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**Methods:** A review of interchangeable prosthetic heart valve models between 1984 and 2022.

**Results:** Eight types of bioprostheses with interchangeable mechanisms, intended for heart valve prosthesis implantation and rapid substitutions during reoperations, aim to describe their framework's mechanical structure and increase knowledge of their coupling mechanisms. These are intended to reduce the surgical risks associated with the excision of the old, worn bioprosthesis and shorten the reoperation time.

**Conclusion:** These new experimental paradigms should prove the operability of the removal mechanism of all types of interchangeable bioprostheses and the effectiveness of the new quick connector and its perfect locking parts during heart valve reoperation, which should facilitate the reoperation operation, faster and safer.

**Keywords:** heart valve diseases, heart valve prosthesis implantation, biological heart valve, bioprosthesis, reoperation.

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## I. INTRODUCTION

Since 1968, the introduction of biological heart valves has involved a tremendous amount of work and research that has utilized effective valve replacement therapy to treat valvular heart disease.<sup>(1)</sup>

The future of heart valve treatments discusses improving valve structure and degradation of bioprostheses and compares pericardial heart valves to porcine valves.

In addition, implantation of a prosthetic heart valve (PHV) can be considered a risky surgery and may aggravate if subsequent reoperation is required to replace the worn prosthetic valve.

This mechanical bioengineering approach encompasses the coupling and uncoupling mechanisms of their components.

## II. METHODS

Relevant literature databases on eight types of i-BHVs were searched on PubMed and MEDLINE from 1984 to 2022.

Martin J.R. et al. (1984) developed the first i-BHV, which consisted of three parts: the sewing ring, the i-BHV, and the retaining ring. The sewing ring mounts onto the high-profile support ring, which has an internal stop for docking with the i-BHV support structure and an inner channel for attaching the retaining ring. The support framework for the i-BHV has on its underside a small flap that forms a step protruding from the outside, intended to track the inner circular stop of the ring that supports the sewing ring. They implanted the prototype in the tricuspid position. At the follow-up operation, which took place after eight months, the valve was changed in 8 minutes. The ring supporting the sewing ring in situ facilitated the procedure. They reported no thrombotic phenomena or periprosthetic leaks. The wound healed, and growth of fibrotic pannus and underlying tissue less than 1 mm thick was found. Finally, the authors propose another new project to optimize the reduction of the effective valve area of this model.<sup>(2)</sup>

Fernandez J et al. (1987) described the Tasconbioprostheses, consisting of the sewing ring and the i-BHV. The plastic material screw locking mechanism was used for the coupling and engagement between the sewing ring and the support framework for the porcine bioprostheses. It reported implant safety in 25 patients and satisfactory short-term hemodynamic properties. However, the fibrous tissue blocked the screw thread in the longterm, making it difficult to separate the parts and safely remove the i-BHV.<sup>(3)</sup>

