Laser texturing of a St. Jude Medical Regent (TM) mechanical heart valve prosthesis

Vigano, Giorgio; ten Brink, Gert H.; Groenendijk, Max; Sipkema, Ronald; Pollack, Daniel K. M.; Mariani, Massimo A.; Kooi, Bart J.

Published in:
Interactive Cardiovascular and Thoracic Surgery

DOI:
10.1093/icvts/ivab185

Interactive CardioVascular and Thoracic Surgery 33 (2021) 986–991
doi:10.1093/icvts/ivab185 Advance Access publication 19 July 2021

ORIGINAL ARTICLE

Cite this article as: Vigano G, ten Brink GH, Groenendijk M, Sipkema R, Pollack DK., Mariani MA *et al.* Laser texturing of a St. Jude Medical Regent^{TM} mechanical heart valve prosthesis: the proof of concept. Interact CardioVasc Thorac Surg 2021;33:986–91.

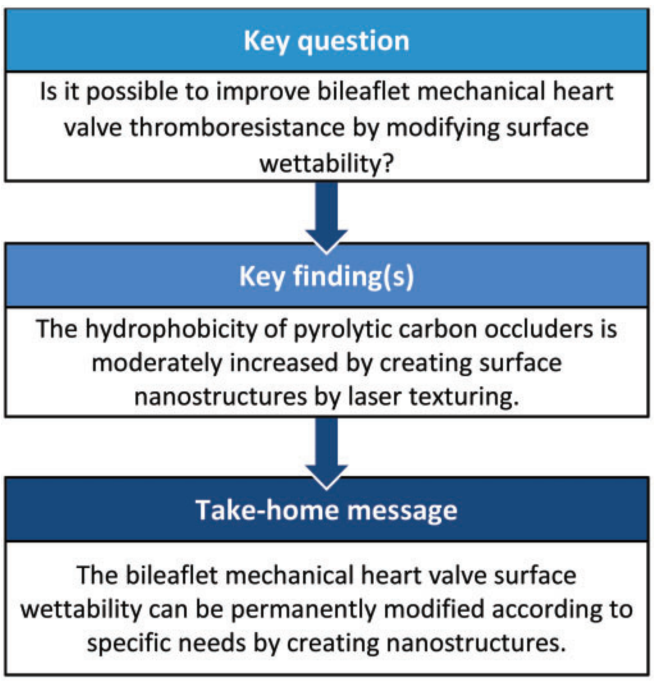
Laser texturing of a St. Jude Medical Regent^{TM} mechanical heart valve prosthesis: the proof of concept

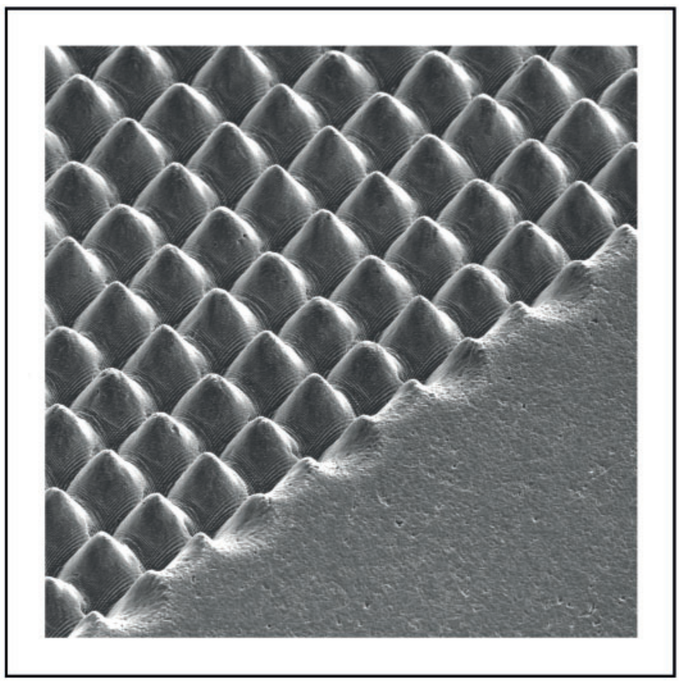
Giorgio Vigano [a,*], Gert H. ten Brink [b], Max Groenendijk[c], Ronald Sipkema[c], Daniël K.M. Pollack[a], Massimo A. Mariani[a] and Bart J. Kooi [b]

