Healthcare Robotics

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About the Project

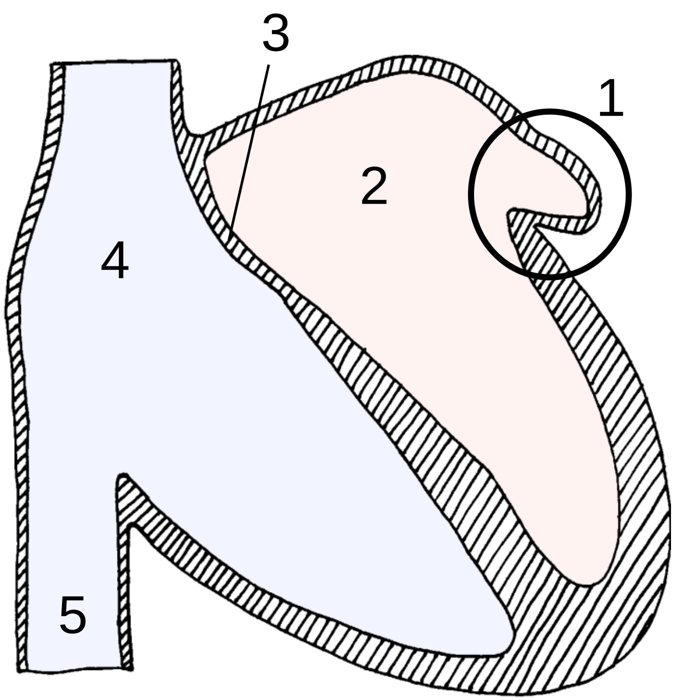
- MiMed (Professor Lüth)
- Supervisors
  - Professor Lüth
  - Professor Knoll
- General Electric Global Research Europe
  - Contact: Dr. Victor Samper
- Started in June 2013

Clinical Contact

- German Heart Center Munich
  - Contact: Professor Dr. med. Ilka Ott

Introduction

- 1,5 – 2 % of the population in developed countries suffers from atrial fibrillation
- Atrial fibrillation increases the risk for strokes
- Patients with additional risk factors need a treatment to prevent strokes
- Primary origin of the thrombi is the left atrial appendage (LAA) (1)

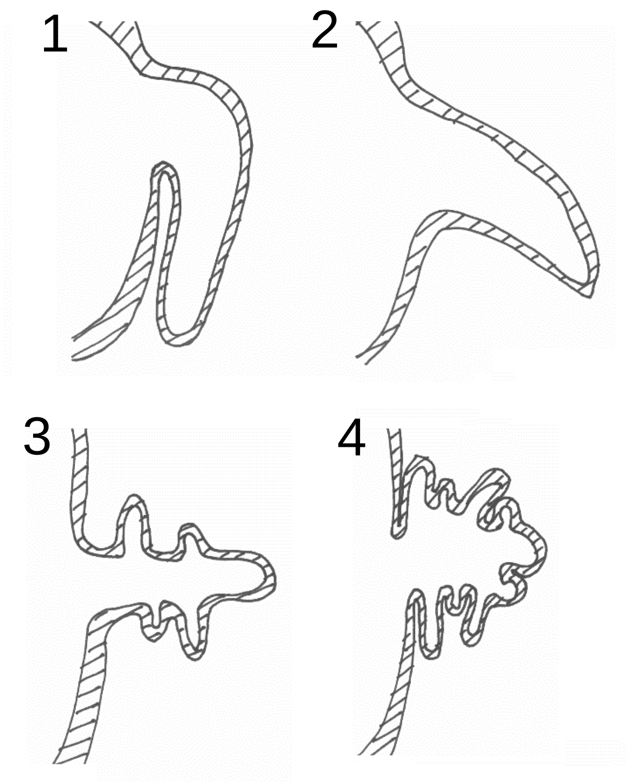


Cross section of the heart
1 Left atrial appendage
2 Left atrium
3 Atrial septum
4 Right atrium
5 Inferior vena cava

