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Right ventricle outflow tract prestenting: In vitro testing of rigidity and corrosion properties

Bjorn Cools, MD[1] | Stephen Brown, MD, PhD[1,4] | Martine Wevers, PhD[2] | Jan Van Humbeeck, PhD[2] | Derize Boshoff, MD PhD[1] | Cis Verdonckt, MSc[3] | Marc Gewillig, MD, PhD[1]

[1]Pediatric and Congenital Cardiology, UZ Leuven, Leuven, Belgium

[2]Department of Metallurgy and Materials Engineering, University of Leuven, Leuven, Belgium

[3]Corrosion Engineering, Metalogic, Rotselaar, Belgium

[4]Pediatric Cardiology, University of the Free State, Bloemfontein, South Africa

Correspondence
Marc Gewillig MD, PhD, University Hospital Gasthuisberg, Herestraat 49, B-3000 Leuven, Belgium.
Email: marc.gewillig@uzleuven.be

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Abstract

Background: The aim of this study was to assess the resistance to compression (stiffness) of frequently used stents for right ventricular outflow tract prestenting. In addition, to assess the corrosion potential when different types of stent alloys come into contact with each other.

Method: Different stents were tested in vitro in various combinations at specialized metallurgic laboratories. A bench compression test was used to assess resistance to compression of singular and joined combinations of stents. Corrosion was evaluated by standardized electrochemical galvanic tests in physiological solutions at 37°C. Single stents and combinations of stents were evaluated over a period of 4–12 weeks.

Results: Relative stiffness of the stents Optimus/Andrastent XXL/Intrastent LD Max/8zig Cheatham-Platinum, expressed as load per length to deform the stent for 1 mm at 22 mm was 100/104/161/190. Adding additional stents to a single stent significantly strengthened the joined couples ($P < 0.001$). The lowest galvanic corrosion rates (about 0.000001 mm/year) were observed for the joined CP-Andrastent, Andra-Sapien, and Andra-SapienXT. The corrosion rate for coupled CP-Sapien and CP-SapienXT was somewhat higher (about 0.000003 mm/year). The materials with the highest corrosion rates resulted in material losses of, respectively, 17 and 24 μg/year, which is negligible over a lifetime.

Conclusion: Adding stents to a single stent significantly increases stiffness which will reduce the risk of metal fatigue failure. Corrosion of individual stents or stent combinations occurs, but is negligible over a human lifetime with low risk of biological effects. No mechanical integrity problems are thus expected as there is only 0.3% of the initial diameter of the struts of a stent that will be lost as a consequence of corrosion after 100 years.

KEYWORDS
Andrastent, corrosion, CP stent, electrolysis, Intrastent, melody, Sapien, stent, stent fracture

1 | INTRODUCTION

Stent dysfunction such as fracture and recompression is a major concern for long-term function after percutaneous pulmonary valve implantations (PPVI), as it may lead to hemodynamic compromise [1–5]. A valved stent is exposed to mechanical stress loads resulting in recompression and strain, which ultimately may result in metal fatigue and stent fractures. Stent fractures have been described in up to 20% of Melody® (Medtronic Inc., Minneapolis, MN) implants during the first year with hemodynamic compromise requiring reintervention [6]. Lack of data regarding physical properties of large stents such as resistance to deformation and corrosion hampered guiding principles for the use of stents to prepare the right ventricular outflow tract (RVOT) for a valved stent [7]. As a result, the Melody valve was initially implanted without prestenting of the conduit. However, soon after the initial experiences, RVOT obstruction and stent fractures forced protocols to

TABLE 1 Various stents used in testing

Stent CP bare	Manufacturer Numed, NY	Materials Platinum iridium	Laser weld, gold cover	Closed cell	8Zig pattern	Strut thickness (μm) 330
Andra XXL	Andramed, Reutlinger, Germany	Cobalt chrome	Laser cut	Hybrid		250
Optimus	AndraTech, GmbH, Koblenz, Germany	Cobalt chrome	Laser cut	Hybrid		270
Intrastent LD Max Sapien	EV3, Plymouth, MN Edwards Life Sciences Inc., Irvine, CA	316L stainless steel 316L stainless steel	Laser cut Laser cut	Hybrid Stented valve		270 520*
Sapien XT	Edwards Life Sciences Inc., Irvine, CA	Cobalt chrome	Laser cut	Stented valve		500*