[a] Department of Cardiothoracic Surgery, University Medical Centre Groningen, Heart Centre, Groningen, Netherlands
[b] Zernike Institute for Advanced Materials, University of Groningen, Groningen, Netherlands
[c] Lightmotif B.V., Enschede, Netherlands

* Corresponding author. Department of Cardiothoracic Surgery, University of Groningen, University Medical Center Groningen, PO Box 30.001, 9700 RB Groningen, Netherlands. Tel: +31-50-3611327; fax: +31-50-3614391; e-mail: g.vigano@umcg.nl (G. Vigano).

Received 16 January 2021; received in revised form 5 May 2021; accepted 3 June 2021





Abstract

OBJECTIVES: The liquid–solid interactions have attracted broad interest since solid surfaces can either repel or attract fluids, configuring a wide spectrum of wetting states (from superhydrophilicity to superhydrophobicity). Since the blood–artificial surface interaction of bileaflet mechanical heart valves essentially represents a liquid–solid interaction, we analysed the thrombogenicity of mechanical heart valve prostheses from innovative perspectives. The aim of the present study was to modify the surface wettability of standard St. Jude Medical Regent^{TM} occluders.

Presented at the 34th Annual Meeting of the European Association for Cardio-Thoracic Surgery, Barcelona, Spain, 8–10 October.

METHODS: Four pyrolytic carbon occluders were irradiated by means of ultra-short pulse laser, to create 4 different nanotextures (A–D), the essential prerequisite to achieve superhydrophobicity. The static surface wettability of the occluders was qualified by the contact angle (θ) of 2 µl of purified water, using the sessile drop technique. The angle formed between the liquid–solid and the liquid–vapour interface was the contact angle and was obtained by analysing the droplet images captured by a camera. The morphology of the occluders was characterized and analysed by a scanning electron microscope at different magnifications.

RESULTS: The scanning electron microscope analysis of the textures revealed 2 different configurations of the pillars since A and B showed well-rounded shaped tops and C and D flat tops. The measured highest contact angles were comprised between 108.1° and 112.7°, reflecting an improved hydrophobicity of the occluders. All the textures exhibited, to different extents, an orientation (horizontal or vertical), which was strictly related to the observed anisotropy.

CONCLUSIONS: In this very early phase of our research, we were able to demonstrate that the intrinsic wettability of pyrolytic carbon occluders can be permanently modified, increasing the water repellency.

Keywords: Superhydrophobic • Laser texturing • Warfarin-free • Contact angle

ABBREVIATIONS

BMHV	Bileaflet mechanical heart valve prostheses
CA	Contact angle
PyC	Pyrolytic carbon

