	NA	NA	74% limb salvage
<b>Zhou 2006</b>	Evaluate effectiveness ELA+PTA for CLI	Retrospective monocentric	15	84	6	57	NA	NA
<b>Rastan 2007</b>	Safety and efficacy of ELA bias sheath catheter for SFA	Prospective monocentric	6	79	1	NA	NA	ABI 0.8 increase and Rutherford increase 3 points
<b>Dave 2009</b>	Evaluate EL recanalization for FP lesions	Prospective multicentric	65	100	6 and 12	59 and 54	23.1 (12 months)	NA
<b>Serino 2010</b>	ELA for treatment of CLI in diabetic patients	Prospective monocentric	51	88	12 and 24	97.6 and 82.7	13.4 and 17.3	Limb salvage 100% and 94%
<b>Wisgott 2013</b>	Application of ELA for refractory FP lesions	Retrospective monocentric	40	90	12	58.9	NA	Primary assisted Patency and Secondary assisted Patency 67.8% and 83.2%
<b>Wu 2013</b>	ELA+Spot stent vs ELA+systematic stenting FP disease	Retrospective monocentric	106	100	24	25 (ELA+spot stent) vs 45 (ELA+systematic stenting) (P=.03)	65 (ELA+spot stent) vs 45 (ELA+systematic stenting)	Earlier restenosis 67% (ELA+spot stent) vs 32% (ELA+systematic stenting) (P=.001)
<b>Sultan 2013</b>	Compare outcome of CoolELA vs TA	Retrospective monocentric	42	81	36	NA	14.8% (ELA) vs 36.2 (TBA) (P=.873)	Sustained clinical improvement ELA 81% vs 63.8% TBA (P=.013), Amputation free-survival 95.2% ELA vs 78.7%TBA (P=.016)
<b>Mallios 2017</b>	Clinical results of laser atherectomy in the treatment of PAD	Retrospective monocentric	471	99	28	NA	20	Freedom from major amputation 90% at 5years

Reference	Main objective	Study Design	Results					
			N (lesions)	Technical success (%)	Follow-up (months)	PP (%)	TLR (%)	Others relevant results
<b>Laird 2012</b>	Evaluate treatment FPISR with ELA+viabahn	Prospective multicentric	27	100	12	48	17.4	ABI increased 0.58 to 0.9
<b>Shammas 2012</b>	ELA+PTA FPISR	Retrospective monocentric	40	93	12	NA	48.7	TVR 48.7%
<b>Van den Berg 2012</b>	ELA+DEB for FPISR	Restrospective monocentric	10	100	7.6	70	0	Mean time of occurrence restenosis 7.2months
<b>Gandini 2013</b>	ELA+DEB vs DEB for SFA in stent occlusion for CLI	Prospective monocentric	24	100	6 and 12	91.7 and 66.7 (ELA+DEB) vs 58.3 and 37.5 (DEB)(P=.01)	16.7% (ELA+DEB) vs 50% (DEB) (P=.01)	NA
<b>Schmidt 2014</b>	Evaluate performance of TE and TB for FPISR	Prospective multicentric	90	96.7	6 and 12	64.1 (95CI 53-73.9) and 37.8 (95CI 27.7-49.2)	12.2 (95CI 7-21) and 35.5 (95CI 17.6-59.4)	NA
<b>Van Den Berg 2014</b>	Evaluate midterm follow-up ELA+DEB FPISR	Prospective cohort	14	100	19.4	91.7	7	Mean time of recurrence of restenosis 8.6 months
<b>Dippel 2015</b>	ELA+PTA vs PTA alone for FPISR	Multicentric prospective randomized	168	93.5	6	71.1 (ELA+PTA) vs 56.4 (PTA)	26.5(ELA+PTA) vs 49(ELA) (P<.005)	NA
<b>Armstrong 2015</b>	ELA+PTA vs PTA alone for FPISR	Retrospective multicentric	54	100	24	NA	14 (ELA) vs 44(PTA alone) (P=.05)	Class III ISR treated with ELA: 54% recurrent stenosis vs 91% PTA at 1year (P=.05)

<b>Reference</b>	<b>Study Design</b>	<b>Main Objectives</b>	<b>N (fenestration)</b>	<b>Localization</b>	<b>Type</b>	<b>Follow-up (months)</b>	<b>Results</b>
<b>Murphy 2009</b>	Case Report	Laser ISF after TEVAR covering LSCA	1	LSCA	Retrograde	8	No endoleaks/stent patent
<b>Ahanchi 2012</b>	Retrospective monocentric	Laser ISF during emergency TEVAR	5	LSCA	Retrograde	8	PP 100% /no endoleak related to fenestration
<b>Redlinger 2013</b>	Retrospective monocentric	Laser ISF during emergency TEVAR	22	LSCA	Retrograde	10	PP 100% / 2 type II endoleaks
<b>Sonesson 2016</b>	Experimental study on pigs	Evaluate if Laser ISF generate emboli	7	Iliac	Antegrade	NA	No produce macroscopically visible emboli or clot
<b>Qin 2017</b>	Experimental study on swine and clinical retrospective monocentric	Laser ISF of aortic arch during TEVAR	6 (swine) and 31(human)	Carotid and LSCA	Retrograde	10	No tearing of the fabric/ Technically feasible/ PP 100%/ No endoleaks