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ORIGINAL RESEARCH

Preclinical Feasibility of the ELANA End-to-End Anastomotic Technique in a Porcine Pilot Study

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Purpose: To advance minimally invasive surgical techniques, we developed the sutureless ELANA® End-to-End anastomotic technique. This preclinical study aimed to evaluate the technical feasibility, hemostatic performance, and short-term patency of the new approach in a porcine model.

Methods: Six pigs underwent implantation of the ELANA End-to-End device in a divided in situ right internal mammary artery (RIMA) via partial sternotomy. The pigs were followed-up for either 35 days (N=3) or 90 (N=3) days. Feasibility was evaluated based on technical success, achievement of hemostasis, and anastomotic construction time. Patency was assessed at the end of follow-up through angiography and histological analysis.

Results: The anastomosis was successfully constructed in four of six animals. Among these, hemostasis was achieved in three cases without additional intervention; one required a single hemostatic stitch. The median anastomotic construction time was 18 (15–45) minutes. Technical failure in two animals was due to difficulty maintaining vessel alignment during deployment. All four successfully constructed anastomoses were patent at the end of follow-up (N=2, 35 days; N=2, 90 days), with no evidence of stenosis on angiography or histology.

Conclusion: The ELANA End-to-End technique demonstrated promising patency outcomes. However, the current procedure is technically demanding. Design improvements aimed at stabilizing vessel positioning are warranted to enhance feasibility and reduce construction time.

Keywords: coronary artery bypass grafting, sutureless, anastomosis, minimal invasive, ELANA

Introduction

Minimally invasive coronary artery bypass grafting (CABG) holds significant promise for reducing surgical trauma, hospital stay, and recovery time.[1–3] However, one of the primary technical limitations in such procedures remains the complexity and time consumption of hand-sewn vascular anastomoses, demanding high precision and specialized teams. Limiting the applicability of minimally invasive CABG to specialized centers.

To address this challenge, various sutureless devices have been developed over the past decades, with varying success. All aiming for standardized and simplified anastomotic techniques. Limitations were mainly related to difficulties in device application, diminished patency results when compared to the hand-sewn, and reimbursement issues.[4,5]

Building on this objective, we first developed a sutureless side-to-side coronary anastomosis, the ELANA® Heart Bypass. This device has been evaluated in various preclinical and early clinical settings, showing encouraging feasibility and patency outcomes. However, the findings also underscored critical limitations in the current design, highlighting the need for essential

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modification to enhance performance and reliability.[6–9] The ELANA technique utilizes a mechanical implant to secure vessel attachment and a laser-assisted arteriotomy, thereby minimizing intraluminal foreign material and tissue trauma.

To facilitate a broader range of procedures, the ELANA End-to-End technique was developed. This technique constructs a sutureless end-to-end anastomosis that is characterized by intima-to-intima apposition. In CABG, a simple end-to-end anastomosis allows a larger variety of graft constructions, such as the "I"-fashioned grafts to extend the in-situ IMA with a radial artery.[10] The same mechanism for end-to-end anastomosis could hypothetically also serve in organ transplant surgery, vascular access surgery, peripheral bypass surgery, and reconstructive surgery.

Within this pilot study, we aim to evaluate the technical feasibility, hemostatic performance, and short-term patency of this new ELANA End-to-End technique in a porcine model.

Materials and Methods

This is an uncontrolled pilot study in a pig model, designed to evaluate the technical feasibility and short-term patency of a new sutureless end-to-end anastomotic technique for small-diameter vessels. Six pigs (Topigs Norsvin, female, 50–75 KG) were included. The ELANA End-to-End device was implanted in the divided in situ right internal mammary artery (RIMA) via partial sternotomy. The pigs were followed up for 35 (N = 3) or 90 (N = 3) days, time points appropriate for assessing early patency and vascular integration in preclinical studies. The sample size was determined pragmatically to explore procedural feasibility and biological response in a resource-conscious, ethically justified protocol. The objectives were feasibility and patency. Feasibility included: technical success, hemostasis, and anastomosis construction time. Patency was determined per angiography and histology at the end of follow-up.