INTRODUCTION

Valvular heart diseases represents a major public-health problem and a burden of the upcoming years [1]. As a result, each year thousands failing heart valves need to be replaced with biological or mechanical heart valve prostheses [2, 3]. Commercially available bileaflet mechanical heart valve prostheses (BMHVs) are still based on concepts largely unchanged from the 1980s, with unmet needs for increased thromboresistance [4]. The blood–artificial surface interaction aims to explain the thrombogenicity of mechanical heart valve prostheses mainly focusing on the 3 elements involved: the blood, the surface and the flow [5]. Non-laminar flow, shear stresses and turbulences primarily result into platelet activation and the triggering of the coagulation cascade, further promoting thromboembolic complications. Since shear stress represents one of the strongest platelet activator [6], it has been observed that the BMHVs in computational fluid dynamics simulations activate platelets at a rate more than twice that observed with the monoleaflet [7]. The high stress in the bileaflet models occurs during forward flow and leakage regurgitation, as well as adjacent stagnant flow in the hinge area. Since the blood–artificial surface interaction is primarily a liquid–solid interaction, we addressed the BMHV thrombogenicity from new perspectives, aiming to minimize the contact with the surface, to kill platelet activation and coagulation cascade triggering 'ab origine'. The interaction between liquid and solid has recently attracted broad interest since solid surfaces can exhibit a wide spectrum of different wetting states, ranging from (super)hydrophilicity to (super)hydrophobicity [8]. Complex hierarchical morphologies with dimensions of features ranging from the macroscale to the nanoscale are always behind these superior properties, including extreme wetting, floatation, adhesion, friction and mechanical strength [9–13]. The surface properties, whether hydrophobic or hydrophilic, are mainly determined by 2 factors: the surface chemistry (the surface energy) and the surface roughness (the interface) [2]. The equilibrium or contact angle (θ or CA) describes the primary state of wetting, which occurs on an ideal smooth surface [14]. When a liquid droplet contacts a rough solid surface, it displays an apparent CA with 2 possible configurations to minimize its free energy: the fully wetted Wenzel state or the partially wetted Cassie–Baxter state [15, 16]. The Wenzel state refers to the condition in which the liquid droplet is in complete contact with the surface and the droplet fills up the roughness grooves. If the droplet is in the Cassie–Baxter state, the water droplet sits on the top of the tiny air bubbles and will bounce and roll off. The Cassie–Baxter state leads to high CAs and a surface is considered superhydrophobic if it displays CA >150°. If we translate these concepts into the blood–artificial surface interaction, an equivalence between superhydrophobicity and thromboresistance may be shown. It has been recently demonstrated that the surfaces based on the Cassie–Baxter state improve haemodynamics since fluid slip can exist along the surface, potentially reducing the risk for haemolysis and shear-induced platelet activation [2]. Here, we aimed to texture the surface of standard St. Jude Medical Regent™ BMHVs to obtain a surface micro or nano-sized roughness, that is the fundamental prerequisite to achieve the low wettability substrates and in all likelihood the thromboresistance. The 4 occluders were irradiated by laser pulse-beam, because of the excellent laser control of the surface roughness, thanks to the ability to work with a large range of materials and to the possibility to permanently modify the BMHV wettability properties [17]. Here, we investigated the static wetting properties of the same, focusing on its superhydrophobicity.

MATERIALS AND METHODS

Lightmotif B.V. (Enschede, The Netherlands) is a spin-off company of the University of Twente and the Materials Innovation Institute (M2i), founded in 2008. Company's main interest lies in ultra-short pulse laser processing, software development and mechanical engineering. Ultra-short pulse laser processes enable to tailor surface textures of multiple scales from micro to nanometre range and to control their properties. The technology can be applied on any material and can be used for texturing 3-dimensional curved surfaces. Ultra-short pulse laser texturing enables many new applications of engineered surfaces, where specific surface textures can be used to influence the functional properties, the wetting, tribological or optical properties. Such surfaces are also referred to as functional surfaces.

Heart valve prostheses

Two standard aortic St. Jude Medical Regent (St Jude Medical Inc., Minneapolis, MN, USA) 27- and 25-mm pyrolytic carbon

(PyC) BMHVs were selected for all the experiments. Prosthesis selection was only based on specific valve technical features, which made the disassembling and the reassembling of the occluders easier. In this preliminary phase of research, only the valve occluders were used to obtain accurate measurements. The manufacturers generously provided the samples. At the time of the tests, all the prostheses were sterile and sealed preserved in their own fabric packaging at room temperature. None of the valves was pre-treated or cleaned with any agent. Attention was put on manipulating the valves, always done with surgical gloves and avoiding contact with metal instruments. The valve occluders were gently removed from their housing and put in a case, inside a foam tissue for transport. The static surface wettability of the occluders was qualified by the CA (θ) of 2 µl of purified water using a MilliQ 500 µl Hamilton syringe, using the sessile drop technique. Water was used instead of blood because of its similar behaviours and its ease of use.

