A Virtual Heart Valve Implant System: Characterizing the Value and Implementation Effort for Each Feature

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MEDICAL DEVICES CENTER
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Driven to Discover

Methodology

Purpose

Explore a method to organize ideas from a design idea generation session for a software application.

Methodology: Idea Generation Session

Time frame: 60 minutes total

- Present case study
- Two individual idea generation sessions with focused topics
- Present ideas and conclusions

Participants

Selection based on experience with the use case and related fields. Interdisciplinary groups provide ideas that are all inclusive in scope for an individual project.

Sorting Ideas

Similar ideas are combined and irrelevant ideas are filtered out.

Template

Used to elaborate on each idea.

Idea name

A description of the idea

Why this idea is important?

Characteristics that highlight importance or value of an idea

Value: Estimated user value of the idea (linear scale)

Effort: Estimated work effort (logarithmic scale)

Prerequisites: for realizing the idea

Challenges: to implement idea

Simplifications: How the idea could be broken up into smaller parts

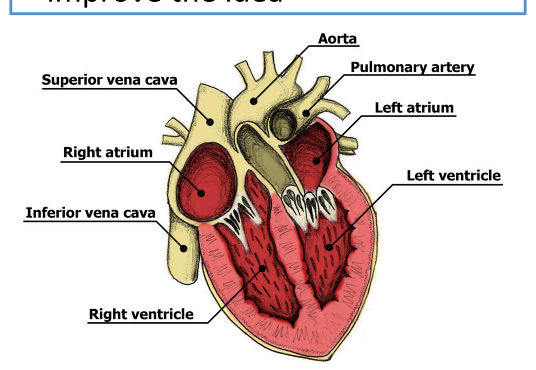
Continued refinements: How to improve the idea

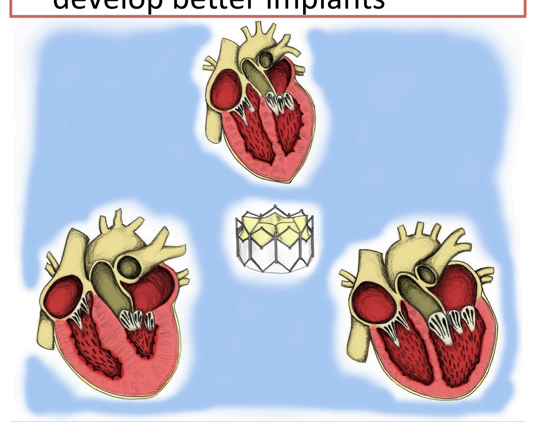
Case Study

Purpose

Investigate the feasibility and features of a virtual heart valve implant system, including:

- Usefulness to clinicians for finding the best transcatheter aortic valve implant model, size, position, and orientation.
- Accessibility to engineers to develop better implants





Participants

10 were recruited

Backgrounds included:

- Biomedical engineering,
- Computer science,
- Mechanical engineering, and
- Medical science disciplines

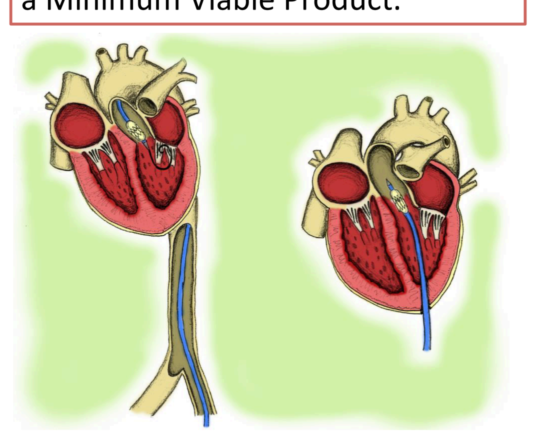
Methodology: Idea Generation Session

Time frame: 60 minutes

- Use case: TAVR procedure
- Idea generation sessions
  - Topic one: Design ideas for valve design, engineering and simulations
  - Topic two: Pre and periprocedural purposes
- Present ideas and conclusions

