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Mechanical study of NiTi intrasaccular aneurysm implants with flaps

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Abstract

Treating wide-neck aneurysms (WNA) remains a clinical challenge, particularly for achieving stable intrasaccular implantation. Current permanent implants prevent reentry to the aneurysm sac, making post-surgery retreatment impossible if it becomes necessary. The conventional implants are braided which leads to key mechanical limitations that can compromise long-term performance, including compaction, dislocation, and poor wall apposition, and can lead to recurrence of the aneurysm. In this study, we present a follow-up study for new class of 2.5D intrasaccular implants that integrate structural and functional layers with distinct thicknesses fabricated by MEMS (Micro-Electro-Mechanical Systems). This approach combines a mechanically robust thick backbone (42 μm) with flexible and mobile thin flaps (7 μm) designed to both occlude an aneurysm and provide sac access. These mobile flaps represent a significant functional advancement, distinguishing our design from conventional, permanent, braided implants, which lack options to re-enter the aneurysm and suffer from wire slippage and limited force tunability. In particular, this study focuses on a detailed mechanical analysis, including radial and compression force testing, to investigate how design variations influence radial force output and flap stiffness. We present four different backbone geometries paired with tailored flap configurations to assess the impact of structural alterations on implant behavior. By systematically addressing key challenges such as device migration and instability, our mechanical and flow analyses provide critical insights into how structural parameters influence implant performance. These findings advance the development of safer, more adaptable treatments for WNA and support the future design of personalized implants with improved clinical outcomes.

Introduction

An aneurysm is a localized bulge or ballooning in the wall of a blood vessel caused by weakening of the vessel wall [1]. Cerebral aneurysms carry significant risks, as their rupture can lead to life-threatening conditions such as subarachnoid hemorrhage, resulting in high rates of morbidity and mortality [2]. Conventional aneurysm treatments include redundant surgical clipping [3] and endovascular coiling, a widely used approach [4]. The aim of such treatments is to prevent blood flow in the aneurysm and avoid rupture. However, these methods are associated with significant challenges. Clipping requires an open craniotomy, which is highly invasive [5], while coiling can be complicated by the complex geometry of an aneurysm. Especially in treating wide-neck aneurysms (WNA) that have the neck diameter greater or equal to 4 mm or the dome-to-neck ratio less than 2 mm [6]. They are especially challenging to treat due to the risk of coil migration and incomplete occlusion. To address these issues, additional support is often provided by devices known as coil-assisting implants [7, 8]. These implants offer structural support, reducing complications and ensuring that the coils remain securely in place.

Intrasaccular devices have emerged as promising stand-alone, single implant alternatives for the treatment of aneurysms, especially WNA. These devices are deployed directly into the aneurysm sac and are designed to stabilize the structure by promoting thrombus formation within the aneurysm while preventing blood flow into the sac. Two main devices are Contour [9] (Stryker, USA) and Woven Endo Bridge [10] (WEB, MicroVention Terumo, USA). These implants are made of braided NiTi wires. However, several critical mechanical limitations hinder the performance and long-term adaptability of braided implants. These limitations can cause medical problems such as recurrence, particularly due to implant compaction, meaning a reduction in volume or expansion capability, as well as implant dislocation or instability [11]. These problems could be due to the hammering effect: after deployment, the implant is subjected to cyclic forces generated by the pulsatile nature of blood flow [12, 13]. This effect might cause bad wall apposition, meaning insufficient coverage of the aneurysm neck, and changes in implant position as one study showed for the WEB and Contour implants [11]. Additionally, these devices offer limited size, flexibility, and radial force tunability, making it difficult to tailor them to patient-specific aneurysm geometries. They are also produced only for a certain diameter, from 5 mm to 11 mm [14]. Indeed, the WEB device operates through lateral expansion during deployment, making it unsuitable for aneurysms smaller than 3 mm or larger than 10 mm [11].

These problems mentioned could be caused by the braided structure of the implants. Braiding causes instability and radial forces are lower as a result of wire slippage [15, 16]. They can be overcome by using thin-film implants and fabricating interconnected structures [17]. Such interconnected structures can also be crucial during deployment because they show higher radial forces. However, as they are also permanent implants, they can restrict future access to the aneurysm sac, preventing potential follow-up treatments such as retreatment and representing an important drawback in cases where aneurysms recur over time. This challenge can be addressed by introducing functional implants based on MEMS technology, which incorporate door-like structures, referred to as flaps in this paper, that can be opened after implantation when needed. This functionality is enabled by so-called 2.5D fabrication technology [18].

The 2.5D concept refers to a MEMS-based fabrication technique by which thin films with varying thicknesses can be integrated within a single design. It typically consists of a relatively thick structural layer (up to 75 μm) that provides mechanical stability, combined with a thinner functional layer (as thin as a few microns) that imparts specific properties to the device [18]. This approach employs photolithography, magnetron sputtering, and wet etching techniques, offering a high degree of design freedom and the ability to fabricate complex geometries. This versatility enables the fabrication of intricate structures, including drug reservoirs, origami-inspired implants [19], and designs with enhanced radiopacity achieved through thin layers of heavy metals such as Pt or Ta [20]. Precise tuning of the implant's mechanical behavior is also possible by varying the layer thicknesses and optimizing the geometric layout within the design.

All these implants are fabricated using the shape memory alloy (SMA) nickel-titanium (NiTi), which possesses unique thermomechanical properties such as shape memory effect and superelasticity [21, 22]. Superelasticity, also known as pseudoelasticity, is a stress-induced, reversible, martensitic phase transformation that occurs at temperatures above austenite finish temperature (A_f) [23, 24]. Under mechanical loading, the material undergoes a transformation from the parent austenite phase to stress-induced martensite, accommodating strains up to 6%–8% [25]. Upon unloading, the martensite reverts back to austenite, allowing the material to recover its original shape without any residual deformation. These properties are particularly advantageous for designing self-expandable aneurysm implants. During deployment, SMAs can be compacted into delivery systems and expand to their predetermined shape once released into the aneurysm sac, making them ideal candidates for minimally invasive medical applications. This reduces the surgery times leading to less exposure to x-rays radiation [26]. Moreover, SMA implants can endure the hemodynamic forces within cerebral arteries without compromising their structural integrity, making them particularly suited for long-term use. NiTi thin films stand out for these applications not only because of their mechanical properties, but they also show excellent biocompatibility [27, 28], magnetic resonance imaging (MRI) compatibility [29], and kink resistance [17].