Target textures

The selection of the texture with the desired functional substrates was demanding, particularly since blood is a living fluid with very peculiar features [18]. Since the surface roughness represents an essential prerequisite to achieve a certain level of (super)hydrophobicity, we pragmatically employed 'egg-box' structures for our purposes, where the scan line separation or pitch (equivalent to the distance between the tops of 2 contiguous textures) and depth (or height of the texture) was theoretically equal. These 'egg-box' structures were made by over-scanning fixed cross-hatch patterns of single lines. The majority of the parameters were fixed (spot size of 20 µm and wavelength of 532 nm), while only the pulse energy was determined based on an ablation curve experiment, in which the pockets were machined with increasing fluences (power), with the same total applied laser dose (see Supplementary Material, Fig. S1). The depth of the pockets directly reflected the efficiency of the process. The surface morphology of textured surfaces was strictly related to the laser power and the pitch. Pitch variation was arbitrarily set on 20 and 30 µm, where the former resulted in a well-rounded top and the latter in a flat surface on the top. We allowed a little variation in width and depth of the pillars, to analyse the variation of the wettability, selecting 2 depths for each pitch.

Surface characterization and morphology

The morphology of the laser-treated valve occluders was characterized by a scanning electron microscope, model FEI NovaNanoSEM 650 operated in high vacuum mode 5.00 kV operating voltage and SE mode. The whole surface of the occluders was randomly analysed at different magnifications, from 100× up to 100 000×. The CA was measured using the static sessile drop method, in which the sessile drop CA was measured by a CA goniometer using an optical subsystem to capture the profile of a pure liquid on a solid substrate. The angle formed between the liquid–solid interface and the liquid–vapour interface was the CA and was obtained by analysing droplet images captured by a camera Dataphysics OCA-20 V4.3.7 build 1032 software. Several individual measurements were performed at different instants (0.5 and 8 s) over the time (on days 1 and 15) to investigate possible differences of the wetting behaviours, also in relation to the air exposure.

RESULTS

Texturing process and valve texturing

Four hierarchical nanotextures were obtained (A–D). In our first test, we observed that pitches of 20 µm (smallest pitch) with the smallest depth resulted in pillars with a flat top, whereas we aimed for a well-rounded peak. Therefore, all the pitches were reduced by 4 µm, to 16 and 26 µm. The actual size of the groove depths for a given number of overscans was greater for the smaller than for the larger pitch (Supplementary Material, Fig. S2). This could be likely due to the unusual anisotropic properties exhibited by PyC, which is one of the best planar thermal conductors available. Reasonably smaller dimensions of the pitch were able to impact this thermal behaviour.

Macroscopic and microscopic findings

Figure 1 shows the microscopic characteristics of the laser-treated areas of the occluders at different magnifications. The configuration of the textures was significantly different since A and B had well-rounded shaped tops and C and D flat tops. In addition, all the textures showed, to different extents, an orientation (horizontal or vertical), which was strictly related to the observed anisotropy. The anisotropy of the textures represented an unexpected finding, for which 2 different wetting behaviours coexisted at the same time, depending on the specific orientation of the texture.

Contact angles and wettability properties

Wetting tests are shown in Fig. 2. The CAs were measured from 2 different views, rotating the occluders 90 degrees about the *Z*-axis, with respect to the camera, from the front and from the side view. The CA was 3 times simultaneously measured and was extrapolated from the software analysis of a 10-s movie, to obtain the most stable CA. All the textures were found anisotropic at different extents, being directionally dependent. This peculiar feature implied that the wetting state of the texture strictly depended on the orientation of the textures. The measurements of CA's were also performed outside the laser track (standard untreated valve occluders) for comparison purposes (Fig. 3). Since the droplets resting on the untreated occluders (polished PyC) showed a pronounced tendency to flatten out and to wet the surface more extensively in the course of time, 2 measurements were performed at 2 different moments, at 0.5 and 8.0 s, as after this time lapse the droplets were completely stable (Supplementary Material, Fig. S1). All textures showed to fairly improve the water repellency or in any case to increase the CA, which was the aim of the present study. This applied to both directions, excepted for the texture C, in which the CA measured from the side view was consistently smaller than the angle measured outside the laser track after 0.5 s, but equal to the angle measured outside the laser track after 8.0 s.