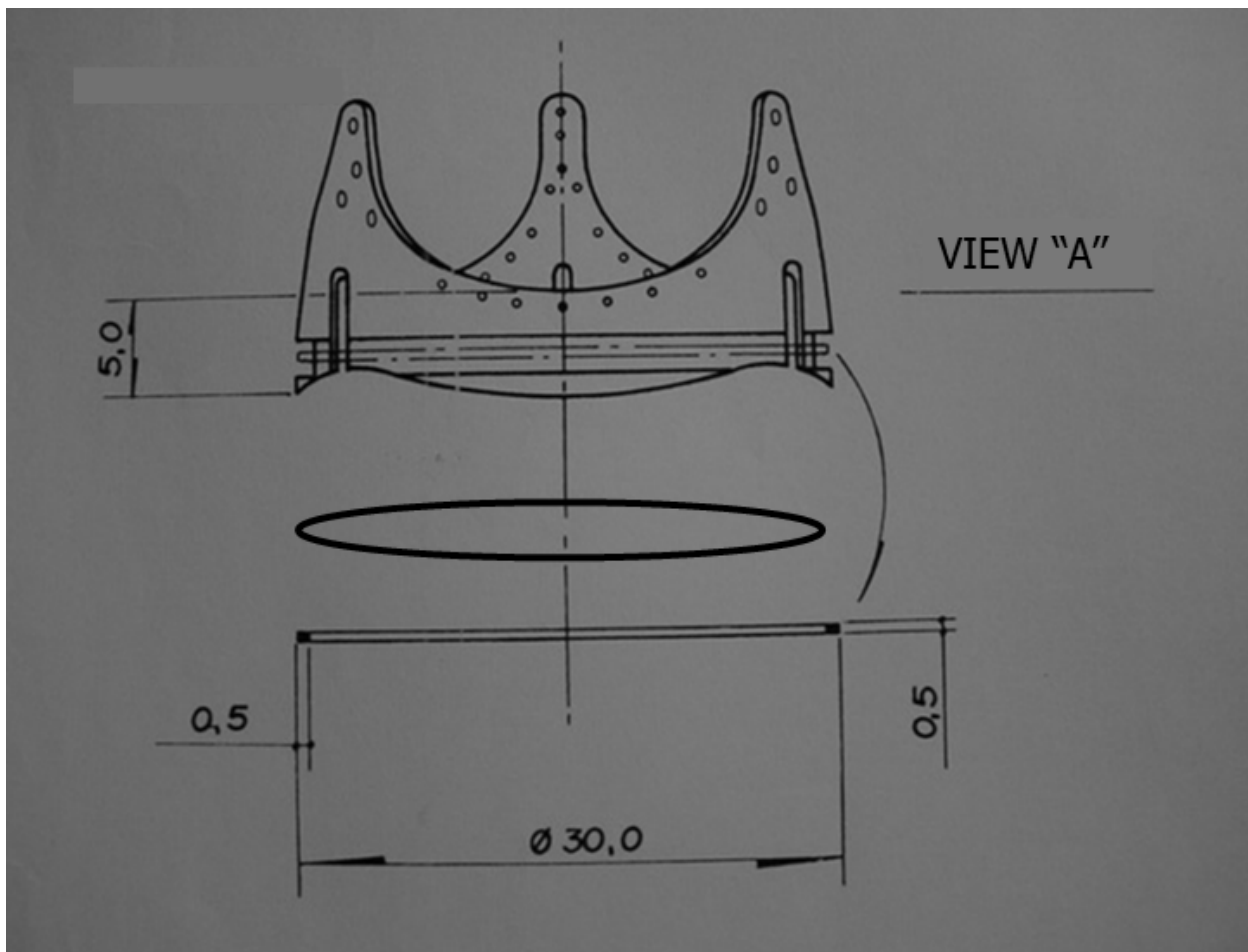
Cooper DK et al. (1988) used a Bjork-Shiley mechanical valve prosthesis as an interchangeable model. He mentioned that this interchangeable coupling mechanism could also be used for bioprostheses. The project consists of two parts: the sewing ring and the i-BHV. The engagement and disengagement between the parts are possible thanks to the spring-mechanical property of the steel half-ring covered by the sewing ring. The half-ring is made of malleable stainless-steel wire in the form of a self-locking type semi-circular clamp. Each end of the half ring is shaped like two small rings visible and accessible from outside the sewing ring. Tweezers with hooked ends were developed for these rings. When activated, it increases the circumferential diameter of the half-ring by a few millimeters; when the pressure is removed, the ring returns to its original diameter at rest. At rest, the half-ring has a diameter that encompasses the outer groove

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of the i-BHV in a circle way. Enlarging with the forceps allows insertion to dock the new i-BHV and its removal. In vivo tests were carried out on ten baboons.<sup>(4)</sup>