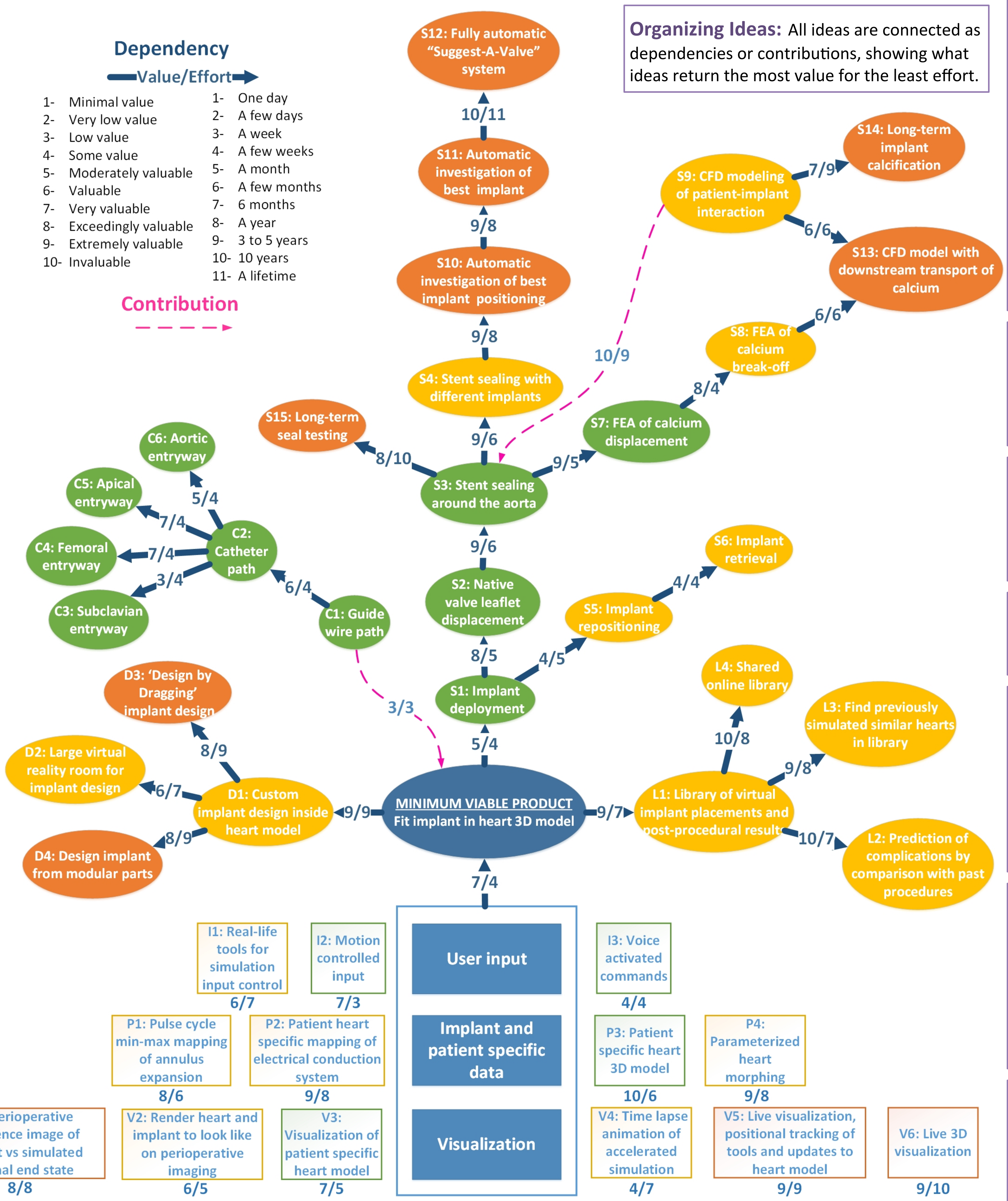
Organizing Ideas

43 ideas were documented and evaluated in detail with a focus on a Minimum Viable Product.



Idea Connection Tree: A Virtual Heart Valve Implant System

Organizing Ideas: All ideas are connected as dependencies or contributions, showing what ideas return the most value for the least effort.



***Minimum Viable Product (MVP):** sits in the middle of the diagram.* Branches develop from the MVP by organizing the ideas and evaluating which features must be in place to develop the next idea. For example: this MVP is placement of a 3D model inside a 3D model of a heart. Four idea categories are branching off the MVP idea, including (from left to right); implant design branch, catheter operation and implant delivery (detached branch), simulation branch, library or database branch.

***Value/Effort:** is displayed for each idea.* The user value, work effort and the value-effort ratio. Scales can be found in the top left corner of the Idea Connection Tree.

***Blue Arrows:** dependency connections.* For example: Idea S2 is dependent on the realization of idea S1, which is dependent on the minimum viable product

Pink Dashed Arrow: value contribution. For example: S9 would contribute to the value of idea S3.