DISCUSSION

Since its very first clinical introduction, BMHVs are mainly constituted of PyC, especially with regard to the surface. PyC is very similar to graphite, from which it differs in forming a single

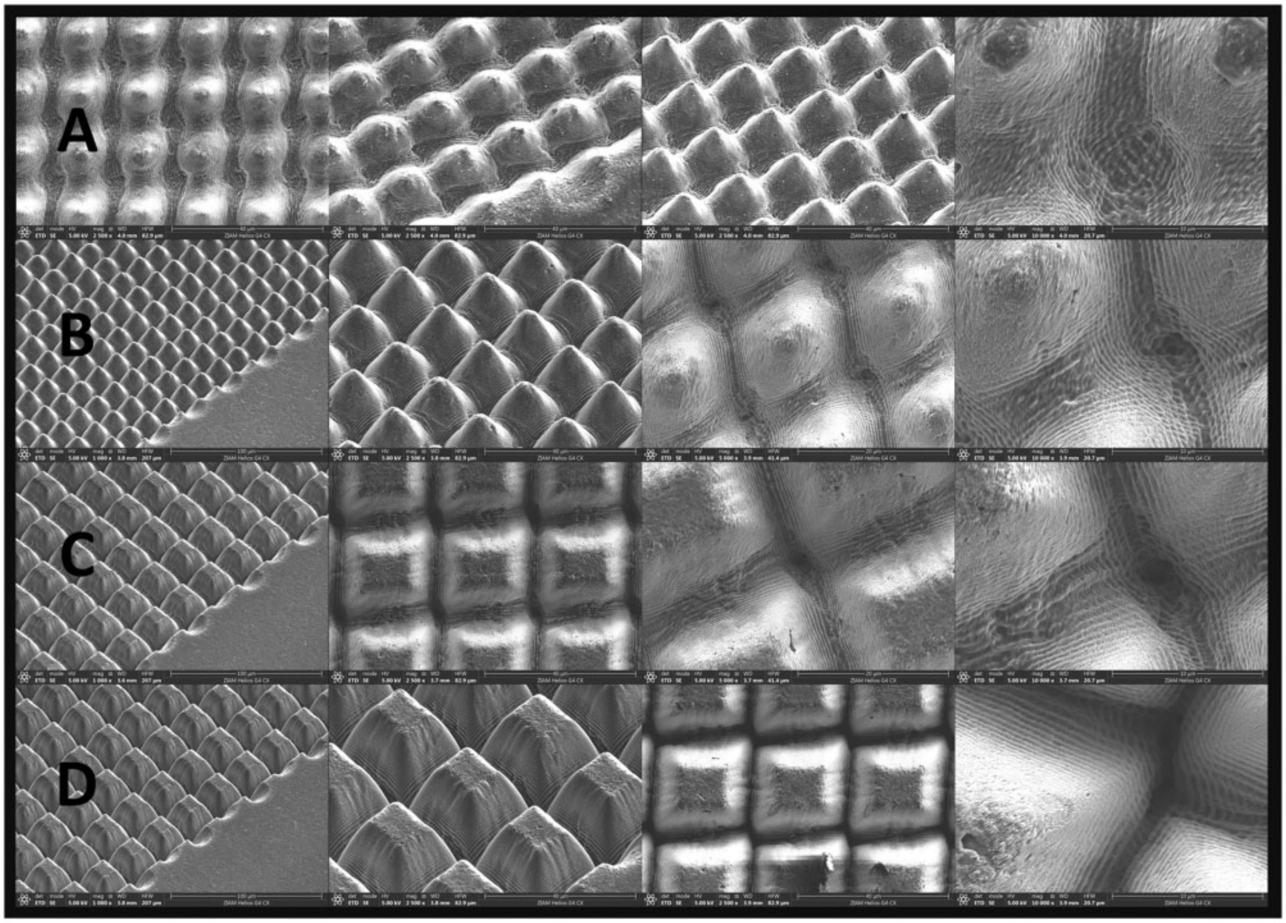


Figure 1: Scanning electron microscope images of textures at different magnifications.

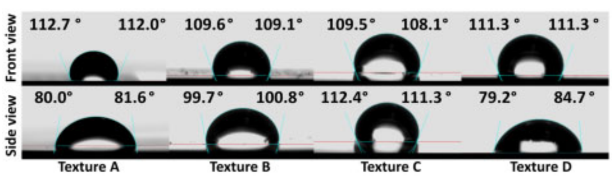


Figure 2: Wetting tests of a water droplet resting on the laser irradiated surface, on the textures A, B, C and D, from a front and a side view.

