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In vitro evaluation of a new resilient, hard-carbon, thin-film coating as a bearing material for ventricular assist devices

——In Vitro Bearing Evaluation of BioMedFlex

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ABSTRACT

Our aim was to evaluate the potential use of BioMedFlex® (BMF), a new resilient, hard-carbon, thin-film coating, as a blood journal bearing material in Cleveland Heart's continuous-flow left and right ventricular assist devices (VADs). BMF is not classified as a diamond-like carbon (DLC) and differs from other thin-film carbon coatings by its high flexural strength, radiopacity, and wear resistance. A 2- to 4-µm-thick BMF adhesion layer was deposited on the VAD journal bearing surfaces. A commercial DLC coating used in other clinical blood pump applications was used as a control. Durability and reliability of the BMF coating was verified in severe pump start/stop testing using 20 BMF-coated journal bearing pairs. The BMF-coated surfaces showed no coating failures, whereas 57% of the DLC bearing pairs developed scratches through the carbon coating, documenting that BMF can provide a durable coating in our blood journal bearing application. In conclusion, BMF has shown qualities that support its significant advantages as an alternative journal bearing material in Cleveland Heart pumps. Our plan includes biocompatibility testing with ongoing animal studies, endurance testing with submerged pumps running in saline, and assessment of batch coating processing capability.

Keywords: Heart Assist Device; Diamond-Like Carbon; Materials Testing; Wear Resistance; Journal Bearing

1. INTRODUCTION

Implantable ventricular assist devices (VADs) are a reliable treatment option for patients with terminal-stage heart failure who are unresponsive to conventional therapies. Although current designs demonstrate adequate performance, reliability remains a significant issue, as these devices are implanted for extended durations (well beyond 1 year) and may likely be intentionally implanted in patients as permanent ("destination") therapy. Because components of implantable pumps must withstand difficult *in vivo* environments and running conditions, carbon materials (diamond-like carbon [DLC] and pyrolytic carbon) have emerged as promising coating materials for pump components to enhance durability and biocompatibility characteristics. Some of these carbon coatings are chemically inert, wear and corrosion resistant, and bio- and hemocompatible. These coatings may also minimize platelet adhesions and activation, prevent thrombogenicity, and improve performance by decreasing power usage or increasing pump output.

The continuous-flow VADs of Cleveland Heart (Charlotte, NC) have been adapted from the CorAide LVD-4000 Left Ventricular Assist System (Arrow International, Reading, PA), developed at Cleveland Clinic. Detailed descriptions of the pump have previously been published [1,2]. The left and right ventricular assist devices (LVADs and RVADs, respectively) consist of three subassemblies: the volute housing, the rotating assembly (RA), and the stator assembly (**Figure 1**). The RA contains a cylindrical four-pole magnet and spins around the titanium stator housing post, which contains the motor windings. The RA is supported axially by permanent magnets and radially by a thin film of blood, forming a patented blood journal bearing which, except for startup and shutdown, makes no mechanical contact during use. The blood journal bearing materials, dimensions, clearances and geometry are shared by both VADs. The volute housings and RA impeller blades are optimized for the different afterload conditions that occur in the RVAD

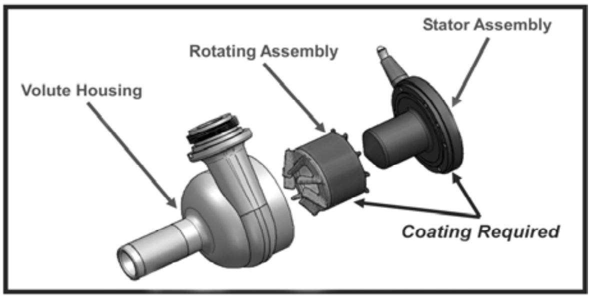

Figure 1. Depiction of an LVAD subassembly. RVADs differ only in RA impeller and in volute housing design.

vs. LVAD.