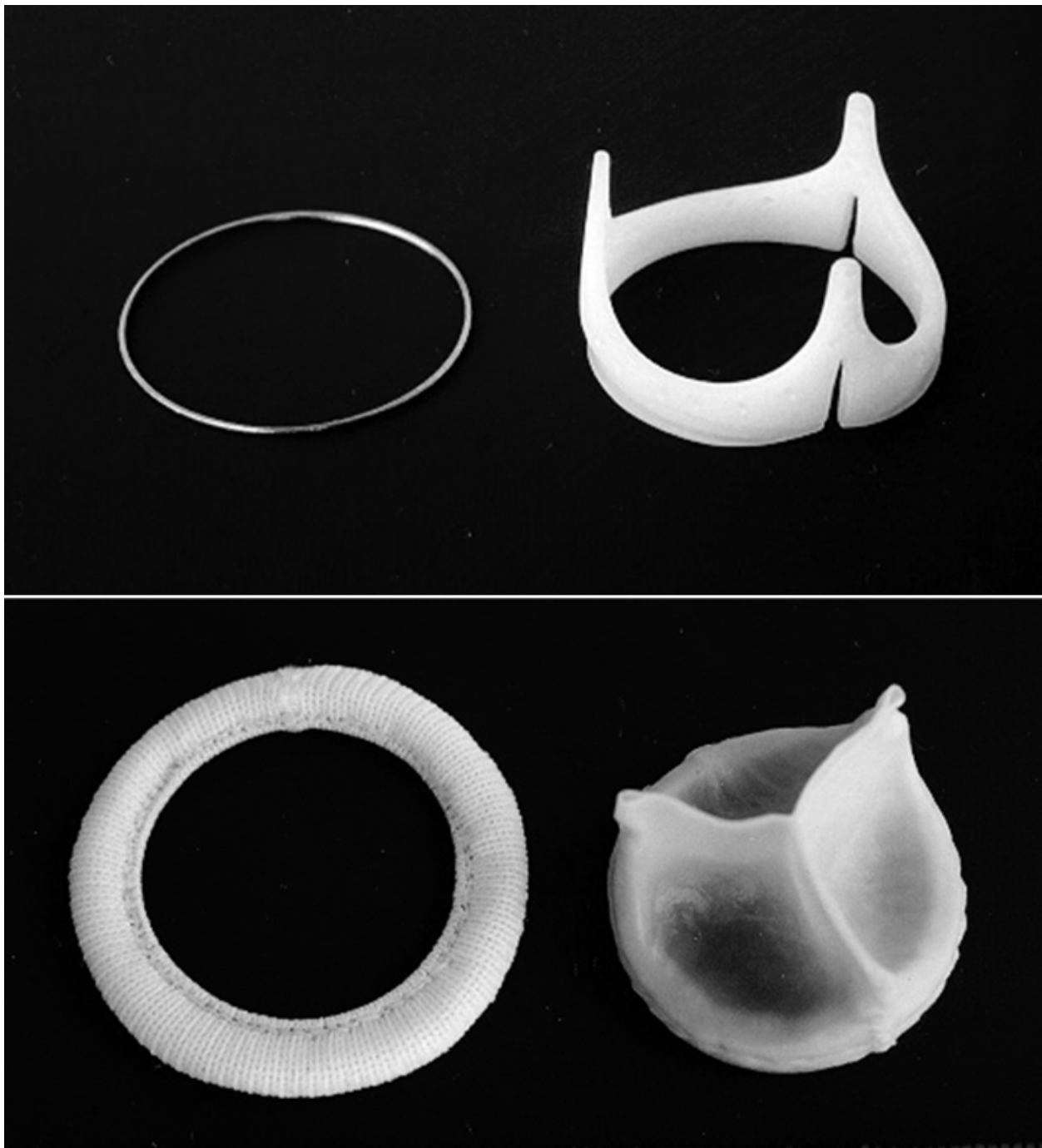
Lyra et al. (1992) developed an i-BHV consisting of the metal ring that supports the sewing ring and the

coiled framework made of a flexible plastic structure with spring properties (*Figure 1*).



*Figure 1:* VIEW "A": drawing in millimeters of the sinuous support for the bioprosthesis with the interchangeable framework in the front view and the ring that holds the sewing ring in the oblique view and the front view.

The bioprosthetic framework has a sinuous and circular shape that gives it malleability and behaves with the mechanical properties of a spring. As a result, this penetrates with its underside framework during its circular compression, then relaxes again and snaps into engagement with the sewing ring (*Figure 2*).



**Figure 2:** Interchangeable Bioprosthetic Heart Valve =i-BHV. Photographs view of the i-BHV separated from its sewing ring. The top left photo is the stainless-steel framework, one of which is used to make the sewing ring to support it and cover it with mesh, as shown below. Above right, the framework of the i-BHV is made of flexible plastic polymer and covered with bovine pericardium. This mechanism aids in the assembly of the bioprostheses, as shown below.

The i-BHV separation can be achieved by breaking the framework at its three posts with laminectomy surgical forceps, allowing decoupling with the sewing ring. The i-BHV model was tested in a pulsed pneumatic ventricle simulator and behaved like ordinary bioprostheses. No animal testing was performed.<sup>(5)</sup>

Jansen et al. (1992), this model consists of its sewing ring and the i-BHV. A metallic ring made from a

metallic nickel-titanium alloy (nitinol) was incorporated into his sewing ring. This metal alloy with plastic properties allows its diameter to change significantly when subjected to a temperature variation between 20 and 37 degrees Celsius and has excellent temperature-induced conformation and memory properties, with the ability to regain its predetermined shape. This diameter variation enabled the coupling mechanism around the

external channel of the i-BHV support framework obtained through the thermal contraction of the metal ring of the sewing ring. Its detachment occurs with an increase in temperature, which expands the diameter of the metal ring, making it possible to detach the i-BHV from the metal ring of the sewing ring. There are no animal studies in the literature.<sup>(6)</sup>