To minimize animal use and align with refinement-reduction-replacement (3Rs) principles, pigs were simultaneously included in a separate ELANA End-to-Side study (manuscript submitted). In each animal, the End-to-End device was implanted in the divided in situ RIMA, while the End-to-Side device was implanted in the left internal mammary artery (LIMA) to left anterior descending coronary artery (LAD). Both procedures were carried out in the same operative session, starting with the implantation of the End-to-End device. The procedures were anatomically distinct and did not interfere with each other's outcomes. The animal ethics committee of the Utrecht University approved this study (AVD1150020185105-1-02), all procedures were conducted in compliance with the Dutch act on animal experimentation (2014) and European Directive 2010/63/EU.

Medication and Surgery

The medication administered was similar to the simultaneous ELANA End-to-Side study and in accordance with the protocol previously described.[9] All invasive procedures were performed under complete anesthesia. Antithrombotic therapy was given from three days prior to surgery until the end of follow-up; Acetylsalicylic acid 320 mg and Clopidogrel 75 mg daily. During the interventions Heparin was administered: partial heparinization (Heparin titrated to activated clotting time (ACT) >2.5 times baseline) during surgery, partial heparinization (5000 IU Heparin, repeated every 90 minutes) during angiography, and complete heparinization (25000 IU Heparin) before euthanasia. Perioperative analgesia was administered for each surgery and angiography, euthanasia excluded: Buprenorphine 35 µg transdermal from one day preoperative, until day three post-operative. In case signs of distress were detected, extra analgesia was added in consultation with the institute's veterinarian.

Surgery was performed by MH (researcher) under supervision of BP or PK (cardiothoracic surgeons). Following manubrium-sparing partial sternotomy, the RIMA was skeletonized from the first rib to the distal bifurcation. The RIMA was transected in the middle, to be reconnected per ELANA End-to-End anastomosis. When a small caliber RIMA was detected, the anastomosis was performed more proximal. Also, eventual vascular spasm was treated by the administration of Papaverine solution (1.0 mg/mL) on the adventitia. As much of the RIMA was harvested as was needed to construct a tension-free anastomosis.

ELANA End-to-End Technique

The End-to-End clip used for this technique serves as an implant. It consists of a clip body that contains a spring, and two rings that are decorated with pins as is presented in Figure 1. The spring delivers the force needed to align both vessels within the anastomosis. The pins on the outside of the ring are there to position the vessel during application.

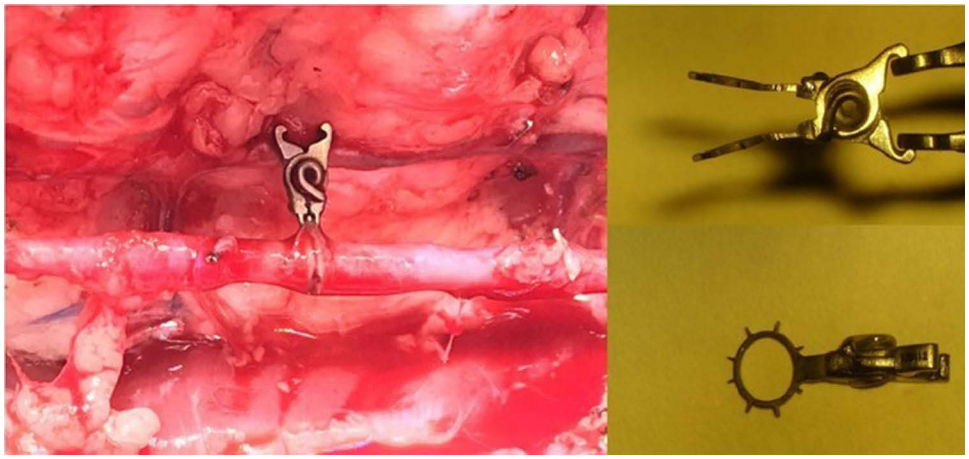

Figure 1 ELANA End-to-End clip.

An applicator is used to open the End-to-End clip. The proximal end of the RIMA is introduced into the ring and folded (inside out) over the pins on the outside of the ring. This step is repeated for the distal end of the RIMA. Thereafter, the End-to-End clip is closed and remains in situ.