Abbreviations: CP, Cheatham platinum stent; AN = Andrastent XXL; OP = Optimus XXL stent; IN = Intrastent LD Max.
*Measured, not provided by manufacturer.
*See text for details.

be adapted and prestenting became routine in the majority of implanting centers [6–8].

The aim of this strategy was to create an ideal landing zone and to reduce the risk of development of stent fractures. Medium-term follow-up has demonstrated that prestenting of the conduit significantly reduces the risk of developing hemodynamically important stent fractures [3,8,9].

Prestenting adds stiffness and stability by creating a framework in the valve landing zone which redistributes stresses over the whole metal frame, reducing strain and metal fatigue in the material and, therefore, delays or may avoid fracture over a human lifetime. Several different stents are available and stents are selected based on length, diameter, cell design, material, compressibility, shortening, dilatability, rigidity, strut thickness, sharpness of edges, and covering. In the clinical setting, either one or more different stents with different metallic contents may be used. However, when different metals are in close physical contact, galvanic currents may develop which may give rise to corrosion [10,11]. Corrosion may also be influenced by electromagnetic and thermodynamic forces in the body. As a result of continued corrosion, theoretically, stents may be at risk of not maintaining their strength. Metal ions may be released into the surrounding tissues; in hip replacements early degeneration of prostheses was associated high serum levels of cobalt chrome which may be toxic [10,11].

Data on metal fatigue and fracture rates of the different stents used in PPVI is not available, especially data on combinations of different types of stents as used during prestenting. After Palmaz and Mullins published their first results of stent use in humans in 1988, accounts of the biological behavior of stents in vascular structures emerged in the following years [12–14]. Reports of corrosion testing of stents composed of nitinol, titanium, and stainless steel have been published [15–19]. There is, however, limited published data of strength and corrosion tests for the commonly used stents during PPVI.

The aim of this study was to assess the resistance to flattening (stiffness) of frequently used stents for RVOT prestenting and the corrosion potential when different types of stent alloys come into contact with each other.

2 | MATERIALS AND METHODS

Different stents were tested in vitro in various combinations at specialized metallurgic laboratories: Department of Metallurgy and Materials Engineering, University of Leuven and METALogic NV, Rotselaar, Belgium.

The stents were tested in vitro in various combinations. The individual stents and composition can be viewed in Table 1. The stents were coupled in various combinations consisting of one to three stents. AN = Andrastent XXL (Andramed, Reutlingen, Germany); OP = Optimus XXL stent (Andra Tech, Koblenz, Germany); IN = Intrastent LD Max (ev3, Plymouth, MN); CP = 8 zig Cheatham Platinum (NuMED, Hopkinton, NY).

2.1 | Mechanical stiffness testing

The different stents and stent combinations were carefully expanded up to an internal diameter of 22 mm and loaded for compression testing in a hydraulic compression system to quantify compression of the stents (Figure 1). This diameter was selected to simulate the most common clinical (in vivo) diameter used during PPVI. Before testing, the dimensions of the stent (diameter and length) were measured. Single stents and the combinations of 2–3 stents were loaded for compression testing between two plates on a universal Instron 4467 test bench, using a 1 kN load cell (catalog number: 2525–806) (Figure 1). Displacement was monitored with an extensometer with gage length of 0.25 mm. The compression rate was 1 mm/min up to 5 mm. Tests were repeated for all single stents and combinations to control validity and repeatability of the measurements. Testing consisted of single CP, AN, OP, IN and the following combinations: CP + CP & CP + CP + CP and CP + AN & CP + AN + AN, CP + IN, CP + IN + IN.