Using the 2.5D fabrication technology, our earlier work showed that the NiTi-based implant design supports effective coil deployment. Its flow dynamics were compared to those of the commercially available coil-assist device Neqstent [30] (Stryker, USA). Our designs featured thick structural backbones that provide the necessary radial force for implant stability, along with thin, mobile flaps that maintain access to the aneurysm sac, supporting potential retreatment options even after implantation. Digital subtraction angiography (DSA) showed that coiling can be performed successfully through the flaps of our implant without disturbing its position. The study further confirmed that the position of the implant remained stable throughout the procedure. These results validate the functional design of the flaps and support the potential of the implant as a stand-alone or adjunct device in aneurysm treatment [31]. Though the preliminary work showed the feasibility of such novel devices and their benefits over conventional braided devices it lacked systematic mechanical analysis of the proposed design.

The current study strongly compliments the previous work as it focuses on a more detailed mechanical analysis to explore the effects of design alteration on the radial forces and flap stiffness of these flap implants. We present four different backbone structures with modified and optimized flap designs tailored to each backbone. Different types of flap geometries (full and meshed) were investigated to understand their influence on the stiffness and device stability. Initially, all flaps were designed as full flaps without any integrated mesh. However, some of these designs exhibited displacement either due to insufficient radial force generated by the backbone or excessive stiffness of the flaps, both of which can lead to complications such as device migration. To address these limitations, modifications to the flaps were made to the selected design. These design modifications involved integrating a mesh into the flaps to reduce structural flap stiffness and resolve the instability issues. Stiffness could not be directly measured because the forces were below the sensitivity threshold of the force sensor. However, it was derived using the Euler–Bernoulli beam theory. This approach modeled the deflection of a triangular beam fixed at one end (representing the connection of the flap to the backbone) under a single-point load applied during microcatheter insertion. By enhancing our understanding of the challenges of instability and migration based on our experimental results, these novel designs and the mechanical studies provide valuable insights into design dynamics and offer promising results for safer and more effective aneurysm treatments.

Materials and methods

Design and fabrication

Free-standing NiTi thin films are fabricated by using microsystem technologies as follows: photolithography for structuring, magnetron sputtering, and wet chemical etching with HNO_3 for a copper sacrificial layer. This process is described in detail by Bechtold *et al* [18]. Implant designs are transferred onto a 4-inch Si wafer by photolithography (Karl Suss MA6, Germany). Two masks are used, one for flaps and one for backbones with alignment markers. The flaps of the implant are $7\text{ }\mu\text{m}$ thick and the backbone $42\text{ }\mu\text{m}$, which are deposited using a Von Ardenne CS730S (Von Ardenne, Germany) cluster magnetron sputter device from a 4-inch $\text{TiNi}_{46.5}$ (at %) target (Inguls GmbH, Germany). The schematic of the process flow (figure SI1) and details can be found in SI. The deposition parameters and material composition are identical to those used in our previous work. Additionally, the tensile test and differential scanning calorimetry (DSC) results are provided in the Supporting Information (SI) section of this publication [31].

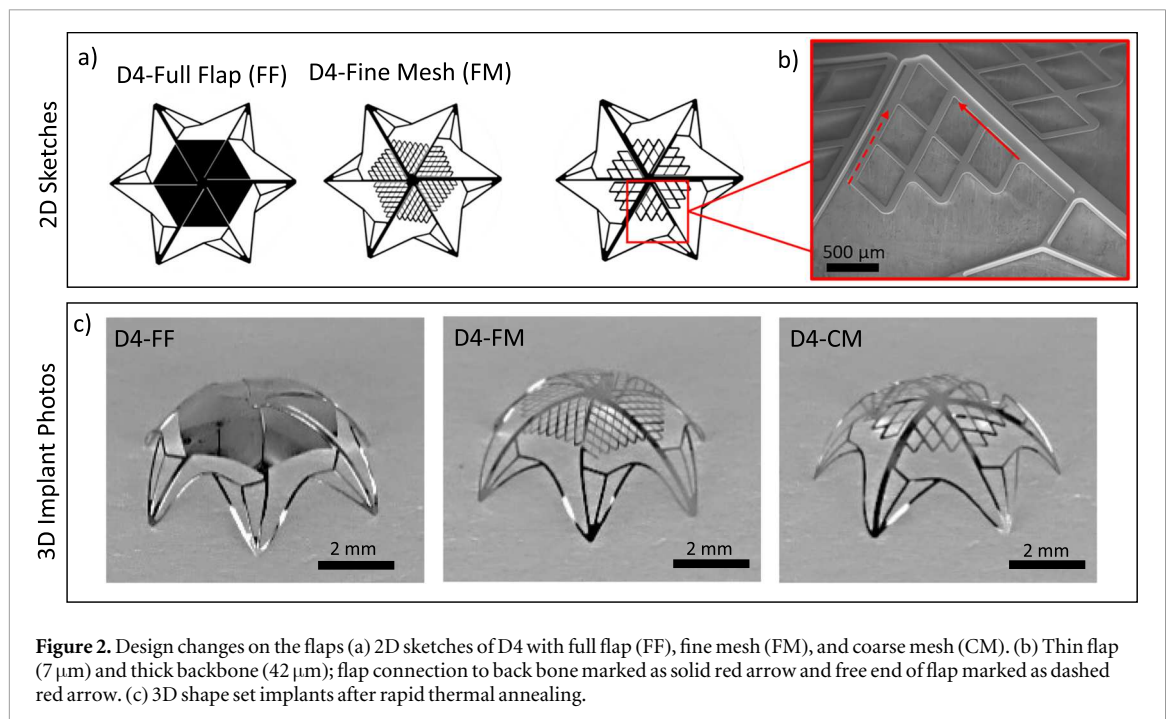
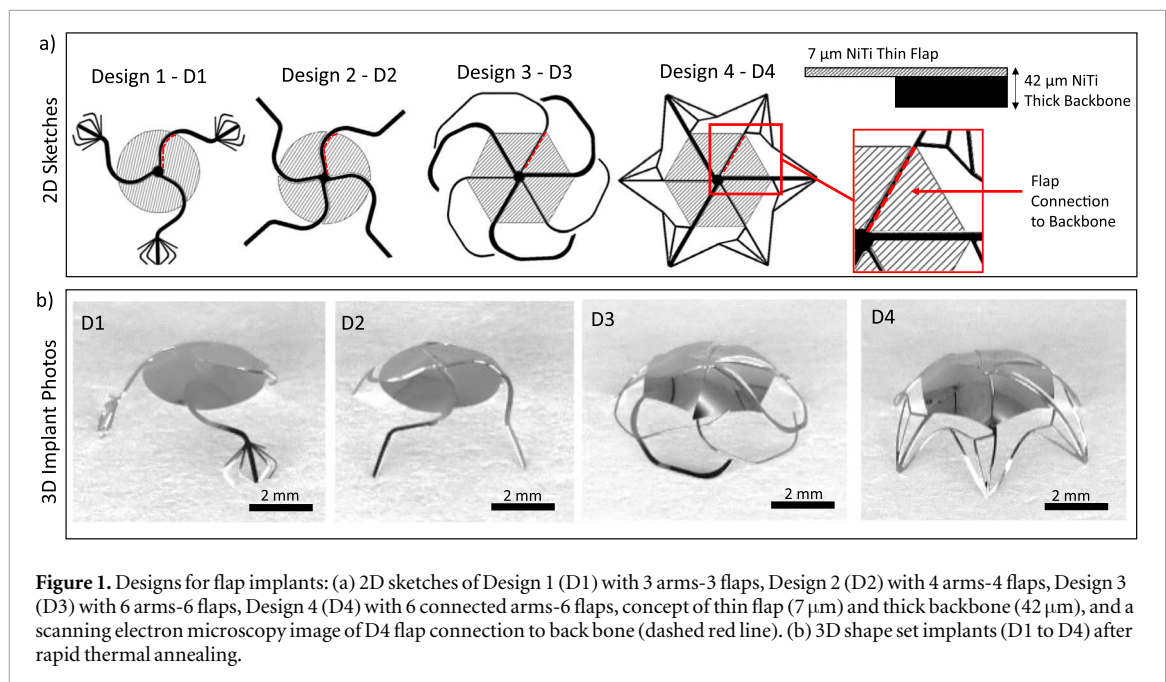
After deposition and lift off, the free-standing NiTi thin films are amorphous, and flat in shape. The shape is then set by placing the devices inside a hemispherical titanium fixture and using rapid thermal annealing (RTA, CreaTec RTA-6 SY09, Germany) at $700\text{ }^\circ\text{C}$ for 300 s. This step is used for setting the shape to 3D and to crystallize the implants with a diameter of 6.3 mm.

