Development of a Vacuum Catheter for Minimally Invasive Mitral Valve Fixation

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Abstract

This paper presents the development of a novel vacuum catheter system for minimally invasive mitral valve fixation. Traditional mitral valve repair methods mostly involve surgery and therefore anaestesia and the use of extracorporeal circulation, which is often unsuitable for older frail, high risk patients. We herewith propose a new approach using a vacuum suction device combined with a catheter to precisely fixate the mitral valve and enable targeted needle passage for knot formation. Through iterative prototyping and testing, we developed a system capable of securely attaching to pericardial tissue and facilitating needle passage. This study demonstrates the potential for a less invasive approach to mitral valve repair, which could lead to faster patient recovery and reduced post-operative pain.

Keywords: mitral valve repair, vacuum catheter, minimally invasive surgery

1 Introduction

Mitral valve regurgitation is a common heart valve disorder affecting millions of people worldwide [4]. Traditional surgical repair methods, while effective, often involve open-heart surgery, leading to prolonged recovery times and increased risks for patients [5]. Minimally invasive techniques have emerged as promising alternatives, but current approaches like MitraClip [1] and Pascal [2] are limited to fixating the valve at its base.

Our research aims to develop a novel catheter system that can fixate the mitral valve at its top, mimicking traditional surgical techniques while maintaining a minimally invasive approach. This paper describes the iterative development of a vacuum catheter prototype designed to securely attach to the mitral valve leaflets and facilitate targeted needle passage for repair.

2 Background and Related Work

Mitral valve repair techniques have evolved significantly over the past decades. Traditional surgical methods can nowadays performed minimally invasive but still involve cardiopulmonary bypass, which, while effective, carry substantial risks in particularly for old and frail patients [5]. Minimally invasive interventional approaches, such as the MitraClip system from Abbott [1] and the Pascal system from Edwards Lifesciences [2], have shown promise in reducing procedural risks. However, these systems are limited to fixating the mitral valve at its base.

Our approach aims to combine the precision of traditional surgical techniques with the benefits of minimally invasive procedures. By developing a vacuum-based fixation system, we seek to enable attachment at the top of the valve leaflets, where they connect to the heart muscle and where regurgitation is most likely to occur.

3 Methodology and Prototype Development

We employed an iterative prototyping approach to develop our vacuum catheter system. All prototypes were created using a Formlabs 3 Resin Printer [3] and tested on pericardial tissue to simulate mitral valve conditions.

3.1 Prototype 1: Single Large Cup

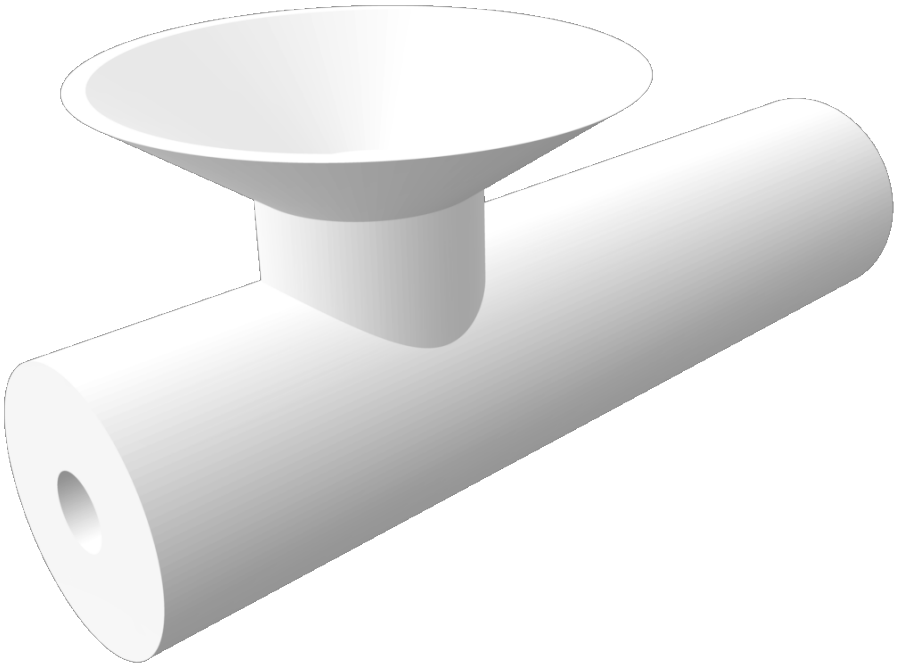

Figure 1: Prototype 1: Single large suction cup design

The initial prototype consisted of a single, large suction cup attached to a balloon catheter. While

it successfully attached to the pericardial tissue, the suction was insufficient for needle passage, and the tissue was drawn too deeply into the cup.