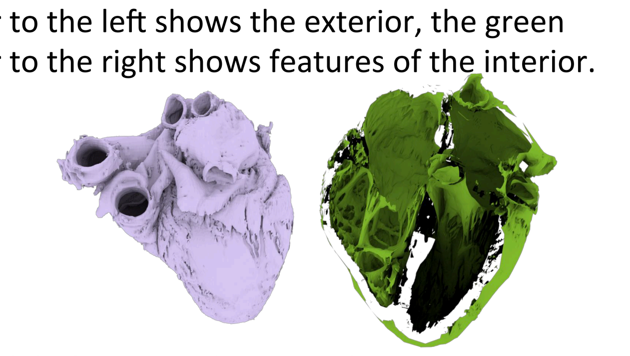
***Tree Trunk:** sits below the MVP.* Ideas are collected in the trunk that do not depend on other ideas but would contribute to the value of MVP. For example, three segments were identified: visualization, implant and patient specific data, and user input.

Challenge Level: visualized by color of each idea. Green indicates an easy ideas, or has already been implemented elsewhere. Yellow means the idea is considered tough or challenging, while orange indicates that the idea is considered very difficult.

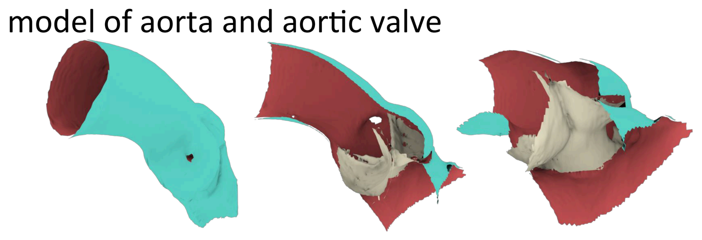
Idea description prefixes: tie related ideas together in branches or roots. For example, S are all ideas corresponding to simulation ideas for the MVP.

Alpha Prototype

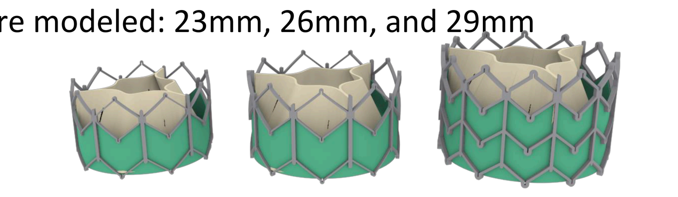
Reconstructed heart 3D model in Mimics. The purple render to the left shows the exterior, the green render to the right shows features of the interior.



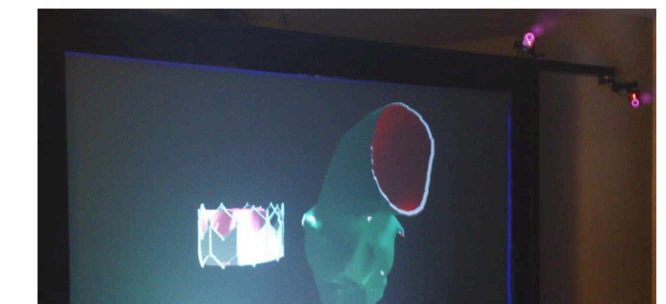
3D model of aorta and aortic valve



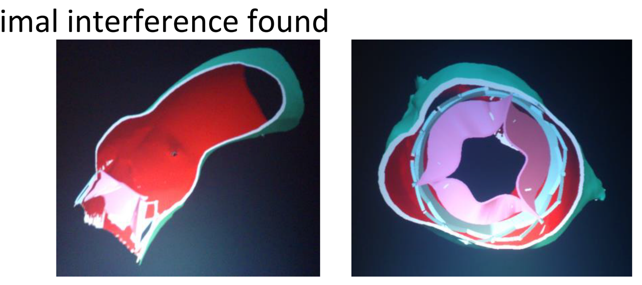
Three Edwards Sapien XT Transcatheter Heart Valves were modeled: 23mm, 26mm, and 29mm



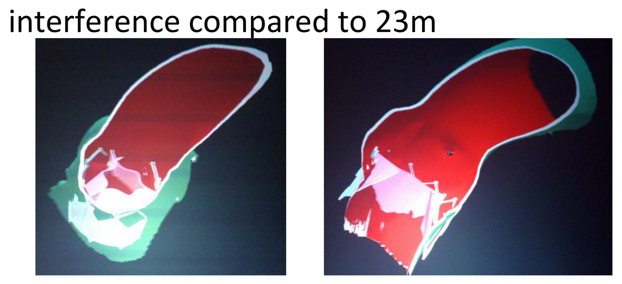
Minimum Viable Product



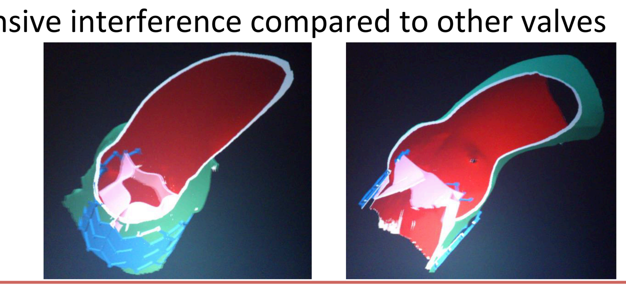
23 mm implant fitted inside aorta
Minimal interference found