Figure 1 illustrates the structural variations of the flap implant designs. Figure 1(a) presents 2D sketches of four designs: Design 1 (D1) with three arms and three flaps; Design 2 (D2) with four arms and four flaps; Design 3 (D3) with six arms and six flaps; and Design 4 (D4), which also features six flaps and arms but with the arms connected to form a star-shaped outer ring. The sketch of a 2.5D structure consisting of a thin ($7\text{ }\mu\text{m}$) flexible flap and a thick ($42\text{ }\mu\text{m}$) stable backbone, alongside a scanning electron microscope (SEM; Zeiss Ultra 55 Plus, Germany) image highlights the flap-to-backbone interface (marked with a dashed red line). Figure 1(b) shows the hemispherical 3D shape of the implants after rapid thermal annealing. All four initial designs incorporate full flaps without any mesh modifications.

Figure 2 illustrates the flap design modifications aimed at tuning mechanical behavior. Figure 2(a) presents schematic 2D views of three flap variations applied to Design 4 (D4), a full flap with continuous coverage, a fine mesh, and a coarse mesh with dense and larger perforations, respectively. These variations are intended to modulate flap stiffness and porosity. Figure 2(b) shows a SEM image of the flap structure, highlighting the difference between a thin flap ($7\text{ }\mu\text{m}$) and a thick backbone ($42\text{ }\mu\text{m}$). The flap–backbone junction is marked with a solid red arrow, indicating the fixed connection, while the dashed arrow denotes the free end of the flap that enables deflection. Figure 2(c) displays the final 3D shape-set implants after rapid thermal annealing, confirming successful shape setting of all designs. The scale bar represents 1.5 mm.

Radial force set-up

The radial force of the device was investigated by placing it in a crimping set-up that was assembled in-house whose design was based on a modified version of that in Goff *et al* [32, 33]. Here, the device to be tested is placed inside an iris formed by 12 individual polyetheretherketone (PEEK) prisms, which when moved together changes the diameter of the iris. All the PEEK plates were connected to a ring, which is connected to an actuator assembly (M-229.26S and L-306.011100, PI miCos GmbH, Germany) via a force sensor (FN 3148-10N, Disynet GmbH, Germany). The input of the force sensor was 10 V through a power supply (E3631A Triple output DC,



Hewlett Packard, USA) while the output varied between ± 2 V, which corresponded to ± 10 N force. The output was recorded in a personal computer via a data acquisition tool (DAQ, S. No: 309B913, NI myDAQ, National Instruments, USA). Figure SI2a shows the simple sketch of radial force setup. The set-up was programmed using a LabVIEW program (V17.0f2 (32-bit), LabVIEW2017, National Instruments, USA).

A calibration experiment was conducted to evaluate both the elasticity of the machine and the frictional force that is generated during the experiment. From this a calibration coefficient was calculated and used to correct the recorded data, which is detailed elsewhere [31]. The devices were tested at 37 °C to mimic human body temperature in a controlled temperature chamber. Each measurement was repeated five times and the data plotted with mean and standard deviation.

Compression set-up

To evaluate the compression force, the implants were placed between two PEEK plates. While the bottom plate was stationary, the top plate moved with the implant in between. The implants were placed in a cylindrical

indentation (diameter of 6.5 mm and a depth of 1 mm) on the bottom plate. The top plate is further connected to a force sensor (FN 3148-10N, Disynet GmbH, Germany) and an actuator (L-306.011100, PI miCos GmbH, Germany) assembly. Figure SI2b shows the simple sketch of compression force setup. A power source, DAQ, and LabVIEW program similar to that used for the radial set-up were used for the compression set-up. The set-up has been described in detail elsewhere [31].

The implants were compressed from 0–0.4 mm while the resistance force was being recorded. The measurements were performed at 37 °C to mimic human body temperature in a controlled thermal chamber, each implant measurement was repeated ten times, and the mean and standard deviation were plotted.