During European clinical trials of the CorAide LVAD, it was found that the original fluorinated ethylene propylene (FEP) coating on the journal bearings delaminated from its titanium substrate. The authors have since searched for the best alternative bearing material to use on both the LVAD and RVAD; this article focuses on the preliminary *in vitro* evaluation of the BioMedFlex (BMF) thin-film coating (BioMedFlex, Denver, NC).

2. MATERIAL AND METHODS

2.1. BioMedFlex Coating

The BMF coating is deposited on substrates by a proprietary plasma-assisted chemical vapor deposition process in a high-vacuum environment at temperatures below 200℃. Because this coating is created from layers of nano-crystalline diamond and nano-crystalline silicon carbide in a matrix of the noncrystalline forms of both compounds, BMF's unique characteristics are set apart from other thin-film carbon coatings used in biomedical applications [3]. Its high flexural strength, its radiopacity, and its wear resistance are surpassed only by pure diamond thin films. Several other material properties of the BMF coating that make it a good candidate for use in blood journal bearing applications include chemical resistance, dimensional stability, and low coefficient of friction. BMF does not absorb water and does not corrode in saline. These two key qualities prevent dimensional changes due to absorption or corrosion in the high-tolerance clearance and profile of the journal bearing-conditions that occurred with the FEP coating in the CorAide clinical trial. BMF is a clean, reliable, high-technology coating process that is not line-of-sight and does not require parts to be rotated in the chamber. The BMF coating is 2-4 μm thick and aggressively adheres to titanium surfaces, requiring sandblasting to remove it from the surface of coated parts. For reference, a matrix comparing the material properties of BMF vs. titanium nitride, a commonly used material in the field, is provided below as **Table 1**.

2.2. Journal Bearing Starting Conditions

Once running, the bearing allows the RA to revolve levitated from the stator housing post surfaces on a film of blood, deriving lift from its own motion and thereby eliminating any surface contact between moving parts until the pump is shut down (**Figure 2**). However, there is transient (300 ms) sliding and vibrating contact (800-900 g) load between the RA and stator assembly at start-up and again during stopping (**Figure 3**); the only mechanical loading the bearing undergoes is during its start/stop cycles. The worst-case expected loading sustained by the bearing over its lifetime was established based on the fact that, on average, the pump is started and stopped six times during manufacturing and three times during clinical implantation. During its service life with the patient, the pump may be started and stopped (in a worst case) eight times per year due to external component changes, software upgrades, or simple patient connection mistakes. These values translate to about 50 starts and stops in a 5-year period. Multiplying by a safety factor of 2, the number of starts and stops that will approximately simulate the worst-case service life is 100.

Table 1. Comparison matrix of material properties: BioMedFlex vs. Titanium nitride.

Typical values	BioMedFlex	Titanium nitride
Inert	Yes	No
Flexural strength	High triaxial	Low single axis, brittle
Optical transparency	50Å Yes, 2 μm No	No
Mechanical wear	Low	High
Conformal	Yes	No: Line of sight
Hardness (V)	3800	2500
Young's modulus (GPa)	130-180	600
Adhesion (PSI)	> 8500	< 2000
Coefficient of friction	0.10-0.15	0.65
Thickness (μm)	0.1-4	0.25-12
Surface Ra (μm)	0.10	0.20

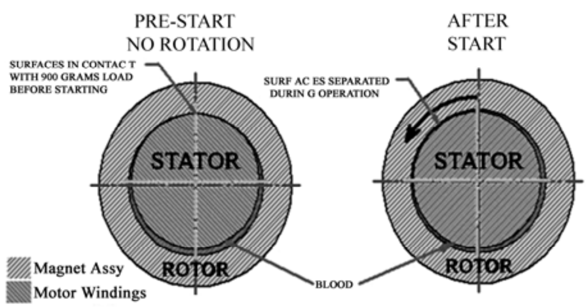

Figure 2. Journal bearing. Left: Inner surfaces of the RA are in contact with stator when pump is not running. Right: After starting, the RA is separated from the stator and rides on a film of blood during operation. Assy, Assembly.