(Camm *et al.*, 2012), (Paranskaya & Nienaber, 2013)

Introduction

- **Left atrial appendage (LAA)**
  - Muscular pouch at the left atrium
  - Situtated between the upper left pulmonary vein and the left ventricle
  - Four types of morphology
  - Sizes differ between patients



Types of LAA morphologies
1 Chicken wing
2 Windsock
3 Cactus
4 Cauliflor

(Wang *et al.*, 2010), (Cruz-Gonzalez *et al.*, 2010)

Stroke prevention
State of the art

Medication treatment

- Warfarin or Aspirin
- Reduction of stroke risk 68% respectively 25%

(Gage *et al.*, 2000)

Surgical excision or exclusion

- Additionally to an open chest surgery for patients with mitral valve disease or coronary artery bypass grafting
- Excision: Scissors or amputating stapler device
- Exclusion: Suturing or stapling

(Kanderian *et al.*, 2008)

Stroke Prevention
Limitations of the State of the Art

Oral Anticoagolation

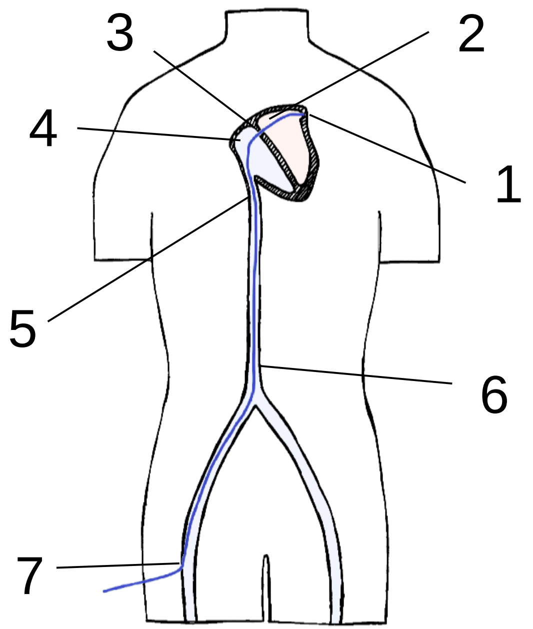
- Not accepted well by patients
- Risk of bleeding complication
- Narrow therapeutic window (Holmes *et al.*, 2009)

Surgical excision or exclusion

- Only in combination with other open chest surgery
- Poor success rate
- Risk of major bleeding (Camm *et al.*, 2012)

Minimally Invasive LAA Occlusion- State of the Art

- Implantation of a foldable structure that occludes the LAA
- The structure is unfolded in the LAA and is anchored by jamming
- The implantation is minimally invasive through an endovascular access
- Imaging: Fluoroscopy and transoesophageal echocardiography (Paranskaya & Nienaber, 2013)
- In 2012: 2128 interventions in Germany (Statistisches Bundesamt, 2014)