Visual inspection

A WNA was replicated by using acrylic due to its transparency. Using this material allows for control over proper placement on the neck and illumination during photography. The WNA has a 4 mm bore hole, representing the aneurysm neck. It is enlarged on one end to correspond to the dimensions of a 5.5 mm aneurysm width. The top part has a cut of 5 mm, providing the possibility for visual inspection of the flap opening with a microcatheter. The dimensions and shape of the aneurysm replica are based on findings published in the literature [34].

For visualization, crimping is imitated with a pipette tip, and the tip diameter is cut as 1 mm. Nikon D850 with AF-S micro Nikkor 60 lens is used for taking photographs and videos of the implants. The photo sequences are taken while the microcatheter is being inserted, and all these images are combined to create a GIF by using Matlab (see SI video V1). Both visualization studies were performed at RT 25 ± 2 °C

Stiffness

Based on the Euler–Bernoulli beam theory, the flaps are taken as triangular, single-end, fixed cantilevers. A point load is applied by the catheter to open the flap. The deflection is derived in equation (1) [35];

$$\delta_{\max} = C \frac{1}{A} \text{ Where } C = \frac{3 P I^4}{E h^3}, \text{ concluding that } \delta_{\max} \propto \frac{1}{A}. \quad (1)$$

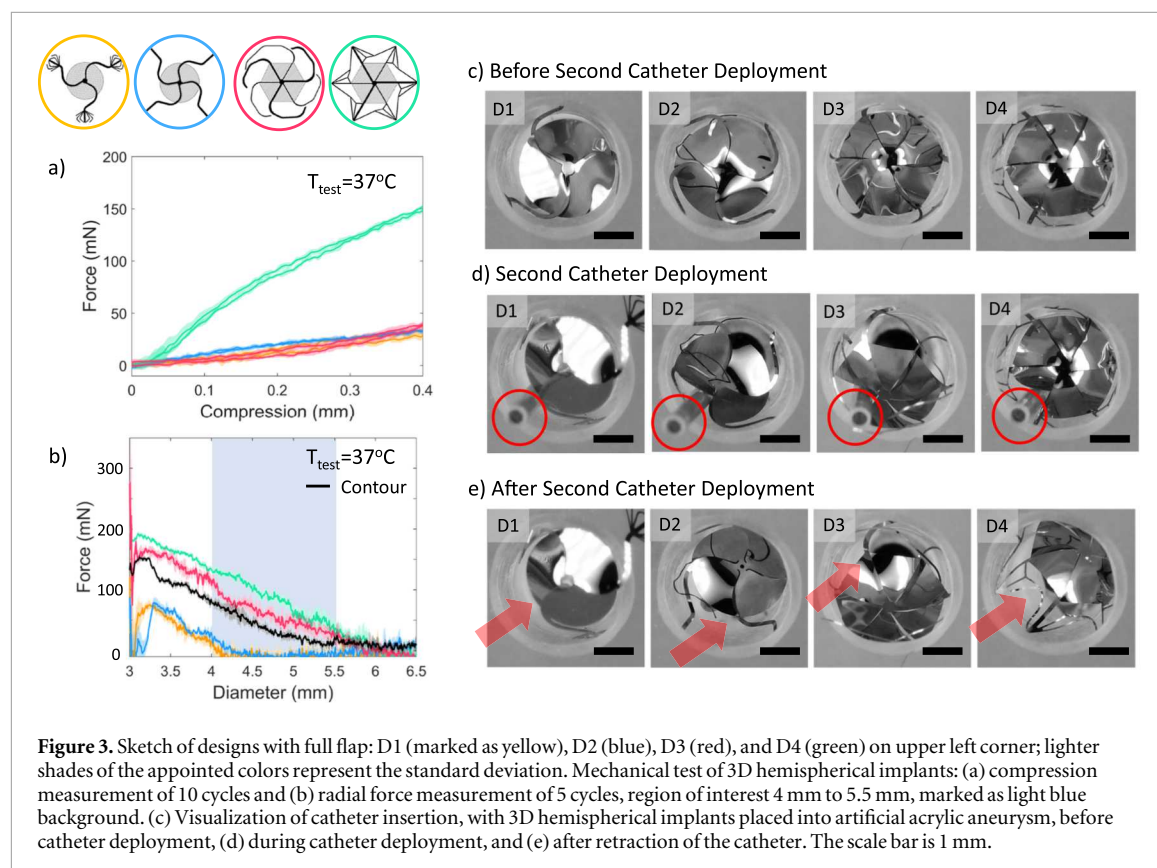
where δ is the deflection of the cantilever, A is the area of the cantilever, P is the load at the end of the cantilever, I is the length of the triangle cantilever, E is elastic modulus, and h is thickness. Based on the derivation, it is concluded that the more the area increases, the deflection decreases, which means stiffness increases for the same hinge length (connection length of the flap to the backbone). Detailed derivation and sketch (figure SI3) of the cantilever can be found in the SI.

For calculating the area of the implants, the hatch tool is used from AutoCAD. The 2D area for the D4 implants as calculated by the AutoCAD hatch tool for full flap is 20.54 mm², for coarse mesh 11.24 mm², and for fine mesh 11.33 mm².

Results and discussion

The mechanical characterization of the implants focused on compression and crimping tests to evaluate their structural stability and deformation behavior. Compression tests were conducted to simulate the water-hammering effect caused by pulsatile blood flow [12, 13], which can challenge the mechanical integrity and anchoring of the implant. In addition, crimping tests were used to evaluate the radial force exerted by the implants, which is critical for ensuring proper wall apposition and device stability during and after deployment. Crimping tests were also conducted on the commercially available 7 mm Contour intrasaccular implant in order to directly compare the results with our implant designs. Thus, we could evaluate the radial force output and mechanical performance of our devices relative to a clinically used standard. Identical testing conditions were applied to ensure consistency for comparing structural integrity and deployment characteristics.

The mechanical results are presented for compression (figure 3(a)) and radial force (figure 3(b)), with D1 marked in yellow, D2 in blue, D3 in red, and D4 in green. The lighter colors show the standard deviation of the experiment cycles (5 cycles for crimping and 10 cycles for compression). The radial and compression force measurements showed that designs without connections to the outer ring exhibited lower forces, while the connected D4 has the highest force. The compression forces are: 35 mN for D1, 37 mN for D2, 40 mN for D3, and 150 mN D4 at maximum compression (0.4 mm). A subtle increase in compression force is evident from D1 to D3 as the number of the arms increase (from 2 arms in D1 to 6 arms in D3). The highest compression force of D4 could be attributed to the ring that connects all the arms, with an almost four-fold increase compared to D3 (having same number of arms). The radial forces are measured between 6.5 mm to 3 mm. However, for a 7 mm commercial Contour the aneurysm dome size was recommended to be between 4 and 5.5 mm. This region is highlighted as light blue on the graph. At a 4 mm diameter, the measured radial forces were: 135 mN for D4, 119



mN for D3, 89 mN for Contour, 16 mN for D1, and 23 mN for D2. At 5.5 mm diameter, the forces decreased to: 36 mN for D4, 21 mN for D3, 21 mN for Contour, while D1 and D2 exhibited nearly zero force. Overall, in the recommended region between 4 mm–5.5 mm the Contour implant exhibited higher radial force values than D1 and D2, but lower than D3 and D4.