Data Collection

Baseline RIMA inner diameter was measured using epicardial ultrasound (Medistim MiraQ™ Cardiac System). Data was processed in Excel for windows V2402. Data was reported in median (minimum – maximum) or count (percentage) or as described otherwise. No statistical analyses were performed other than data description.

Feasibility

During the ELANA End-to-End procedure, the following feasibility outcomes were noted; technical success (defined as the possibility to align vessels in the anastomosis), hemostasis, and the duration of anastomotic construction.

Angiography

Angiography was performed at the end of follow-up under general anesthesia. A 6 French sheet was inserted via a side branch of the femoral artery. An IMA-catheter was advanced into the RIMA over a guidewire (J-wire). At least two directions were filmed. In case the RIMA could not be catheterized (because of its technically unfavorable position in the porcine anatomy), the angiography was repeated post-mortem with direct catheterization of the RIMA. Images were scored on Fitz-Gibbon classification (A, 100% open anastomosis; B, >50% open anastomosis; C, <50% open anastomosis) and on the percentage of (relative) stenosis.

Histology

At the end of follow-up, euthanasia (intravenous potassium chloride, 200 mmol, followed by exsanguination) was performed under general anesthesia after full heparinization (25000 IU heparin). The anastomosis was excised from the thoracic wall with >5mm RIMA on both ends. The sample was fixed (4% neutral buffered formaldehyde), embedded (methyl methacrylate), sawn (diamond sawing, thickness ± 350µm), and hematoxylin and eosin (H&E) stained according to the previous protocol presented by our research group.[4] All anastomoses were analyzed by WB (veterinary pathologist) and MH (researcher), on mid-anastomotic diameter, amount of intima hyperplasia, RIMA-apposition, thrombus, inflammation, aneurysm formation, and signs of tissue trauma (interrupted intima, necrosis, cellular debris in the vessel wall).

Results

Six pigs were included in this study. Four pigs with an ELANA End-to-End anastomosis completed follow-up (N = 2, 35 days; N = 2, 90 days).

Table 1 Perioperative Feasibility

Animal	Inner Diameter RIMA, mm	Success	Hemostasis	RIMA Damage	Construction Time, Minutes
1	Missing	Yes	Yes	No	45
2	Missing	No	NA	No	NA
3	2.4	Yes	Leakage	No	21
4	2.5	Yes	Yes	Yes	15
5	2.8	Yes	Yes	No	15
6	2.4	No	NA	Missing	NA
TOTAL	2.5 (2.4–2.8)	4 of 6	3 of 4	1 of 5	18 (15–45)

Notes: Data is presented for each separate case, and in total as median (minimum – maximum), or count. Success is maintained when both sides of the RIMA are positioned within the anastomosis. Missing is used when data was not adequately registered.
Abbreviations: RIMA, right internal mammary artery; mm, millimeter; NA, not applicable.

Feasibility

As presented in Table 1, in four of the six pigs the anastomosis was successfully constructed. In two pigs the anastomotic construction was not successful because RIMA-position could not adequately be maintained before closing the device. The pins on the outside of the ring should (partially) pierce the vessel wall to maintain position. In these cases, the pins were blunt or damaged, causing the vessel to slip before the device could be closed properly. In some other cases, this caused a prolonged construction time, the median anastomotic construction time was 18 (15–45) minutes. In one case, the RIMA was damaged at the anastomotic site. The RIMA was trimmed at the anastomotic site and the anastomosis was successfully constructed in a second attempt. In three out of four anastomoses, hemostasis was directly achieved. In one case, a successful single hemostatic stitch was placed.

Angiography

Four anastomoses were found patent at follow-up. Three anastomoses were patent in angiography (Fitz-Gibbon A) at the end of follow-up (N = 1, 35 days; N = 2, 90 days). In one case (35 days follow-up) we did not succeed in catheterization of the RIMA due to the unfavorable anatomy, but patency was confirmed post-mortem ex situ. Figure 2 presents the angiography images. The growing pig exhibited an increase in RIMA diameter, whereas the size of the end-to-end anastomotic device remained constant. This resulted in a relative narrowing of 30% (10–30%). No narrowing or stenosis was detected within the anastomosis.