2.2 | Corrosion testing

2.2.1 | Galvanic corrosion test

A galvanic corrosion test is performed to determine the corrosion currents/rates which occur when two or more different metals come into contact with each other. Table 2 shows the stents and combinations that were analyzed. Couples were made with the stents described and those that are currently used in the valved stents: the CP is used in the Melody valve, and the Sapien and Sapien XT consist of, respectively, 316L stainless steel and a cobalt–chromium alloy (Edwards, Irvine, CA). Both the Intrastent and Sapien stent consist of 316L stainless steel, only the latter was used in the corrosion tests.

All tests were performed in a buffered physiological solution (Plasmalyte AKE0324, Baxter, Lessines, Belgium) at 37°C to simulate

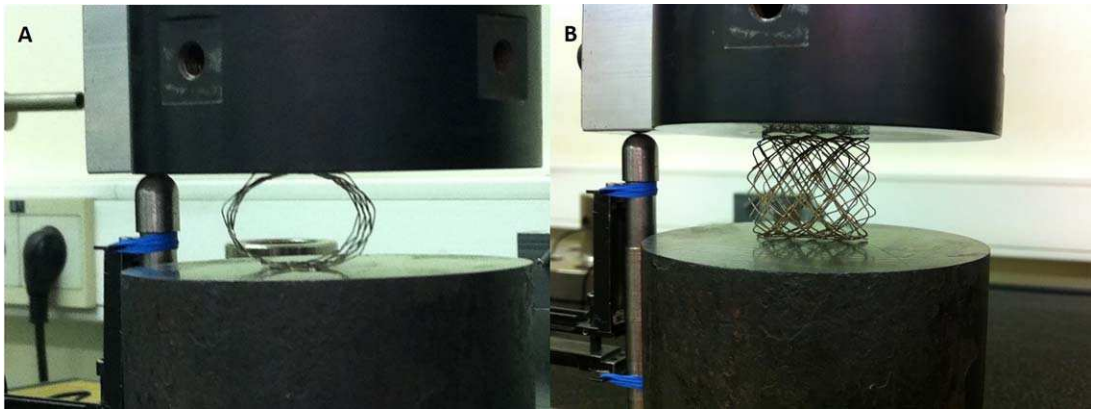

FIGURE 1 Compression bench testing. Instron bench testing demonstrated. A, Single CP stent; B, CP combination [Color figure can be viewed at wileyonlinelibrary.com]

conditions in the body (Figure 2). This solution was refreshed weekly to prevent microbial contamination and to keep the pH of the solution around pH 7.4. The electrochemical galvanic tests were performed at a cathode:anode surface area ratio of 1:1 to simulate two stents positioned within each other. The exposed surface of every test specimen was 1.5 cm^2. The electrochemical measurement procedures were performed as follows:

- Samples were immersed without galvanic contact for 24 hr (allow equilibration of the test surfaces). After this period, the open circuit corrosion potential (OCP) of every material was determined against an Ag/AgCl reference electrode. These measurements result in the galvanic series representing the initial surface conditions.
- The samples were then coupled to each other (Table 2). The galvanic zero resistance amperometry (ZRA) current and the mixed potentials were measured for 1 hr after 24 hr of equilibration.
- After 1 and 2 weeks of exposure, new galvanic ZRA current and mixed potential measurements were performed for every couple (1 hr per measured couple).
- The test was continued for a period of 4 weeks, followed by new galvanic ZRA current and mixed potential measurements.
- All measurements lasted 1 hr to ensure that a stable condition was measured.

At the end of the immersion test, the materials were inspected by visual and stereomicroscopic investigation to determine the type of corrosion and the extent of the corrosion effect on the stent surfaces.

2.2.2 | Prolonged exposure corrosion test

The following test combinations were applied for a prolonged exposure test: CP + AN, AN + Sapien, An + SapienXT, CP + Sapien, CP+ SapienXT. Both stents of every couple were folded within each other resulting in a direct physical contact between both stent materials, simulating the actual physical condition. The samples were immersed in the saline solution at 37°C for a total period of 3 months to determine corrosion rates. Conditions were further identical as applied during the galvanic corrosion test.