26 mm implant fitted inside aorta
More interference compared to 23m



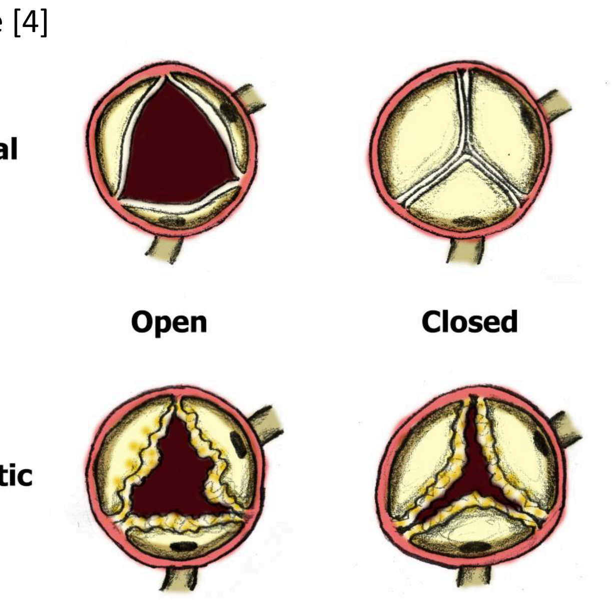
29 mm valve implant fitted inside aorta
Extensive interference compared to other valves



Background: Aortic Stenosis

Cardiovascular disease was the leading non-communicable cause of death in 2010 [1]

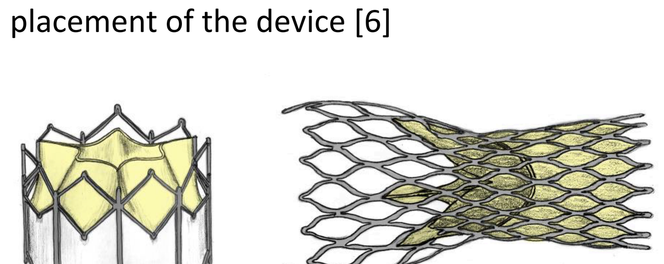
- Narrowing of the aortic valve
- Caused by calcium deposits on the valve cusps and reduces function [2]
- Congenital or caused by rheumatic valve disease [3,4]
- Severe symptoms of aortic stenosis include angina, syncope (transient loss of consciousness) and heart failure [4]



Normal aortic valve compared to aortic valve with calcific stenosis

Transcatheter Aortic Valve Replacement (TAVR)

- Procedural option for replacing an aortic valve in high surgical risk patients [5]
- Utilizes a thin flexible catheter to deliver the implant with access through the femoral arteries, subclavian arteries or aorta
- Self-expanding or deployed by balloon expansion
- Imaging technology is used to ensure proper placement of the device [6]

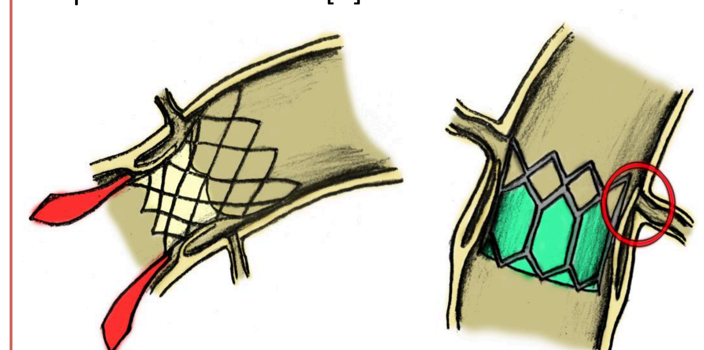


Examples of TAVR implants. Left: Balloon-expandable. Right: Self-expandable.

- Implants vary by size, biological leaflets, surrounding materials, deployment method, and features of redeployment, repositioning, and retrieval [7]

TAVR Complications

1) Paravalvular regurgitation – ejection of blood back into the left ventricle, due to prothesis-patient mismatch [6]



Paravalvular regurgitation illustrated by red features.

Coronary artery occlusion shown inside the red circle.