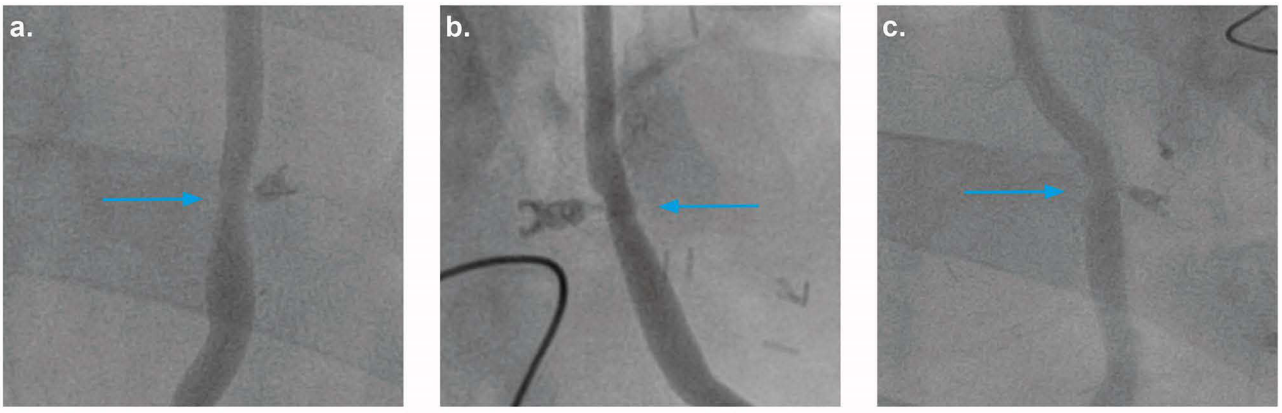

Figure 2 Angiography. (**a**) 35 days postoperatively; (**b**) 90 days postoperatively; (**c**) 90 days postoperatively. The RIMA is filled with contrast. The blue arrow points at the anastomosis. The clip body of the End-to-End clip is visible lateral to the RIMA.

Table 2 Histology

Follow-Up	N	Mid-Anastomotic Diameter, µm	Intima Hyperplasia, µm	Thrombus	Tissue Trauma	Aneurysm Formation
35 Days	2	2292	43	0	0	0
90 Days	2	3223	106	0	0	0

Notes: Data is presented as mean or count. Tissue trauma was scored for interrupted intima, necrosis, intraluminal cellular debris.
Abbreviations: N, number; µm, micrometer.

Histology

Histology results obtained at the end of follow-up are presented in Table 2 and Figure 3. Patency was confirmed in all four anastomoses. At the end of follow-up, a slight amount of streamlining intima hyperplasia was detected, with a median thickness of 68 (40–122) µm. Although the amount of intima hyperplasia seems to increase between 35- and 90-days follow-up, the maximum amount is limited in relation to the median anastomotic opening; 2526 (2155–3822) µm.

Overall, the clip was adequately positioned, with intima-intima apposition of the distal and proximal RIMA. No non-intima surface or foreign material was exposed inside the anastomosis. In two of the anastomoses (N = 1, 35 days; *N* = 1, 90 days follow-up), apposition could not definitively be determined. The inner surface was covered with neo-intima; however, the