Fukamachi et al. (2008) proposed an i-BHV consisting of the sewing ring and the i-BHV. The researchers incorporated a magnetic metal ring into the sewing ring and another into the support framework of the i-BHV. The model used the magnetic attraction between two magnetic rings to couple and lock between the parts. The prototype met the target in vitro tests and withstood the separation force in a pulsating pneumatic ventricle simulator. In vivo testing demonstrated the hemodynamic effects of i-BHV in acute experiments on three sheep. All experiments efficiently performed both fixing and loosening between the magnetic pieces using forceps specially designed to break the magnetic attraction between the components. The next i-BHV was magnetically coupled to the sewing ring to simulate re-exchange during reoperations.<sup>(7)</sup>

Ebner et al. (2012) proposed an i-BHV that consists of two parts: the sewing ring and the i-BHV. Both frameworks were made of plastic material, giving them enough malleability to allow for the mechanical coupling between the parts. The shape of the ring that supports the sewing ring went through modifications, and its framework has three ascending bars with hooks at the ends designed to couple to the i-BHV's support framework. The i-BHV's support structure is sinuous and circular. And it has three horizontal bars added to its three ascending bars, where there is a quick coupling mechanism between the two parts. The three hook bars at the ends of the ring that supports the sewing ring penetrate the interior of the i-BHV's sinuous support framework and are connected to its three horizontal bars by quick-connect couplings. Therefore, the coupling between the pieces takes place at these three points. The forced engagement between the parts is only possible due to the deformability of the plastic material of the two parts. The three struts of the top can be compressed internally while the tortuous support structure of the bioprosthesis expands. After the coupling hooks pass the horizontal bars of the i-BHV support framework, the two parts lock and return to their rest positions. In three patients, the i-BHV set behaved like conventional bioprostheses. Performance was excellent, and it was easy to insert the first surgical implant. The coupling lasted 3 to 6 minutes intraoperatively.<sup>(8)</sup>

Eren et al. (2022) described a novel transcatheter aortic valve implantation (TAVI) with a valve system consisting of two components: A retention device that could be surgically implanted or attached to a catheter and a novel valve system called

exchangeable-TAVI (e-TAVI). To facilitate the minimally invasive removal and replacement of an e-TAVI, a novel e-TAVI electromagnetic vascular catheter was developed to remove and retrieve a failed e-TAVI, followed by the immediate placement of a new valve. The experimental research revealed the need to define new bond-coupling constraints between the electromagnets and the ferromagnets in the cladding simulations, suggesting that another physical coupling mechanism is required to realize the e-TAVI concept. Moreover, the attachment between the catheter and the e-TAVI framework should be tight enough to allow its removal through the catheter pathway.<sup>(9)</sup>

### III. DISCUSSION

The innovative i-BHV is ahead of its similar, not interchangeable, not enhancing its durability or performance, but rather the ease and the security of detaching and then replacing it with the next i-BHV when reinserted in the next operation.

Therefore, the perspectives and limitations of these reviews, with multicenter publications and a small number of cited surgeries, make it difficult to generalize the results.

The engagement and decoupling between parts are possible thanks to these innovations. Fukamachiet al.<sup>(7)</sup> report the desirable advantages of an i-BHV, such as:

1. Simple surgical fixation of the sewing ring together or not with the i-BHV.
2. Reduction of operational risks related to removing the bioprosthesis's old, worn-out sewing ring.
3. Ease and safety in removing the i-BHV during reoperation.
4. Hermetic sealing between parts.
5. No growth of fibrotic tissue at the internal junction interface between the pieces.
6. The optimized lumen-to-ring ratio is to obtain the largest possible area of the valve opening, despite the addition of the coupling mechanism between the parts.
7. The sewing ring frameworks and the framework that stents the valve prosthesis leaflets must be made of medical grade material, malleable, and fatigue resistant.
8. Durability and security of the coupling and locking mechanism between the parts.
9. Absence of long-term fragility or mechanical stress fractures due to structural changes in the bioprosthesis support framework and sewing ring.

Due to the degeneration of bioprosthetic heart valves, the interchangeable bioprosthetic heart valve (i-BHV) describes new paradigms based on the innovative hypothesis of heart valve surgery to improve reoperations, supposedly making them safer and faster.<sup>(10)</sup>

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*Abbreviations and acronyms:*

PHV = prosthetic heart valve

TAVI = transcatheter aortic valve implantation

e-TAVI = exchangeable transcatheter aortic valve replacement

BHV = bioprosthetic heart valves

i-BHV = interchangeable bioprosthetic heart valve

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