3.2 Prototype 2: Multiple Small Cups

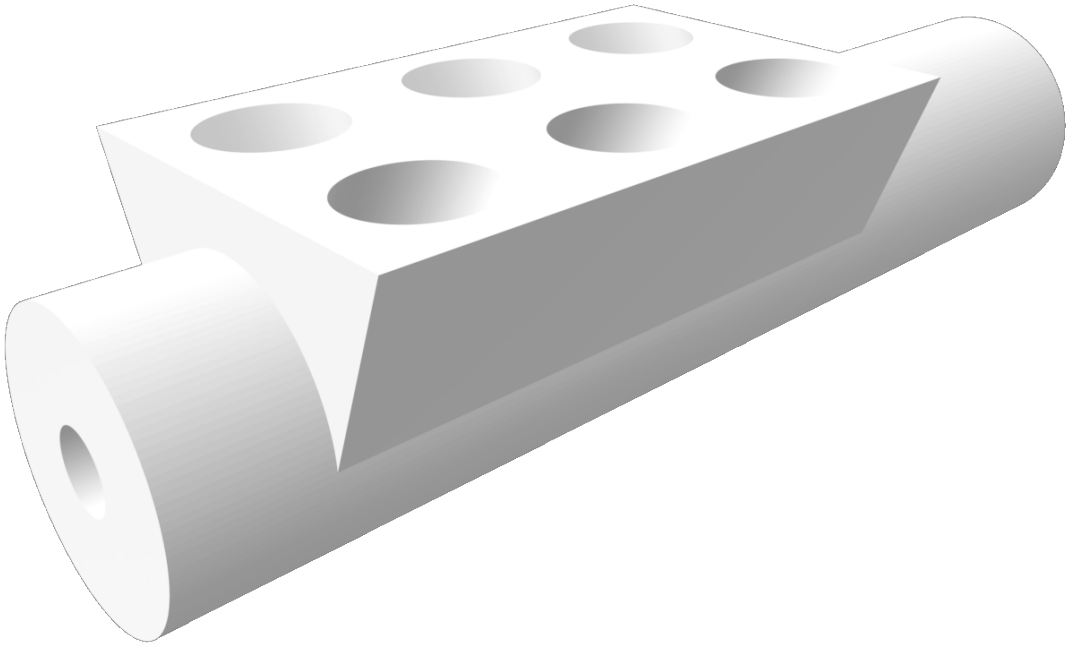

Figure 2: Prototype 2: Multiple small suction cups design

To address the issues of the first prototype, we designed a system with multiple smaller cups. This improved suction force but led to difficulties in vertical lifting of the tissue.

3.3 Prototype 3: Two Large Cups

Returning to a larger cup design, we created a prototype with two cups featuring larger outer diameters and smaller inner diameters. This design prevented tissue lift-off and provided secure fixation.