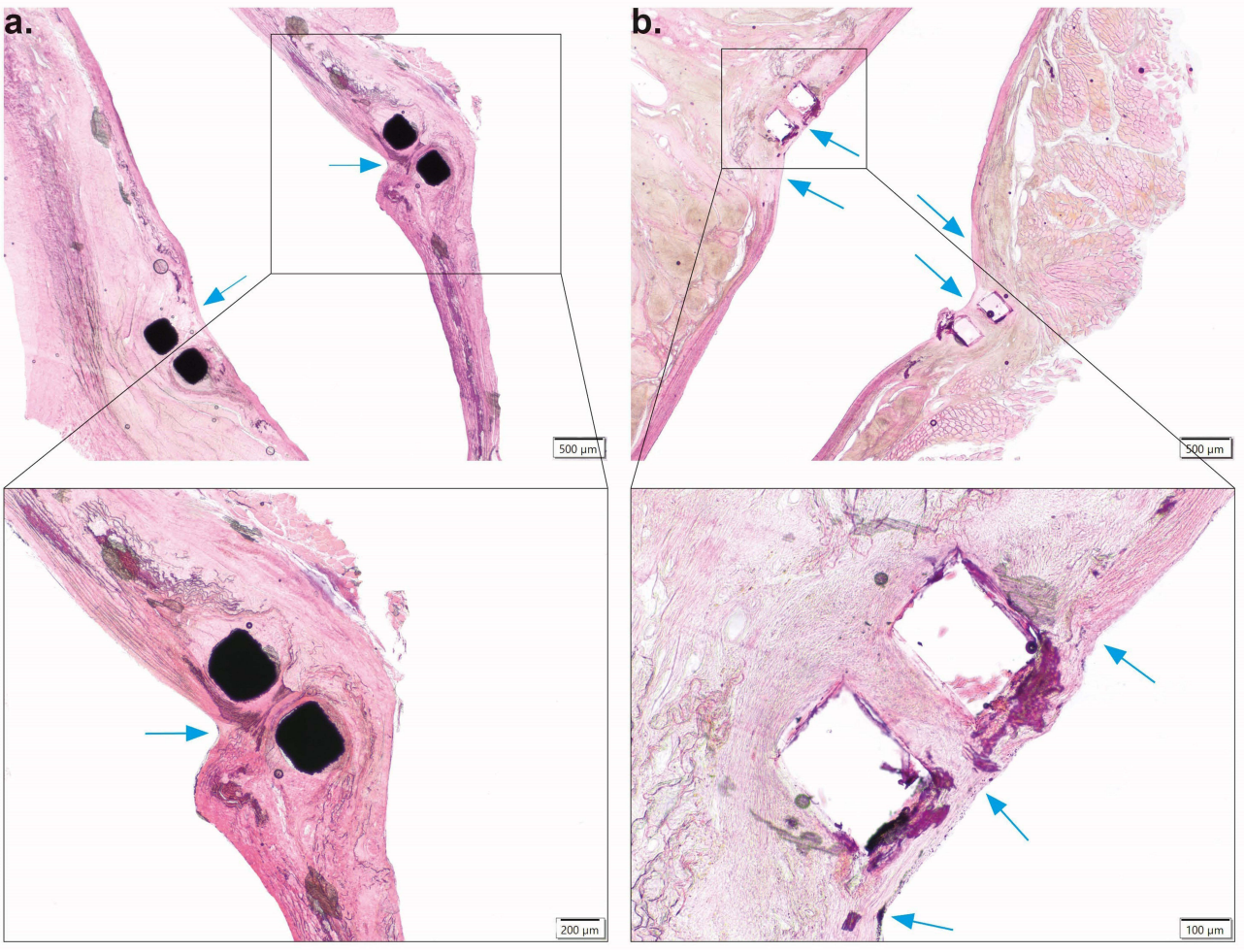

Figure 3 Histology. Transversal, H&E stained slides of the End-to-End anastomosis. (**a**) 35 days postoperatively; (**b**) 90 days postoperatively. The metal of the device (ring) is visible as black square (or as blank square resulting from an artefact). Blue arrows appoint streamlining intima hyperplasia. Tissue disconnection from the metal and an irregular aspect of the metal are artefacts from sawing during slide preparation.

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original vessel wall appeared retracted from the anastomosis without signs of leakage or aneurysm formation. A moderate granulomatous inflammatory response was detected, centered on the clip. There were no signs of aneurysm formation.

Discussion

In this initial pilot study with the ELANA End-to-End anastomosis, we assessed the feasibility of the technique. Results indicate that construction of the ELANA End-to-End anastomosis is feasible. However, the median anastomotic construction time was 18 minutes and technical success was achieved in only four out of the six anastomoses. The long construction time was primarily due to difficulties in maintaining vessel wall position on the proximal end whilst positioning the distal end, and vice versa. Consequently, frequent repositioning of the vessels was necessary, which consumed time and increased the risk on tissue damage.