The evaluation at the end of this phase was executed based on the following investigations:

- Visual and stereo microscopic investigation of the surfaces (determination of the corrosion type).
- Determination of the maximal local corrosion depth if a local corrosion type could be observed, defined as more than 10 μm.
- Weight decrease analysis (calculation based on the measured corrosion rate of the metals).

TABLE 2 Measured open circuit corrosion potentials after 24 hr equilibration

Stent couples		Potential difference (mv)	Corrosion driving force
CP stent (Pt–Ir–Au)	Andrastent (Co–Cr)	101	+
Andrastent (Co–Cr)	Sapien (316L)	132	++
CP stent (Pt–Ir–Au)	Sapien (316L)	25	+++
Andrastent (Co–Cr)	Sapien XT (Co–Cr)	104	+
CP stent (Pt–Ir–Au)	Sapien XT (Co–Cr)	237	+++

Abbreviations: Pt, platinum; Ir, iridium; Au, gold; Co, cobalt; Cr, chrome; 306L, stainless steel; Ag, silver; Cl, chloride: reference electrode.
*Calculated potential difference between the materials of all couples and a qualitative estimation of the driving force for galvanic corrosion.
Mixed potentials (in mV vs Ag/AgCl) of all couples in function of time were measured.

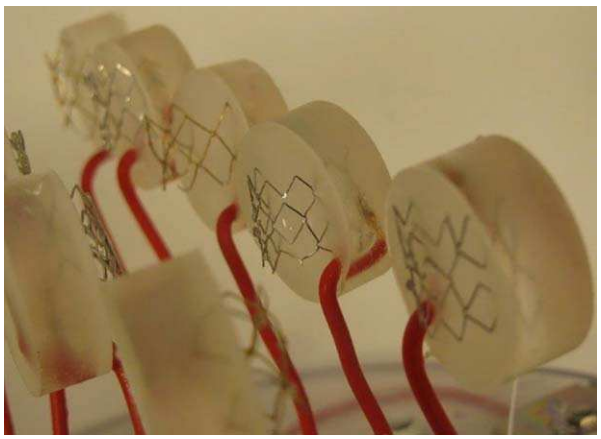

FIGURE 2 Galvanic corrosion test. Applied samples for galvanic corrosion test (see text). The samples were connected with a copper wire (left) for the electrochemical measurements and mounted in epoxy to isolate the copper material from the test solution [Color figure can be viewed at wileyonlinelibrary.com]

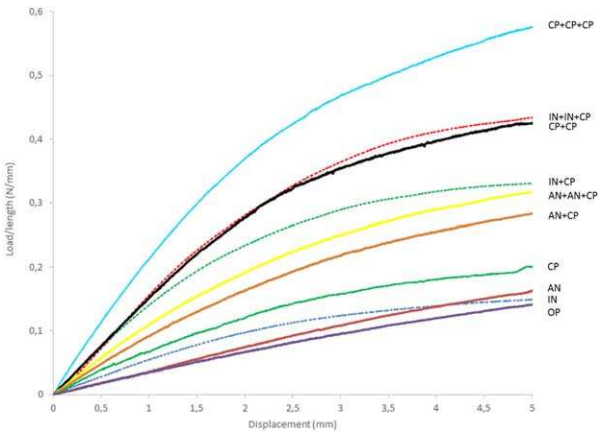

FIGURE 3 Compression force versus displacement of stents [Color figure can be viewed at wileyonlinelibrary.com]

2.3 | Statistics

Data were analyzed using standard statistical software (SPSS for windows, SPSS Inc., IBM company, Chicago, IL, version 18). A student *t* test was used to compare normally distributed data. A *P* value <0.05 was considered significant.