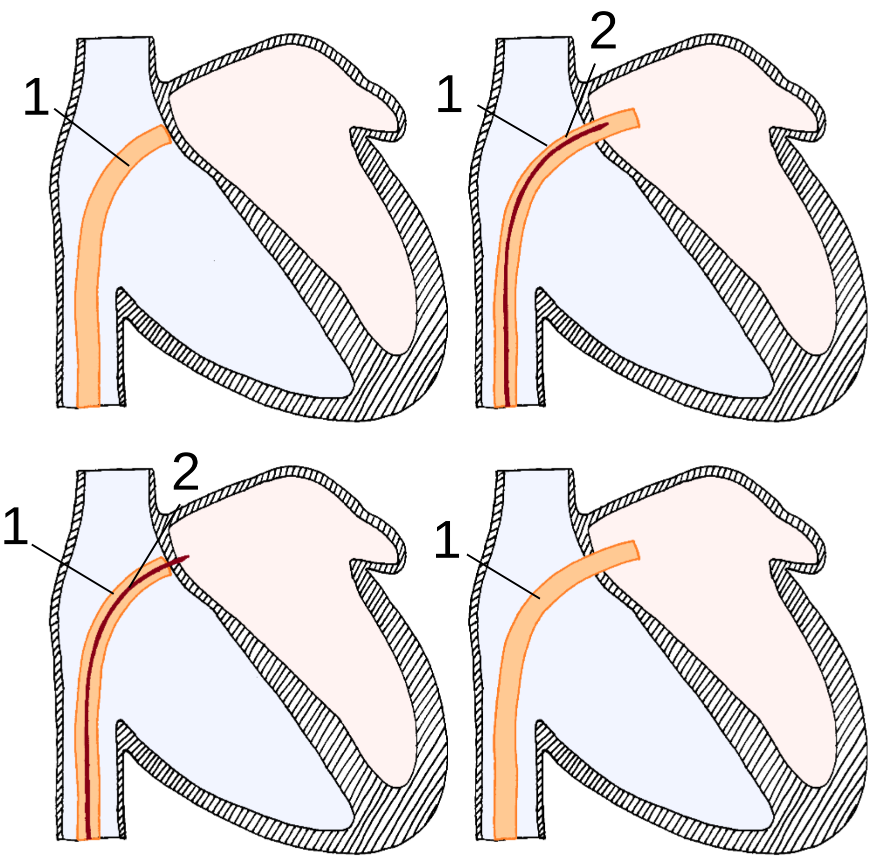
Endovascular Access Path
1 Left atrial appendage
2 Left atrium
3 Atrial septum
4 Right atrium
5 Vena cava inferior
6 Endovascular Access
7 Femoral vein

(Lapp & Krakau, 2013)

Minimally Invasive LAA Occlusion- State of the Art

Punction of the atrial septum

- A guiding catheter (1) is inserted into a femoral vein and advanced through the endovascular system to the right atrium
- A catheter with a needle-tip (2) is used to cross the atrial septum
- The guiding catheter (1) is advanced to the left atrium
- The needle (2) is removed



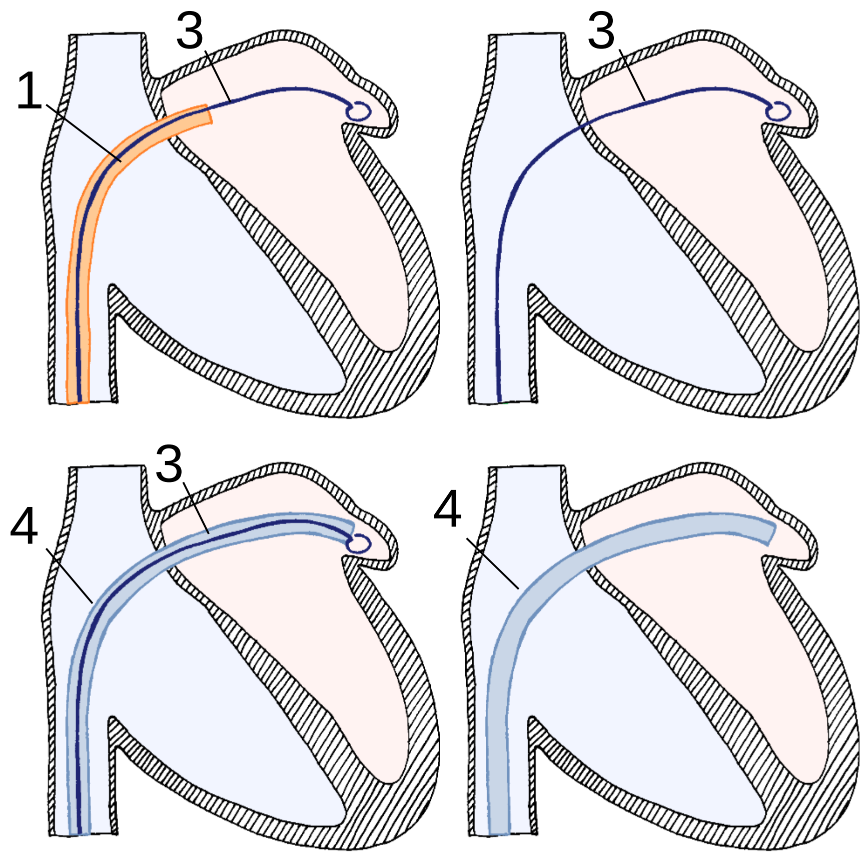
Punction of the atrial septum
1 Guiding catheter
2 Needle-tip catheter