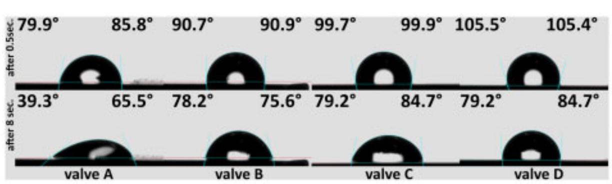


Figure 3: Wetting tests of a water droplet resting on the standard surface occluder (outside the laser irradiated segments) of a St. Jude Medical Regent™ heart valve prosthesis.

crystallographic structural plane, as opposed to graphite which is randomly oriented. PyC has the advantages of extreme hardness, unsurpassed durability and good biocompatibility. Initially, strength and wear resistance of PyC were increased by adding silicon, but subsequent improvements led to what we call 'pure carbon'. Although it could appear as if material science at least has provided us with hardly improvable, optimal material for BMHVs, thrombogenicity remains the major unsolved problem [4, 19]. We attempted to address this 'final issue', from innovative perspectives, applying the innovative topic of superhydrophobic nanotechnology into what per definition is a liquid–solid interaction: the blood–artificial surface interaction. Since the consistency (evenness) of superhydrophobicity and thromboresistance has not been demonstrated yet, we first investigated the differences between water and blood resting on the occluders of 4 commercially available standard PyC BMHVs. In these experiments, 4 standard, unaltered pyrolytic BMHV prostheses were analysed: On-X® CryoLife, Inc. Mitral (On-X), Carbomedics LivaNova, Bicarbon LivaNova and St. Jude Medical Regent Abbott. The surface static wettability of as-received occluders was qualified by the CA (θ) of 2 μl of water or blood droplets. Water and blood showed similar behaviours under atmospheric conditions (CA = 98.18 ± 2.98 and 102.3 ± 7.40, respectively), reflecting the propensity of the occluders to repel both, being hydrophobic in their nature. An accurate analysis of the wetting ability of blood, saline solution, vitamin E and distilled water on different carbon surfaces, roughness dependent, was performed by Torrisi and Scolaro [20]. The results were aligned with our findings since blood and water showed very similar CAs and the same patterns, depending on the carbon-based materials. The CA and the surface roughness appears to be in mathematical relation since high CAs (superhydrophobicity) could be obtained only at low surface roughness and very low CAs (superhydrophilicity) above a near threshold value of ∼4 μm for biocompatible carbons. In the

EXPERIMENTAL

same study, PyC was indicated as a good hydrophobic surface, where low-cell adhesion and low-wetting ability are expected. The benefits of a superhydrophobic BMHV on blood–material interactions and haemodynamics have been recently investigated by Bark *et al.* [2]. In their pioneering research, the superhydrophobic coating was able to dramatically reduce blood cell adhesion in a static environment relative to bare PyC, demonstrating a reduction in the risk for thrombosis based on blood–material interactions. This study aimed to assess the performances of a superhydrophobic BMHV, using a commercially available superhydrophobic coating, with inherent concerns, particularly regarding the durability. Despite the limitations, the authors were able to demonstrate that superhydrophobicity may reduce the propensity of BMHVs for thromboembolic complications. In our study, we aimed to achieve superhydrophobic patterns, starting from what we learned from nature, primarily creating a certain roughness on the surface of BMHV occluders. This tailored approach allowed us to permanently modify the wettability of BMHV by means of ultra-short pulse femtosecond laser, according to specific needs. Our purposes indeed clash with the concept behind all currently available BMHVs. The leading objective of the latter was to create an ideal solid, smooth, mirror-polished surface and minimize the frictions or resistances between the fluid (blood) and the solid (valve occluders), where the advancing and receding CAs were equal. In our experiments, the water droplet resting on the surface hierarchical nanostructures, thus with a high roughness, showed high CAs. In support of this, the water droplet resting on the untreated surface occluder showed a clear tendency to flatten out over time, though with similar CAs at the beginning. This phenomenon was certainly related to the intrinsic surface energy of PyC and to a relatively high wettability of BMHV occluders. Since still very little is known in this field, the profile of the surface roughness, as well as the morphology of the desired hierarchical texture and the reactions of the carbon material under laser pulses were part of the research and still require further investigations. The hierarchical textures remarkably showed to be anisotropic. This peculiarity likely lies in the chemical and physical structures of PyC that make this material an ideal planar thermal conductor. Anisotropy represents a unique feature, possibly enabling the differentiation of the wetting patterns of the occluders, in their different areas, as promoting the laminar flow, as preventing blood stagnation. Further investigations and studies are required to determine the interrelations among water repellency, thrombogenicity and haemodynamic performances. Besides, the ideal nanotexture, on which superhydrophobicity is shown at its greatest, thus the blood–artificial interaction is virtually cancelled, has yet to be discovered.