3 | RESULTS

3.1 | Mechanical tests

Figure 3 shows the specific force (F/tested length) versus displacement of the plates during compression for the different types of stents. Relative stiffness of the stents OP/AN/IN/CP, expressed as load per length to deform the stent for 1 mm at 22 mm was 100/104/161/190. Relative stiffness was influenced by the thickness, material, and structure of the cells. The deployment of a stent within another stent considerably increased stiffness. The CP stent was 54%–56% stiffer than the other stents (IN, AN, and OP), but this difference was not statistically significant ($P = 0.14$). The cobalt–chromium stents differed little compared to each other. The deployment of a stent within another stent considerably increased stiffness. The addition of one more stent stiffened up the combined units by a minimum of 17% compared to a single CP stent ($P = 0.03$). Furthermore, adding more stents (CP + AN +AN) stiffened combinations by another 19%. Similar results were found when more stents of the same kind (CP) were inserted into each other. The stiffness of the combination increased by 74% by addition of one and by 178% by adding two additional CP stents ($P = 0.01$). This indicates that, in combinations of more than 1 stent, for the same applied external forces, less strain will be experienced in the stent which also means less flexibility or strain in the most critical places in the stent.

3.2 | Corrosion testing

3.2.1 | Galvanic currents and mixed potentials

Galvanic corrosion potentials indicated that the CP stent was composed of the most noble metals and thus corrosion resistant, followed by the cobalt–chromium stents (Table 3).

Mixed potentials (in mV vs Ag/AgCl) of all couples in function of time were measured. The galvanic currents showed that a steady state corrosion rate for couples 1, 2, and 4 were established after 4 weeks and remained quite low thereafter. The currents for couples 4 and 5 were somewhat higher, but showed a similar decrease to a steady state after 4 weeks. The lowest galvanic corrosion rates (about 0.000001 mm/year) were observed for the joined CP + AN, AN-Sapien, and Andra-SapienXT. The corrosion rate for coupled CP-Sapien and CP-SapienXT was somewhat higher (about 0.000003 mm/year). The materials with the highest corrosion rates (CP + Sapien and CP + Sapien XT) will result in material losses of respectively 17 and 24 μg/year, estimated for a coupled stent system. The material loss of the other couples was only about 10 μg/year.

3.2.2 | Exposure corrosion test

The maximum calculated uniform corrosion rates varied from 0.000008 to 0.0000028 mm/year for the coupled stents. No visible signs of corrosion could be observed on the materials of the platinum iridium or cobalt chromium stents, based on macroscopic and stereomicroscopic investigation of the surface after an exposure in physiological solution over 3 months (Figure 4).

TABLE 3 Galvanic series based on the measured average open circuit potential (Eoc) of all tested materials

Stent	Metal	Potential (mv)	Galvanic series
CP stent	Pt–Ir–Au	91	More noble
Andrastent	Co–Cr	42	
Sapien XT	316L	−102	
Sapien 316	Co–Cr	−129	Less noble