(Bertog *et al.,* 2013), (Lapp & Krakau, 2013)

Minimally Invasive LAA Occlusion-State of the Art

Placement of the catheter inside the LAA

- A not steerable pigtail catheter or guidewire (3) is advanced and positioned inside the LAA
- The guiding catheter (1) is retracted
- The precurved delivery catheter (4) is inserted into the LAA
- The pigtail catheter or the guidewire is removed (3)



Placement of the catheter in the LAA
1 Guiding catheter
3 Guidewire of pigtail catheter
4 Delivery catheter

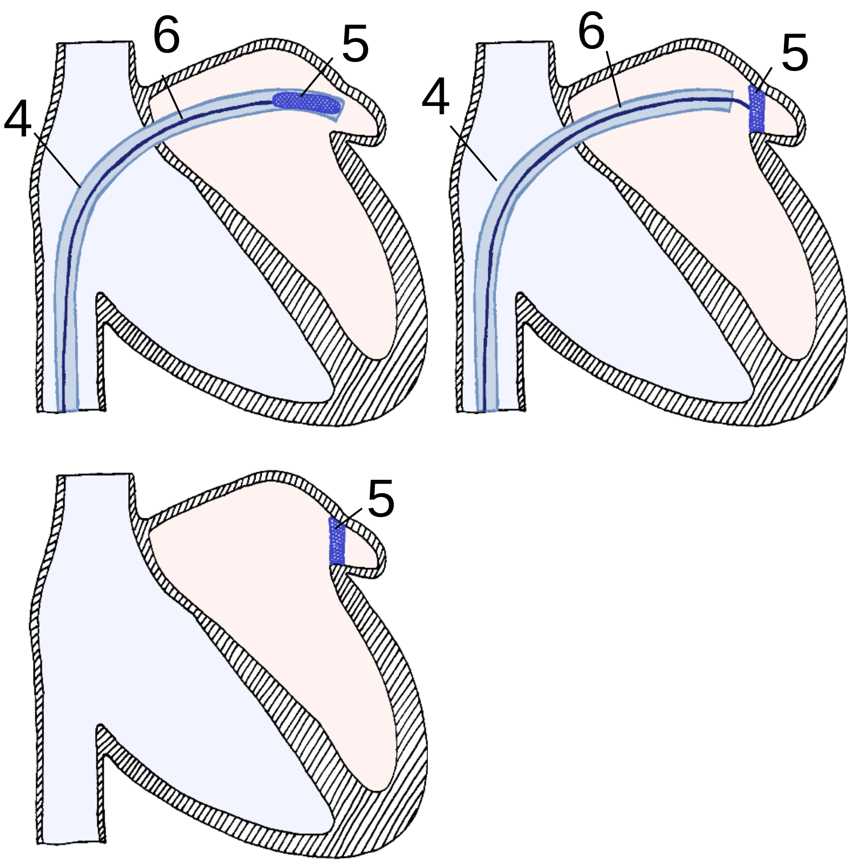
(Bertog *et al.,* 2013), (Lapp & Krakau, 2013)