For those anastomoses that were successfully constructed, excellent patency rates were observed at the end of follow-up. Intima hyperplasia formed a streamlined layer, and the anastomotic diameters were adequate, suggesting a normal healing response following the intervention. The anastomoses had an everted intima to intima apposition with limited tissue trauma. These patency results reflect the line of expectations based on previous research on vascular anastomoses using intima-to-intima apposition techniques.[11–14]

The current study was limited by the small number of animals included. To strive towards reduction of animal trials, it was convenient to add pilot research to an existing study. Follow-up research in larger numbers is essential to confirm feasibility and patency. Yet, this pilot study provided essential information due to the level of detail in the follow-up evaluations. This information could already be used for an inevitable design change.

Based on the challenges encountered during anastomotic construction, we propose two potential design improvements for future prototypes. First, repositioning the pins to function like barbs could enhance stability by preventing the vessel ends from slipping out of the anastomosis during manipulation. Alternatively, incorporating an additional ring to secure the proximal end while adjusting the distal end could achieve the same goal. These modifications aim to enhance usability and reduce the time required for anastomotic construction, while maintaining the intima-to-intima apposition. This apposition might be crucial, as initial follow-up results indicated only streamlining intima hyperplasia at the end of follow-up, while a granulomatous inflammatory response was detected outside the anastomosis. We hypothesize the observed inflammatory response and the lack of intima hyperplasia build-up to result from the current anastomotic design. This design keeps the manipulated and foreign materials external to the anastomosis.

Various techniques were previously developed for a sutureless end-to-end anastomosis; stent-grafts, laser welding, adhesives, magnet-based couplers, separate clips, staplers, and mechanical connectors.[15–18] Of these, the U-clip® (Medtronic) and the nonpenetrating clips (AnastoClip®, LeMaitre) have been clinically introduced. Both techniques construct an anastomosis with an intima-intima apposition and without the need for knot-tying. Whereas these techniques are reported for end-to-end anastomoses, various techniques were also clinically evaluated for coronary end-to-side or side-to-side anastomoses; again separate clips, staplers, mechanical connectors, and magnet-based couplers. Of these, the U-clip (Medtronic) and the C-port® (Cardica) were clinically available.[4] The C-port is a stapler that facilitates a single-shot end-to-side anastomosis on the coronary artery. Despite their introduction, these techniques were never commonly adopted due to high costs and the limited benefits in open surgery. With the growing trend towards minimally invasive surgical approaches, sutureless anastomotic devices present significant potential benefits. Specifically, for CABG, end-to-side and side-to-side techniques could facilitate coronary and Y/T-graft anastomoses, while the end-to-end technique offers greater flexibility in graft routing. Yet, to our knowledge, none of the devices are currently clinically available for CABG.

Importantly, the promise of the ELANA approach is not limited to coronary bypass surgery as it has already been explored in other vascular territories, starting with neurosurgery. The ELANA clip technique has demonstrated feasibility and safety in intracranial applications.[19,20] These studies underscore the versatility of the ELANA concept and support its broader applicability across various surgical domains, including transplant surgery, dialysis access, peripheral bypass, and reconstructive microvascular surgery.

While our study offers important early-stage insights, it is limited by its small sample size and short follow-up duration. The decision to integrate this pilot study with an existing preclinical study limited the number of animals, although the detailed outcome measure still allowed for meaningful design feedback. Future studies should focus on

mechanical device development based on the current findings and expanded preclinical testing with larger sample sizes and longer follow-up durations to adequately assess technical feasibility and patency.

Conclusion

This first pilot study highlights the potential of the ELANA End-to-End technique. When successfully constructed, the anastomoses showed excellent patency, supporting the promise of intima-to-intima apposition.

However, the procedure remains technically demanding, with failure primarily due to mechanical limitations such as vessel slippage and fixation pin issues. These findings underscore the need for design refinements. Specifically, improved fixation mechanisms like barbed pins or a stabilization ring to enhance stability and ease of use.

While the sample size in this pilot study was limited, the results provide a solid foundation for further studies involving larger cohorts and extended follow-up periods. With continued refinement, the ELANA End-to-End technique could provide a valuable alternative to minimally invasive vascular and coronary surgery.

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Disclosure

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