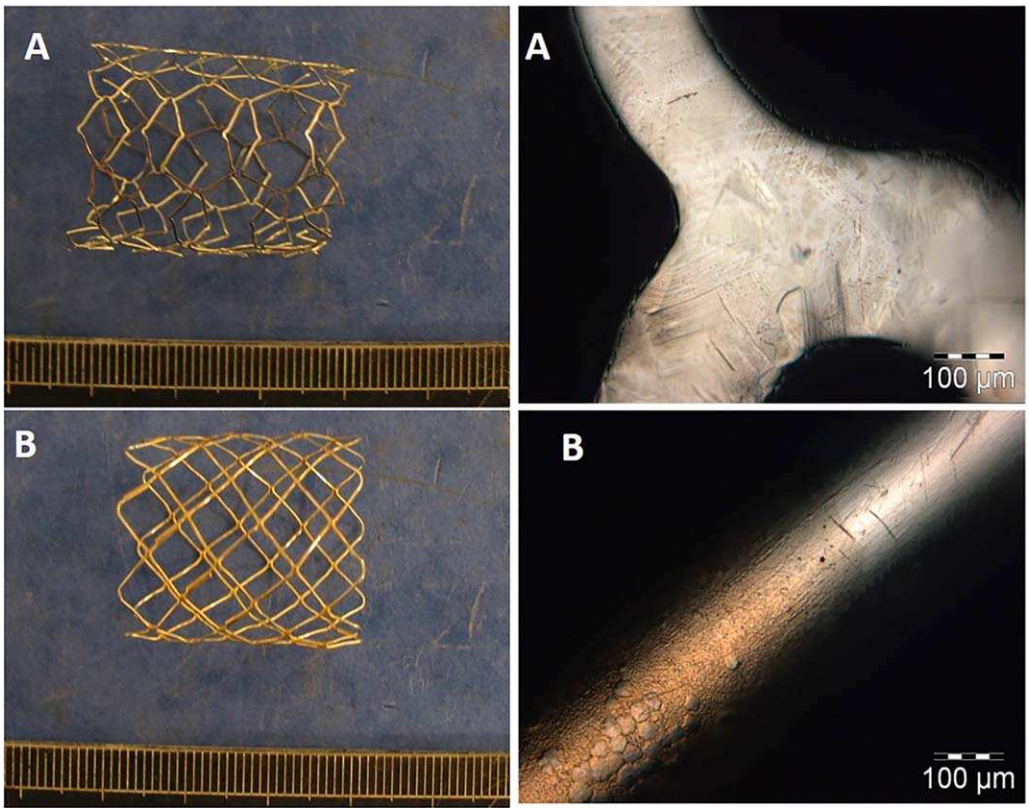

FIGURE 4 Macroscopic and stereomicroscopic images of stents after 3 month corrosion test. *A = AN; B = CP. Note: no pitting observed macro- or microscopically [Color figure can be viewed at wileyonlinelibrary.com]

4 | DISCUSSION

Stent fractures following PPVI give rise to varying degrees of hemodynamic impairment ranging from mild to severe with or without valve dysfunction [1–3,5]. Recent midterm follow-up of the Melody valve identified elements associated with a higher risk of stent fracture [9]. Geometrical anomalies of the stented valve such as deformation and compression increase the risks while implantation within a protected RVOT was proven to lower risks [5,20,21].

Our bench testing shows that a singular (thicker) CP stent is more resistant to deformation than a single Optimus, Andrastent, or Intrastent. More importantly, mechanical compression testing unequivocally confirms what can logically be expected: by adding one or more combination of stents to a single stent, deformation resistance is significantly augmented. The results show that, in combinations of more than 1 stent, for the same applied external forces, less strain will be experienced in the stent which also means less flexibility or strain in the most critical places in the stent.

Fatigue endurance curves of metals are known and show that higher stiffness leads to lower strain amplitude which results in a longer lifetime or higher number of cycles to failure (for mathematical proof, see Supporting Information, 1). This bench testing proves that lowering the strain amplitude by multiple prestenting adds more stiffness and therefore lowers the risk of deformation and ultimately fracture; this is metal fatigue known as the Basquin or Wohler law [22]. Therefore, our findings support clinical observations that a prestented RVOT leads to a lower incidence of stented valve fractures, dysfunction, and reinterventions [6]. The results support what common logic predicts: increasing thickness of the wall of a cylindrical structure (by adding more stents) reduces wall stress and makes the cylinder stronger by an increasing margin. It also has additional benefit in the clinical situation by increasing roundness of the wall, which also improves resistance to fractures [23].