It can be observed that increasing the number of arms from D2 (four arms) to D3 (six arms) results in a substantial, approximately five-fold increase in radial force at 4 mm diameter. D4 shows a further increase of 16 mN compared to D3, although this increment is less pronounced. These results indicate that radial force depends strongly on the number of arms, while the presence of circumferential arm connections plays a secondary role for radial force (although it has a major effect on compressive force). The details can be found in supplementary information in table SI1.

The radial force therefore scales approximately proportionally with the number of arms. However, this trend cannot be extended indefinitely. Increasing the number of arms reduces the spacing between adjacent flaps, which in turn limits the available opening for secondary catheter insertion. Additionally, devices with higher arm counts occupy more space within the delivery catheter, potentially increasing friction and hindering smooth deployment.

Consequently, the design should incorporate as few arms as possible while still achieving sufficient radial force. This threshold can be guided by the performance of commercial devices such as Contour and Neqstent. Both D3 and D4 exceed the radial force of Contour in the clinically relevant region (4–5.5 mm), indicating that a six-arm design provides an effective balance between mechanical performance and deliverability.

Based on the performance of clinically used devices such as Contour (figure 3(b)) and Neqstent [31], which exert radial forces between approximately 21 mN and 115 mN across their deployable diameters, we estimate that the optimal radial-force range for aneurysm-neck-supported intrasaccular devices lies within this interval. Designs D3 and D4 both exceed this benchmark, suggesting adequate anchoring performance.

A visual analysis of microcatheter insertion was performed, with all four designs placed in an artificial acrylic aneurysm sac (see the material and method section for the dimensions); the stages before, during, and after microcatheter insertion are shown in figures 3(c)–(e), respectively. The visual analysis further indicated that D1 to D3 shifted during catheter insertion, whereas D4 remained stable during insertion but moved during retraction.

Few mechanical investigations of intrasaccular implants exist for comparison with our findings. In Kutbay *et al*, compression forces of spherical WEB SL and SLS devices (e.g., W5-4.5-3, W5-7-4, and W5-5-3.6) were measured using a two-plate linear set-up, yielding values between 2.9 and 46.2 mN [36]. This method captures

limited lateral compression along a single axis with partial surface engagement. In contrast, our measurements on Contour implants, which have a hemispherical geometry, were conducted using a 12-segment radial compression system that applies uniform circumferential load. Despite the dimensions of the Contour being smaller than the WEB devices, the measured forces are significantly higher due to full radial confinement, restricted deformation pathways, and complete surface contact. The hemispherical shape of the Contour inherently offers more radial resistance under true 3D loading, highlighting the limitations of simplified, linear compression set-up in capturing clinically relevant anchoring behavior.

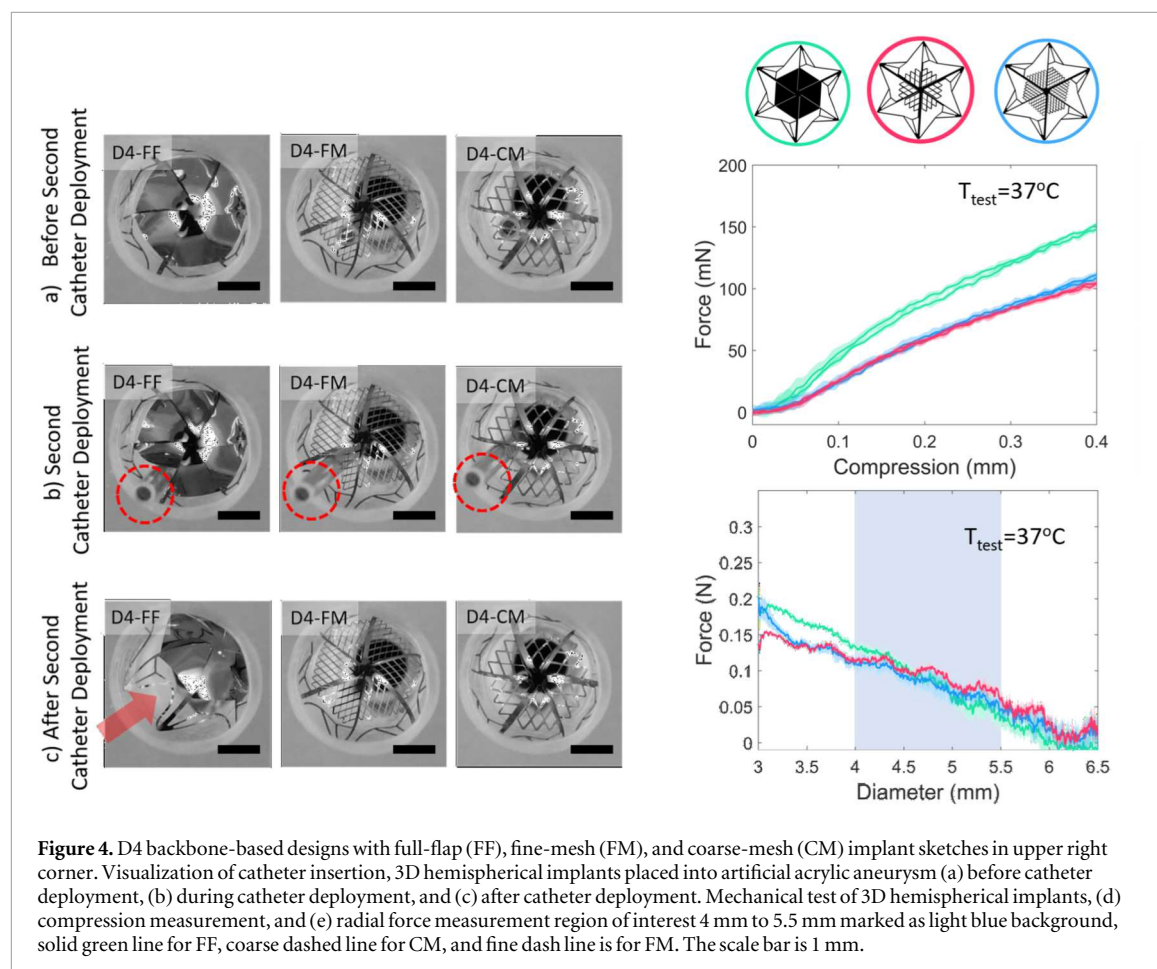
In our previous study, we evaluated both the radial and compression forces of newly designed thin-film intrasaccular implants with the full flap (FF) and mesh flap (MF) and compared them to a commercially available 7 mm Neqstent coil-assisting implant at 37 °C. During radial expansion from 3 mm to 6.5 mm, the FF and MF designs generated forces of 77 mN and 72 mN, respectively, at the critical 4 mm diameter, whereas the Neqstent exerted a higher force of 113 mN. However, both FF and MF implants maintained anchoring capability up to 5.5 mm (16 mN for FF and 13 mN for MF), while the Neqstent's radial force declined to nearly zero [31]. D4 shows larger radial and compression forces compared to our previously published designs. However, the backbone and flap designs differ from the current D4, including variations in flap connection lengths and positions. In the previous design the flap connection to the backbone is shorter. This affects the stiffness of the flap. The single flap area in the previous design is 5.5 mm² and connection length is 0.81 mm, giving a length-to-area ratio of around 14%. Furthermore, in the current study, the D4 single flap has an area of 2.21 mm² and the connection length is 2.09 mm, giving a much higher length-to-area ratio of around 94%, almost a 7-fold increase. Thus, although D4 has higher forces than the previous design, instabilities and device migration were observed during the visual analysis. The flap stiffness should be adjusted accordingly to overcome this problem. Methods to alter the stiffness could involve changing the connection length or/and adding fenestrations to the flaps, which would reduce the total area. Introducing the fenestrations might to enhance thrombosis in the aneurysm [37, 38].