2) Coronary artery occlusion – native leaflet is displaced and occludes a coronary ostium, reducing the blood supply to the heart. [8]
3) Stroke – caused by embolic debris [9]
4) Cardiac arrhythmia and permanent pacemaker implantation – implanted stent may interfere with the heart's own conduction system [10]

Conclusion

- The idea connection tree provides a roadmap to pursue simulation features
- Simulating and evaluating the stent sealing and apposition is of direct use to clinicians during pre-procedure
- Ideas could help engineers to design better sealing implants if they had multiple models of the human aorta

Discussion

- An idea connection tree defines the dependencies and contributions of related ideas
- This method provides a structure for understanding the connections and the overall value to a user
- Provides possibility to recognize how to develop the ideas
- Structuring allows for strategic planning in large and complex development projects

Future Work

- Review work with engineers who design TAVR devices to refine value of each feature.
- Add value by conducting more idea generation sessions
- Continue work on the virtual heart valve implant system, advancing to idea S1: Implant Deployment and then further on to S2: Native Valve Leaflet Displacement.
- Identify interaction devices to move models
- Conduct user studies of alpha prototype to identify additional ideas and features to implement within application
- Develop a user interface for intuitive interaction with the models

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References

[1] World Health Organization, "Global status report on noncommunicable diseases 2010," World Health Organization, 2010.
[2] Follow Your Heart: Anatomy of the Cardivascular System Part I. [Film]. California: University of California Television (UCTV), 2013.
[3] J. Chambers, "Aortic Stenosis - Is common, but often unrecognised," BMJ, vol. 330, pp.801-802, 2005.
[4] B. A. Carabello and W. J. Paulus, "Aortic Stenosis," The Lancet, vol. 373, pp. 956-966, 2009.
[5] R. Nishimura, C. Otto, R. Bonow, B. Carabello, J. I. Erwin, R. Guyton, P. O'Gara, C. Ruiz, N. Skubas, P. Sorajja, T. I. Sundt and J. Thomas, "2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines," Circulation, vol. 129, pp. e521-e643, 2014.
[6] M. Lasala and J. H. Rogers, "Transcatheter Aortic Valve Replacement," in Interventional Procedures for Adult Structural Heart Disease, Saunders, 2014, pp. 73-88.
[7] K. J. Harjai, J.-M. Paradis and S. Kodali, "Transcatheter Aortic Valve Replacement: Game-Changing Innovation for Patients with Aortic Stenosis," Annual Review of Medicine, vol. 65, pp. 367-383, 2014.
[8] H. B. Riberio, J. G. Webb, R. R. Makkar, M. G. Cohen, S. R. Kapadia, S. Kodali, C. Tamburino, M. Barbanti, T. Chakravarty, H. Jilaihawi, J.-M. Paradis, F. S. de Brito Jr., S. J. Cánovas, A. N. Cheema, P. P. de Jaegere, R. del Valle, P. T. L. Chiam, R. Moreno, G. Pradas, M. Ruel, J. Salgado-Fernández, R. Sarmento-Leite, H. D. Toeg, J. L. Velianou, A. Zajarias, V. Babaliaros, F. Cura, A. E. Dager, G. Manoharan, S. Lerakis, A. D. Pichard, S. Radhakrishnan, M. A. Perin, E. Dumont, E. Larose, S. G. Pasian, L. Nombela-Franco, M. Urena, M. E. Tuzcu, M. B. Leon, I. J. Amat-Santos, J. Leipsic and J. Rodés-Cabau, "Predictive Factors, Management, and Clinical Outcomes of Coronary Obstruction Following Transcatheter Aortic Valve Implantation," Journal of the American College of
48 Cardiology, vol. 62, pp. 1552-1562, 2013.
[9] N. M. Van Mieghem, M. E. I. Schipper, E. Ladich, E. Faqiri, R. van der Boon, A. Randjgari, C. Schultz, A. Moelker, R.-J. van Geuns, F. Otsuka, P. W. Serruys, R. Virmani and P. P. de Jaegere, "Histopathology of Embolic Debris Captured During Transcatheter Aortic Valve Replacement," Circulation, vol. 127, pp. 2194-2201, 2013.
[10] N. D. Ferreira, D. Caeiro, L. Adão, M. Oliveira, H. Goncalves, J. Ribeiro, M. Teixeira, A. Albuquerque, J. Primo, P. Braga, P. Simões and V. G. Ribeiro, "Incidence and Predictors of Permanent Pacemaker Requirement after Transcatheter Aortic Valve Implantation with a Self-Expanding Bioprosthesis," PACE, vol. 33, pp. 1364-1372, 2010.

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