The choice of a prestent can be influenced by many factors. A thin sharper laser cut strut with hybrid open cell design will have more friction and retention than a closed cell stent consisting of rounded wire. High retention forces may be an advantage when the prestent is deployed in a soft conduit free outflow tract, but can be a disadvantage when an unprotected valve (typical for the Sapien system) is maneuvered into the landing zone. Stent thickness must also be taken into account when preparing a landing zone in the RVOT: combinations of multiple stents will reduce the inner diameter. This can be a clinical advantage when size reduction of the landing zone is required, or a disadvantage as for the same inner diameter more external compression will occur or when the stents are deployed in a restrictive ring, thereby further reducing the functional lumen. Fractures of a CP stent can readily be seen as the CP stent has a closed cell design with thicker metal struts rendering it more radiopaque. Fractures can thus more easily be observed during routine radiography if cells are distorted as opposed to the thinner, more difficult to visualize hybrid open cells of

laser cut stents. The different designs of the cells of stents may also respond differently to in vivo forces such as fretting and leverage which may accelerate focal metal fatigue.

When using different metals in close contact, corrosion can be expected. Corrosion tests show that the CP stent has the noblest material, followed by the others. When the different stent alloys come into direct contact with one another, the least noble metal undergoes an anodic corrosion reaction, while the more noble metal will not corrode as electrons are held tightly together. The lowest galvanic corrosion rate was present in the combination of CP-Sapien, AN-Sapien, and AN-SapienXT. The corrosion rate for coupled CP-Sapien and CP-SapienXT was only a little higher. More importantly, no pitting corrosion could be observed by stereomicroscopic inspection of the surface of the tested stent materials of the exposed test samples.

The corrosion rate and material loss of all tested stent compounds is very low. No mechanical integrity problems are expected as a result of corrosion as there is only 0.3% of the initial diameter of the wires of a stent that will be lost as a consequence of corrosion after 100 years. Per implication, the stents will outlive the patient. This compares favorably to findings in a study using other stents [10,24]. Similarly, no biological effect can be expected on the organism with such little metal ions being released into the tissues (e.g., safe dose for Cobalt <7 ppb). Even the combination of materials with the highest driving force for galvanic corrosion will result in minimal material losses, which amounts to <0.5 parts per billion (ppb).

Of particular interest, after an initial higher rate, corrosion in the samples appeared to decrease after 4 weeks. This can be ascribed to ions combining with oxygen to form a oxide film over the exposed stent surfaces preventing further corrosion and ion dissolution into the tissues [10,24]. Studies on nickel release of atrial septal defect devices reported similar findings: a calcium phosphate layer is formed over the oxide membrane during endothelialization in the body, further reducing metal ion release; this would likely also occur with RVOT stents [25].

No ideal stent exists and current stents represent a compromise of advantages and disadvantages, but if the behavior of a stent or combinations of stents is known, it can allow clinicians to select the most ideal stent(s) for a given situation and influence future stent performance. There is little evidence to date, in mid-term follow-up, of significant disadvantages of prestenting such as corrosion, fretting, leverage, erosion with puncture of vessel walls, fracture/embolization, and endocarditis risk. Therefore, the potential advantages of adequate prestenting most likely outweigh the long-term disadvantages of prestenting. Adequate prestenting is required to relieve RVOT gradients prior to percutaneous valve implantation, create a stable landing zone to reduce fractures of the Melody valve, and allow a proper circular configuration for better geometry of the Sapien valve [26].

5 | LIMITATIONS

The main limitations are the in vitro nature of the study and results limited to the stents and conditions tested. In vivo, stents are exposed to dynamic circumferential compression forces, which were not tested in this study; the investigators believe that bench compression testing gives a reasonable reflection of stent rigidity. Although electromechanical and thermodynamic forces in the body cannot be simulated, corrosion was simulated using buffered physiological solution at 37°, which is a universally accepted standard.

6 | CONCLUSION

Joined combinations of stents significantly increase stiffness and reduce the risk of metal fatigue failure. Corrosion of individual stents or stent combinations occur, but is negligible over a human lifetime and the concentration of dissolved ions is too low to cause biological effects. Knowledge of physical behavior of implanted materials is helpful when planning and performing RVOT prestenting.

CONFLICT OF INTEREST

Marc Gewillig is proctor for Numed, Medtronic, and Edwards.

ORCID

Marc Gewillig MD, PhD http://orcid.org/0000-0002-4595-5922

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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