Limitations

The present study has a few limitations, strictly related to, but not limited to, the type of the research and the topic. The present study was intended to produce superhydrophobic BMHV occluders by laser irradiation and to explore their features and potentials. The number of the wetting tests was strongly limited by the surface extension of the laser-treated segments of the occluders and by some other limitations. Of 1 cm^2 of laser-irradiated surface available, only the perimeter could be employed for experiments, because of possible overprojections in the camera, when the droplet was placed in the middle. Besides, the costs of the heart valve prosthesis, as well as of the laser treatment certainly impacted the study. In the wetting experiments, water was used instead of blood because of their similar behaviours and its ease of use. According to the literature and to our previous experiments, water and blood resting on PyC BMHV occluders behave similarly, displaying comparable CAs. As already observed in our previous experiments, blood shows a certain instability of the droplet and a propensity of the same to spontaneously migrate, making the measurements critical and inconsistent. This event also occurred warming the blood approximately up to the body temperature of $\sim$36.0°C, adding heparin (1 cc or 5000 IU) to the sample and/or using dedicated Teflon-coated needles. We limited our investigation to the static analysis to pragmatically explore the blood–artificial surface interaction in the presence of superhydrophobicity and to obtain reliable results. A few concepts are not purely medical and therefore not familiar to medical staff. All the experiments were performed under atmospheric conditions, where air exposure certainly played a role in the liquid–solid interactions. Instead the final end point was and still is to demonstrate the superhydrophobicity in underwater conditions or the thromboresistance in the blood. These conditions are very difficult to reproduce; therefore, in this very preliminary phase of the study, it has been decided to begin from the start, to obtain reproducible and reliable results.

CONCLUSION

Since the surface of the occluders of BMHVs is what the blood essentially interacts with, its properties (whether roughness or smoothness) certainly play an important role in the blood–artificial surface interaction and therefore in its thrombogenicity. Although thrombogenicity and superhydrophobicity are undoubtedly different concepts, they could share the same principles indeed. In this study, we aimed to address the thrombogenicity of BMHVs from innovative perspectives, exploring new fields. We observed that a certain surface nano-roughness can improve water repellency, while water and blood similarly behave when resting on PyC occluders. Besides a certain level of anisotropy was observed. The leading objective of the present study was to minimize the blood–artificial surface interaction by creating surface nanotextures. Therefore, it appeared crucial to define the hierarchical structure and to determine how PyC behaves under laser pulses. Since ours are only preliminary results, further studies are required, to fully investigate the potential benefits of a superhydrophobic mechanical heart valve. Besides these results need to be tested on the animals in a later stage of the research, for further improvements and proofs.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

Conflict of interest: none declared.

Author contributions

Giorgio Vigano: Data curation; Validation; Writing—original draft; Writing—review & editing. **Gert H. ten Brink:** Data curation; Investigation; Supervision; Writing—review & editing. **Max Groenendijk:** Formal analysis; Software; Laser texturing. **Ronald Sipkema:** Data curation; Formal analysis; Software; Laser texturing. **Daniël K.M. Pollack:** Data curation; Software; Supervision; Writing—review & editing. **Massimo A. Mariani:** Supervision; Writing—review & editing. **Bart J. Kooi:** Conceptualization; Data curation; Supervision; Writing—review & editing.