Introducing a mesh pattern into the flap design reduces its stiffness due to a decrease in the effective flap area, which is derived for triangular full flap and presented in the SI, figure SI3. Based on the Euler–Bernoulli beam theory, the flaps can be approximated as triangular cantilevers fixed at one edge and subjected to a point load at the tip, applied by the microcatheter during opening (figure SI3). As the deflection is inversely proportional to the flap area (equation (1)), reducing this area by introducing mesh leads to greater deformation under the same load, effectively making the flap more compliant.

For flap stiffness studies, D1 and D2 were excluded from further testing since they show low radial forces compared to Contour in the area of interest and D3 showed lower compression forces and instabilities during microcatheter insertion through the flaps. This shows that the backbone and compression forces have the main contribution to implant stability during second catheter insertion. Additionally, they showed high instability and device migration during visual experiments while inserting the catheter. For investigating flap stiffness and increasing implant stability, D4 demonstrated the highest compression and radial force among the designs. The D4 backbone is used for three different flap designs. The flap designs kept as identical triangles. However, fenestrations are added to change their stiffness. Thus, figure 4 shows D4 full flap (FF), D4 fine mesh (FM), and D4 coarse mesh (CM) implants after setting the shape and placing them in the acrylic aneurysm sac. Visual analysis proves that by creating mesh on the flap the implant could hold its position during and after insertion (see figures 4(a)–(c)). No implant migration was observed.

The mechanical tests were also conducted on the D4-FM and D4-CM implants. They were both found to have a 33% reduction in the compression force at 0.4 mm compared to the D4-FF. This could be due to the material that is removed to create the mesh structures on the flaps. With both D4-FM and D4-CM having similar compression forces. The measured 2D area of D4-FF is 20.54 mm², D4-FM 11.33 mm², and D4-CM 11.24 mm². Thus, it can be assumed that having a larger area means there is more contact area, which leads to the higher force. However, D4-FM and D4-CM implants have almost the same area (with a small deviation of ± 0.09 mm²) which then resulted in similar compression forces. On contrary, the radial forces of all the flap variations were similar, as the main contributor in this case being the backbone rather than the flaps due to the nature of the experiment. As they all shared the same D4 backbone, their resulting radial forces are the same.

A few studies in the literature have investigated cantilever deflection in simple rectangle geometries and introducing fenestrations, showing that such openings increase deflection by reducing the structural stiffness. Du *et al* showed that fenestrations on cantilever structures influence their bending and stiffness behavior by altering the moment of inertia and creating zones of localized compliance. By introducing openings, the overall flexural rigidity of the cantilever is reduced, which increases deflection under applied loads. The geometric alterations such as the size, shape, and distribution of fenestrations. They can be strategically modifying to achieve desired stiffness gradients or enhance flexibility in specific regions. From a stiffness perspective, fenestrations decrease the moment of inertia of the cantilever, resulting in reduced flexural rigidity and increased deflection under the same applied load. They showed that as porosity increases, the beam becomes noticeably



more compliant while its apparent stiffness decreases. Under the same 0.4 N end load, deflection rises from 24.79 mm at 0% porosity to 28.62 mm at 28.09% porosity with an increase of about 15% while the fitted bending modulus drops from 2.49 MPa to 2.16 MPa, a decrease of roughly 13%. In other words, introducing fenestrations steadily reduces overall bending stiffness meaning cross-sectional resistance to bending, producing larger deflections for the same load [39].

Sahu *et al* also showed fenestration effects on the cantilever deflection for different materials (steel, titanium, and aluminum). For each material, placing a single hole 15 mm from the fixed end results in the greatest deflection. This deflection progressively decreases as the hole is positioned further away at 30 mm and 45 mm and reaches its minimum in the full beam (no fenestrations). These results confirm that both material stiffness and hole placement directly control bending resistance; therefore, deflection can be tuned predictably through strategic perforation [40]. These results support our hypothesis concerning the flap area and stiffness correlations.

The introduction of fenestrations inherently might bring a risk of crack initiation under cyclic loading, as the hinges of these features can act as stress concentrators. However, in the context of our design, this risk is significantly mitigated by the limited number of high-stress events the implant experiences, primarily during crimping and deployment. Once implanted, the mechanical loading is dominated by low-amplitude, pulsatile blood flow, which is unlikely to induce fatigue-related failure. With this in mind, we also assessed the compressive behavior of the implant to ensure that no plastic deformation occurs under expected loading conditions, thereby confirming its mechanical stability.