Minimally Invasive LAA Occlusion- State of the Art

Implantation of the occlusion device

- The occlusion device (5) is advanced to the tip of the delivery system (4) by pushing it with the delivery cable (6)
- By retracting the delivery system (4) the occlusion device (5) is unfolded
- If a malpositioning of the device occurs it can be repositioned after inserting it again into the delivery system
- The occlusion device (5) is released by rotation of the delivery cable (6)

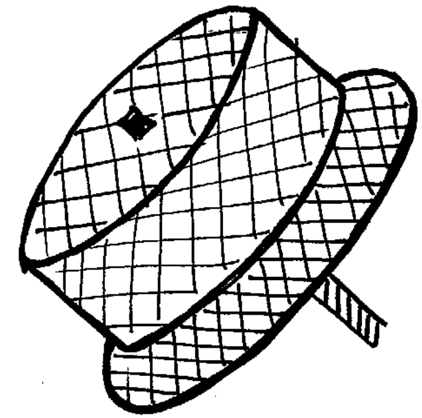
(Bertog *et al.,* 2013), (Lapp & Krakau, 2013)



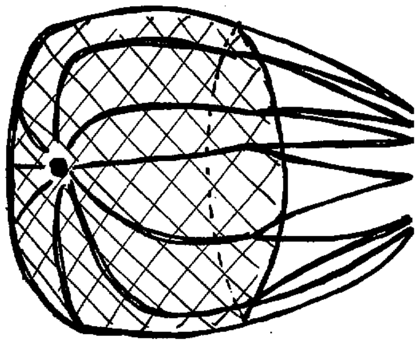
Implantation of the occlusion device
4 Delivery catheter
5 Occlusion device
6 Delivery cable

Available Occluder Devices

- **Amplatzer Cardiac Plug**
  - Two-section foldable nitinol structure consisting of a lobe and a disk
- **Watchman Device**
  - Self-expanding nitinol frame with fixation barbs
- **Delivery catheter**
  - Diameter ~ 5 mm
  - Wall thickness ~ 0,4 mm
  - Thermoplastic elastomer
  - Single or double curved
  - Not steerable



Amplatzer Cardiac Plug
(St. Jude Medical, Saint Paul, USA)



Watchman
(Boston Scientific, Natick, USA)

Minimally invasive LAA closure Limitations of the State of the

- Position and angle of the delivery catheter relative to the LAA are determined by
  - Location of the puncture site
  - Type of catheter
  - Rotation of the catheter
- Position and angle of the delivery catheter can not be actively controlled
- Wrong catheter pose can lead to malpositioning of the device and device embolizations
- Rotations of the catheter can lead to high forces on the LAA and perforations

(Budts, 2013), (Meerkin, 2013)

Positioning of catheters
State of the Art

Manually steerable catheter by pull-wires (Fu *el al.,* 2009)

- Steerable in one or two degrees of freedom
- Pull wire from tip to user interface

Motorized steerable by pull-wires (Camarillo et al., 2008; Ernst & Wood, 2011)

- Two concentric catheter sheaths are moved by pull-wires
- Wires are actuated by motors

Motorized steerable by magnets (Chun et al., 2008; Ernst & Wood, 2011)

- Permanent magnets are moved around the patient
- Catheter with magnets at the tip are aligned with the outer magnetic field

Positioning of catheters
Limitations of the State of the Art

Manual steering with pull-wires (Fu et al., 2009)

- Movement usually in one plane
- Limited range of motion

Motorized steering with pull-wires (Vasilyev et al., 2013; Rafii-Tari et al., 2013)

- Risk of complications because of the big diameter
- Lack of tactile feedback
- Long time to set up system

Motorized magnetic steering (Antoniou et al., 2011; Rafii-Tari et al., 2013)

- Lack of tactile feedback
- Long time to set up system
- OR needs to be changed and system needs a lot of space in the OR