Reviewer information

Interactive CardioVascular and Thoracic Surgery thanks Ari Mennander, Antonio Nenna and the other, anonymous reviewer(s) for their contribution to the peer review process of this article.

REFERENCES

[1] Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. Lancet 2006;368:1005–11.
[2] Bark DL Jr, Vahabi H, Bui H, Movafaghi S, Moore B, Kota AK *et al.* Hemodynamic performance and thrombogenic properties of a superhydrophobic bileaflet mechanical heart valve. Ann Biomed Eng 2017;45: 452–63.
[3] Goldstone AB, Chiu P, Baiocchi M, Lingala B, Patrick WL, Fischbein MP *et al.* Mechanical or biologic prostheses for aortic-valve and mitral-valve replacement. N Engl J Med 2017;377:1847–57.
[4] Lapeyre D, Siegel R, Scotten L, de Mol B, Dembitsky W. Prosthetic heart valves: difficult to make something simple. J Thorac Cardiovasc Surg 2010;139:1371–3.
[5] Bluestein D, Chandran KB, Manning KB. Towards non-thrombogenic performance of blood recirculating devices. Ann Biomed Eng 2010;38: 1236–56.
[6] Paul R, Marseille O, Hintze E, Huber L, Schima H, Reul H *et al. In vitro* thrombogenicity testing of artificial organs. Int J Artif Organs 1998;21: 548–52.
[7] Yin W, Alemu Y, Affeld K, Jesty J, Bluestein D. Flow-induced platelet activation in bileaflet and mono-leaflet mechanical heart valves. Ann Biomed Eng 2004;32:1058–66.
[8] Yan YY, Gao N, Barthlott W. Mimicking natural superhydrophobic surfaces and grasping the wetting process: a review on recent progress in preparing superhydrophobic surfaces. Adv Colloid Interface Sci 2011; 169:80–105.
[9] Skoulas E, Manousaki A, Fotakis C, Stratakis E. Biomimetic surface structuring using cylindrical vector femtosecond laser beams. Sci Rep 2017;7: 45114.
[10] Barthlott W, Neinhuis C. Purity of the sacred lotus, or escape from contamination in biological surfaces. Planta 1997;202:1–8.
[11] Feng L, Zhang Y, Xi J, Zhu Y, Wang N, Xia F *et al.* Petal effect: a superhydrophobic state with high adhesive force. Langmuir 2008;24:4114–9.
[12] Koch K, Bhushan B, Barthlott W. Diversity of structure, morphology and wetting of plant surfaces. Soft Matter 2008;4:1943–63.
[13] Byun D, Hong J, Ko JH, Saputra Lee YJ, Park HC *et al.* Wetting characteristics of insect wing surfaces. J Bionic Eng 2009;6:63–70.
[14] Young T. An essay on the cohesion of fluids. Philos Trans R Soc London 1805;95:65–87.
[15] Cassie A, Baxter S. Wettability of porous surfaces. Trans Faraday Soc 1944;40:546–51.
[16] Wenzel RN. Resistance of solid surfaces to wetting by water. Ind Eng Chem 1936;28:988–94.
[17] Dunn A, Carstensen JV, Wlodarczyk KL, Hansen EB, Gabzdyl J, Harrison PM *et al.* Nanosecond laser texturing for high friction applications. Opt Lasers Eng 2014;62:9–16.
[18] Andrew Dunn, Jesper V. Carstensen, Krystian L. Wlodarczyk, Erica B. Hansen, Jack Gabzdyl, Paul M. Harrison et al. Nanosecond laser texturing for high friction applications. Optics and Lasers in Engineering, 2014;62: 9–16.
[19] Harken DE, World congress on heart valve replacement… Evolution over a quarter of a century. January 15-18, 1989, San Diego, California. Proceedings. Ann Thorac Surg 1989;48(3 Suppl):S1–105.
[20] Torrisi L, Scolaro C. Blood wettability of haemocompatible carbon-based materials. Adv Chem Eng 2017;7:1–6.