The compression force applied by the implant can be converted into pressure to enable direct comparison with literature values, which are commonly reported in kilopascals (kPa). For this, we use an estimate of the flap area in 4 mm neck which is obtained from AutoCAD directly by using Hatch for FF, CM and FM. This area is representing the portion of the implant that is directly exposed to and influenced by pulsatile flow at the aneurysm neck.

The measured compression forces at the aneurysm neck differ depending on the flap type. For the FF configuration, the compression force is approximately 150 mN (0.150 N), while for the CM and FM configurations the force is 100 mN (0.100 N). Using the refined flap area of 12.25 mm² for FF, 5.12 mm² for CM, and 5.02 mm²

for FM the applied pressure can be determined using the standard relation $P=F/A$. This results in a pressure of approximately 12.2 kPa for FF, 19.5 kPa for CM, 19.9 kPa for FM.

Physiological systolic–diastolic pressures of approximately 80–120 mmHg (10–16 kPa) have been reported in the literature. In computational studies, the loading associated with pulsatile blood flow is commonly represented by applying a sinusoidal pressure waveform with an amplitude of 2.6 kPa (20 mmHg) and a frequency of 1.2 Hz to the arterial wall [41]. These values indicate that the proposed implants should withstand pulsatile hemodynamic loading, as their design-specific pressure tolerances exceed this 2.6 kPa amplitude. For crimpability considerations, mesh-based (CM and FM) architectures are preferred, and their operational limits remain above diastolic pressure levels.

Due to pulse-induced diameter changes, the stent experiences strains of 1.45% at diastole and 0.98% at systole, corresponding to a mean strain of 1.22% and a cyclic strain amplitude of 0.24% [13]. Tensile testing and differential scanning calorimetry (DSC) data for the NiTi material, provided in the Supporting Information in our previous publication, show elastic behavior up to approximately 2% strain and superelastic response up to 3%. These results suggest that the material can fully recover under physiological pulsatile loading. Nevertheless, high-cycle fatigue testing is required to validate long-term durability under repeated cyclic conditions.

For intrasaccular aneurysm devices, intra-aneurysmal thrombosis induced by flow disruption markedly reduces intra-aneurysmal flow and motion once the sac is filled with thrombus, the device is embedded in a relatively static clot, so thrombosis is expected to reduce flow known as cushioning effect and leasing reduction in cyclic loading and therefore limit pulsatile fatigue rather than worsen it [37, 42].

Crimping generates the maximum strain state the implant will ever experience before cyclic physiological loading. And the crimping strains in aneurysm implants vary strongly with device design and diameter, as hemispherical Contour implants, spherical WEB devices, and cylindrical stents undergo distinct deformation modes during delivery. These architectures localize strain in different regions such as wire crossovers in braided WEB and Contour devices, or hinge-like strut junctions in in stents leading to significant variation in mechanical loading and fatigue susceptibility.

The crimping is the first and often dominant fatigue-relevant deformation step, even though it is not a cyclic load since the device does not undergo repeated crimping–deployment cycles. However, because this single event sets the highest local strains in the implant, the Berti et al. confirm that without detailed FEM strain mapping of the crimped configuration, fatigue predictions for aneurysm implants would be unreliable [43].

Furthermore, the fatigue risk still can be further reduced through careful tuning of the material properties of NiTi. Increasing the transformation stress and optimizing the fatigue resistance through thermomechanical processing or alloy modification can enhance the structural integrity of the device on the hinges, even in the presence of localized geometric features such as fenestrations or even more complex geometries [44]. Once an optimal backbone and flap geometry are established, the design can be parametrically scaled to produce device sizes comparable to those of existing implants (e.g., Contour), allowing the system to accommodate the wide range of patient-specific WNA geometries.

Even though crimping fatigue could not be studied, the visual analysis of crimping is performed to represent the shape recovery of the implants. D4 implants imitating the crimped shape when it is pulled into a catheter is presented in figure 5. Here, implants were pulled through an opening of 1 mm in diameter. Thus, when the implant is radially pressed and pulled through the tube, flaps overlap with each other, but they still go through high deformations. The A_f temperature of the implant is $15 \pm 1^\circ\text{C}$ but it has superelastic properties at room temperature (RT). Thus, it is expected that these implants all show no plastic deformation. Material properties are presented in the SI of the publication [31]. The videos for figure 5 can be seen in SI Video2.

Using a caliper, the overall height and diameter of the devices were measured before and after deployment. These values were found to remain essentially unchanged, with variations within ± 0.1 mm, which corresponds to the accuracy limit of the measurement instrument.

Finer structural features, including the individual arms and small curved elements, were more challenging to quantify accurately with a caliper due to their geometry and size. Nevertheless, visual comparison of the implants before and after deployment did not reveal any noticeable deformation of these smaller components. To further support this observation, photographs of the implants following crimping have been provided in the Supplementary Information (figure SI4).

Although flow-dynamics experiments were not possible to conduct, the calculated porosity values allow preliminary assumptions about the expected hemodynamic behavior; nevertheless, comprehensive understanding of flow modulation and implant performance will ultimately require digital subtraction angiography (DSA).

FF has porosity in the 4 mm neck area around 3%, CM and FM around 60%. This means that the FF has the highest flow reduction than CM and FM. However, it is known in the literature that an optimal porosity range of approximately 60%–75% consistently emerges as the most effective for achieving substantial intra-aneurysmal flow reduction and thrombosis formation while preventing occlusion in the side branches or flow