Steering of catheters
State of Research

Publication	University	Actuation principle	Angle	DOF / Segment	Number of segments
Bailly & Amirat, 2005	Paris	Fluid pressure	45°	2	1
Chen et al., 2010	Cambridge	Pull wires	Cont.	-	-
Dupont et al., 2010	Boston	Precurved elastic tubes	-	2	2
Guo et al., 1995	Nagoya	Ionic conducting polymer film	42,3°	1	1
Haga et al., 2005	Sendai	Vacuum	160°	1	1
Haga et al., 2000	Nagoya	Shape Memory alloys	70°	2	1
Ikeuchi & Ikuta, 2008	Nagoya	Fluid pressure	20°	1	1
Ikuta et al., 2012	Nagoya	Fluid pressure	> 90°	1	2
Park & Esashi, 1999	Sendai	Shape memory alloys	-	1	3
Webster et al., 2009	Baltimore	Precurved elastic tubes	-	2	3

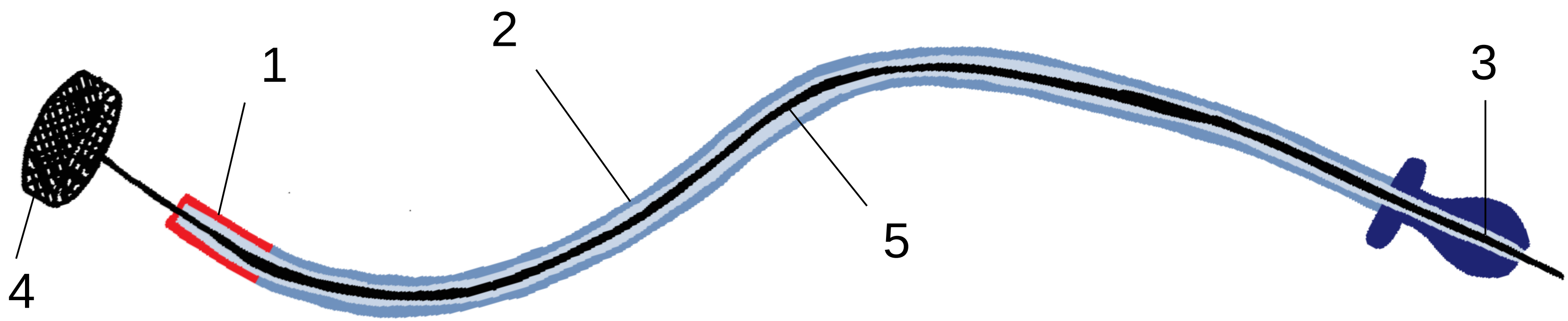
Goals

Development of a mechanism or method to allow control of the position and angle of the delivery catheter for device implantation to achieve a coaxial alignment of the catheter with the planned implant position.

Expected advantages

- With the easier positioning of the catheter procedure times can be reduced
- Due to better implant position device embolizations can be avoided
- Application of torque on the catheters can be avoided and so there is less risk for perforations

Concept (Description of Structure)



1. Mechanism for the positioning of the delivery catheter
2. Delivery catheter
3. User interface

Unchanged:

4. Foldable device for the occlusion of the LAA
5. Delivery cable

Concept (Description of process)

Punction of the atrial septum as described in the state of the art

↓

Pigtail catheter is positioned in the LAA, delivery catheter is advanced over it and pigtail catheter is removed

↓

Delivery catheter is aligned coaxial to the planned landing zone in the LAA with the positioning mechanism at its tip

↓

Foldable structure is advanced inside the delivery catheter, it is unfolded and released

Conclusion and Outlook

- To prevent the risk of strokes the LAA can be removed or occluded.
- There are still unfixes technical issues by the delivery of occlusion devices for the LAA.
- Steering of the distal tip of the delivery catheter is desirable in the later stages of the delivery to ensure a correct orientation of the occlusion device.

→ Mechanisms to guide and orientate the occlusion device are currently developed and evaluated.

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