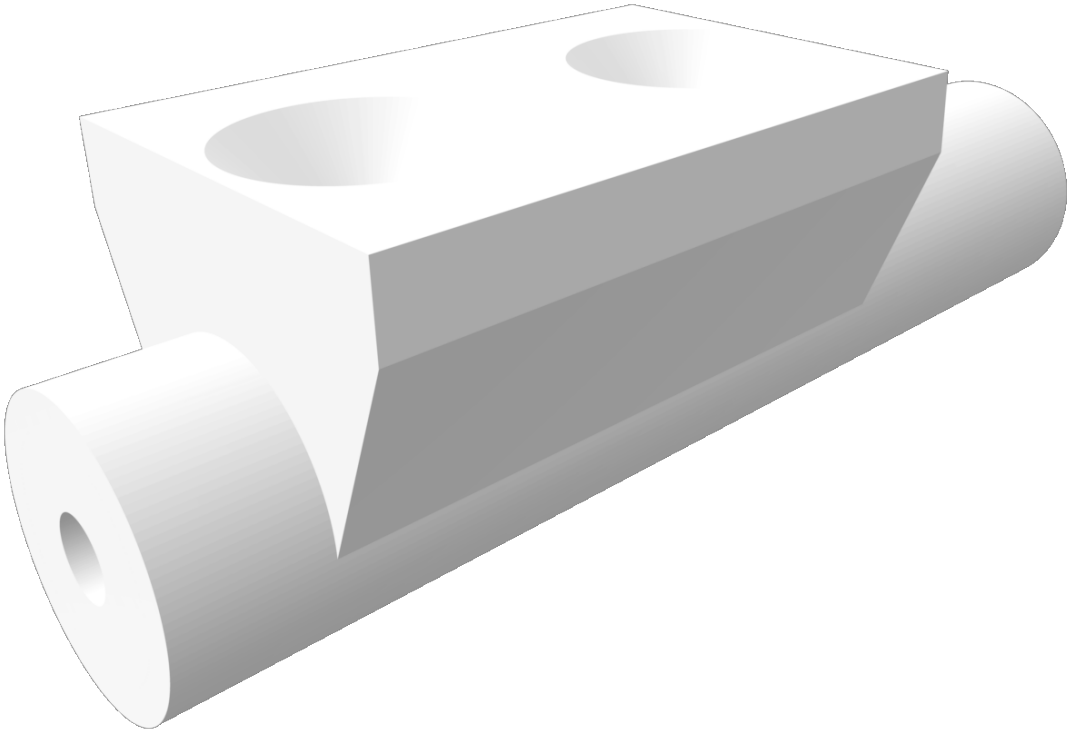

Figure 3: Prototype 3: Two large suction cups design

3.4 Prototype 4: Reoriented Cups

The final prototype reoriented the cups to allow perpendicular needle passage, addressing the difficulties encountered in previous designs.

4 Results

Our iterative prototyping process yielded progressively improved designs. The final prototype (Prototype 4) demonstrated the following capabilities:

1. Secure attachment to pericardial tissue
2. Sufficient suction strength to maintain fixation during needle passage
3. Improved orientation for easier needle manipulation

While quantitative data on suction force and tissue retention were not collected in this preliminary

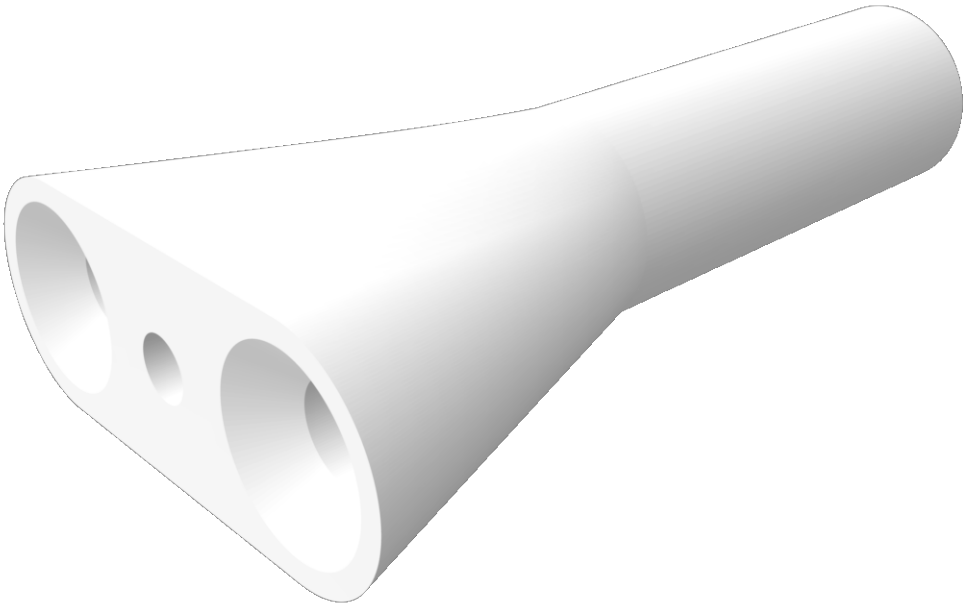

Figure 4: Prototype 4: Reoriented suction cups design

study, qualitative observations indicated significant improvements in performance from the initial to the final prototype.

5 Discussion

The development of our vacuum catheter prototype demonstrates the potential for a novel approach to minimally invasive mitral valve repair. By enabling fixation at the top of the valve leaflets, our system could offer advantages over current minimally invasive techniques.
However, several challenges remain to be addressed:

1. Blood loss management when the catheter is not attached to tissue
2. Risk of tissue damage during attachment and detachment
3. Need for a control system to regulate suction force
4. Development of a multi-lumen catheter for independent control of each suction cup

Table 1: Summary of Prototype Features

Feature	Prototype 1	Prototype 2	Prototype 3	Prototype 4
Number of cups	1	6	2	2
Cup size	Large	Small	Large	Large
Orientation	Vertical	Vertical	Vertical	Horizontal
Suction strength	Strong	Weak	Strong	Strong
Needle passage	Difficult	Moderate	Moderate	Easy
Tissue retention	Moderate	Weak	Good	Excellent

5. Refinement of the needle passage and fixation process

Future work should focus on addressing these challenges and conducting more rigorous quantitative testing. Additionally, ex vivo and in vivo animal studies will be crucial to assess the safety and efficacy of the system before considering human trials.

6 Conclusion

This study presents the initial development of a novel vacuum catheter system for minimally invasive mitral valve repair. Through iterative prototyping, we have demonstrated the feasibility of using vacuum suction for valve leaflet fixation and needle passage. While significant challenges remain, this approach shows promise for improving minimally invasive mitral valve repair techniques, potentially leading to better outcomes and faster recovery for patients with mitral valve regurgitation.

References

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