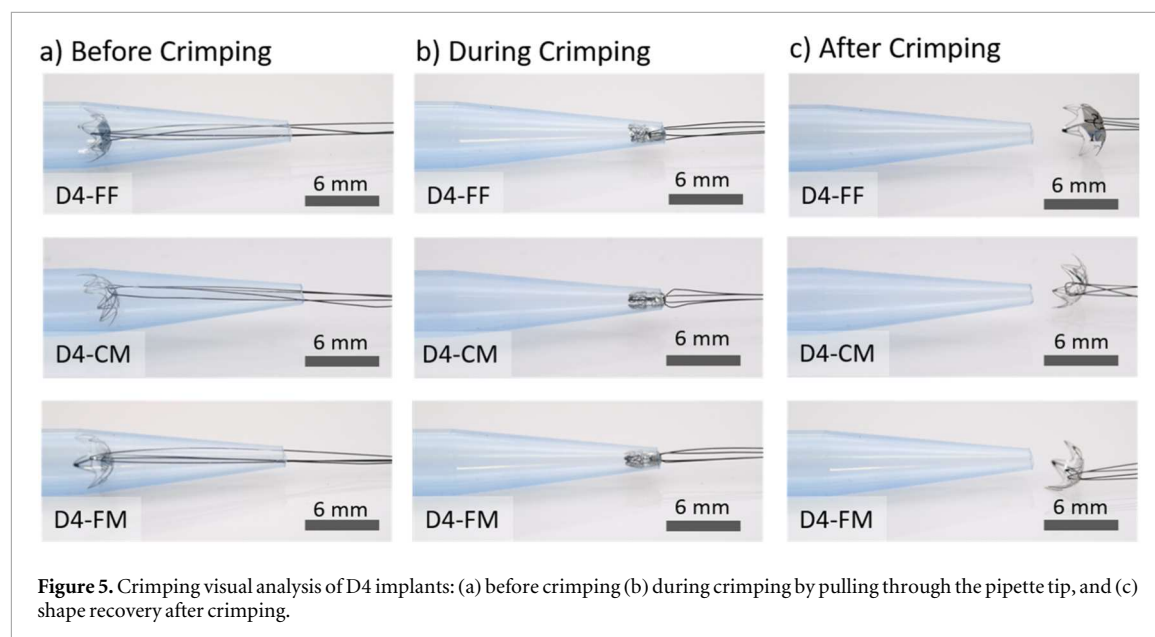


Figure 5. Crimping visual analysis of D4 implants: (a) before crimping (b) during crimping by pulling through the pipette tip, and (c) shape recovery after crimping.

disturbance parent artery [45]. However, all these results are based on flow diverter stents rather than intrasaccular implants.

Augsburger *et al* showed that two stents with the same porosity (63%) produced markedly different reductions in intra-aneurysmal velocity and vorticity, indicating that device design strongly influences flow diversion beyond porosity alone. Overall, a 63% porosity device provides strong flow suppression, reducing velocity to roughly 20%–35% of the baseline depending on flow type. However, the paper clearly shows that design-related factors such as pore shape, strut arrangement, and how the device aligns with inertia-driven inflow. These can cause major differences in performance, despite identical porosity [46]. We further suggest that the conformability of the implant and the quality of its opposition to the artery or aneurysm neck can modify the effective pore structure seen by the inflow jet, thereby contributing to these differences in hemodynamic performance. Thus, DSA should be performed to be able to define the flow dynamics of our designs.

Limitations

This study has several limitations that should be acknowledged. First, no flow analysis was performed to evaluate the hemodynamic impact of the implant geometry or surface configuration. As a result, the device's potential to modulate intra-aneurysmal flow cannot be quantitatively compared to commercially available flow-diverting or intrasaccular implants. Second, push-out force measurements were not conducted in the acrylic aneurysm used in the visualization to assess anchoring performance and procedural safety, including the possibility of accidentally displacing the implant by unintended contact with the backbone during catheter or guidewire manipulation. However, our devices showed higher forces compared to a commercial implant with a similar diameter. Higher radial forces can be correlated with better anchoring implant into the aneurysm implant. And also, the implant design inherently incorporates a safety margin, as its geometry was intentionally developed so that the flexible flap regions occupy a substantially larger surface area than the central backbone. This configuration improves catheter accessibility and reduces the likelihood of unintended mechanical interaction during implantation. Based on geometrical analysis of D4-FF exported directly from the AutoCAD hatch-function, the total neck-relevant surface area is 12.57 mm^2 , of which the backbone accounts for only 1.26 mm^2 . This corresponds to an area fraction of approximately 0.1002, or about 10% of the neck-facing surface. Consequently, the probability of a guidewire directly contacting the backbone is expected to be around 10%, whereas the presence of the guidewire within the catheter lumen during navigation further decreases the likelihood of such contact, offering an additional procedural safety buffer. Finally, the study does not include high-cycle fatigue testing, which is critical for assessing long-term mechanical durability. Without these fatigue data, the long-term stability and reliability of the device remain to be established.

Conclusion

Our results represent a significant development for the treatment of WNA. By incorporating mobile flaps into intrasaccular devices, not only was mechanical performance enhanced but post implantation access to the aneurysm sac was also preserved, making retreatment possible if needed.

With MEMS technology, 2.5D implants can be precisely fabricated, enabling tunability of their radial forces through structural design (e.g. the geometry or the thickness of the backbone). However, it is important to note that other strategies also exist. For instance, adjusting the material thickness, which can be accurately controlled during MEMS fabrication, offers an additional and effective means of fine-tuning mechanical response. Mechanical and visual analyses indicate that D4 mesh structures offer superior anchoring performance, which can be attributed to the number of arms and the ring that connects all the arms. However, in the case of full flaps, a high flap stiffness was observed, which hindered microcatheter insertion for coil deployment without disturbing the implant position. To address this problem, mesh patterns were introduced into the flap regions, significantly reducing stiffness to enhance flexibility. By reducing the flap area and introducing perforations, the flaps became more compliant so that the catheter can be inserted without compromising implant stability. As all designs shared the same D4 backbone, the overall radial force remained consistent, preventing migration. This understanding of the relationship between backbone support and flap compliance can be applied for developing next-generation implants that can function as standalone intrasaccular devices.

Moreover, the use of flexible flaps may allow the aneurysm sac to remain accessible even months after implantation, potentially enabling retreatment in case of complications. While this is a promising feature, it remains to be validated, and further *in vitro* and *in vivo* studies are necessary to confirm long-term accessibility and clinical feasibility.

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Data availability statement

The data cannot be made publicly available upon publication because they are not available in a format that is sufficiently accessible or reusable by other researchers. The data that support the findings of this study are available upon reasonable request from the authors.

Declaration of interest

Olav Jansen reports a relationship with Acandis, Stryker, RH-DT that includes: consulting or advisory. Olav Jansen reports a relationship with Guerbet, Rapid AI, Boehringer, Bayer, mRAY, Lilly that includes: speaking and lecture fees. Duygu Dengiz, Prasanth Velvaluri, Eckhard Quandt, Olav Jansen has patent pending to Kiel University.

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Conceptualization (equal), Data curation (equal), Formal analysis (equal), Investigation (equal), Methodology (equal), Validation (equal), Visualization (equal), Writing – original draft (lead), Writing – review & editing (equal)

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