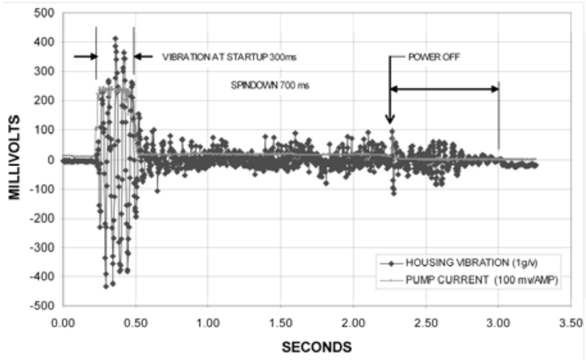

Figure 3. Pump vibration and motor current at start-up and shut-down of a Cleveland Heart VAD.

2.3. Start/Stop Test

To evaluate the durability and reliability of the coating on pump journal bearing mated surfaces, pump assemblies consisting of a BMF-coated stator and RA were exposed to 100 start/stop cycles at the most challenging bearing load conditions: maximum pump speed and wide-open flow conditions in de-ionized water. The pumps were disassembled, and the stator and RA were visually inspected for scratches, delamination, or other damage after 1, 5, 25, and 100 start/stop cycles.

A commercial DLC coating used in other blood pump applications was also applied to another set of bearing surfaces as a control. Twenty different combinations of BMF-coated journal bearing pairs and seven different DLC-coated pairs were exposed to start/stop testing to compare the two coatings for durability and reliability. The high component costs, long lead time for fabrication and coating of parts, and the early and frequent failure of the DLC-coated parts limited the number of DLC test pieces evaluated in this study, as the primary goal of the project was to develop new journal bearing materials. The success criterion was the completion of at least 100 start/stop cycles per bearing pair without damage to the coated surfaces.

3. RESULTS

BMF-coated pumps showed no coating failures (**Table 2**), whereas four of seven commercial DLC bearing pairs developed scratches through the carbon coating (**Table 3**), documenting that BMF can provide a durable coating in our blood journal bearing application. A representative scratch is shown in **Figure 4**; scratches were present on the stator post only, with no damage to the RA on commercial DLC bearing pairs.

4. DISCUSSION

Although titanium alloy has been the material of choice for implantable rotary blood pumps [4], given the bearing loads seen in our pumps at startup and shutdown, it is a very poor choice as a bearing material. It has been a priority to determine the optimum coating material and coating parameters to obtain the bearing properties needed for the Cleveland Heart LVAD and RVAD. BMF's unique thin-film carbon formulation and its layered matrix of diamond and silicon carbide have provided a new biomedical material that combines very high hardness, aggressive substrate adhesion and much higher flexural properties. BMF has proven to be more wear resistant than the commercially available DLC control.

Previous studies of this bearing design have documented

Figure 4. BMF-coated RVAD RA (left) and stator assembly (middle); commercial DLC-coated stator assembly scratches post-test (right).

Table 2. BMF bearing testing results.

BMF Bearing Testing		BMF Coated RA			
		RA BMF-01	RA BMF-02	RA BMF-03	RA BMF-04
BMF-Coated Stator	Stator BMF-01	Passed: No damage	Passed: No damage	Passed: No damage	Passed: No damage
	Stator BMF-02	Passed: No damage	Passed: No damage	Passed: No damage	Passed: No damage
	Stator BMF-03	Passed: No damage	Passed: No damage	Passed: No damage	Passed: No damage
	Stator BMF-04	Passed: No damage	Passed: No damage	Passed: No damage	Passed: No damage
	Stator BMF-05	Passed: No damage	Passed: No damage	Passed: No damage	Passed: No damage

BMF, BioMedFlex®; RA, Rotating Assembly.

Table 3. Commercial DLC bearing testing results.

Commercial DLC Bearing Testing		**Commercial DLC-Coated Rotating Assembly**				
		RA DLC-01	RA DLC-02	RA DLC-03	RA DLC-04	RA DLC-05
Commercial DLC-Coated Stator	Stator DLC-01	Passed: No damage	Passed: No damage	FAILED	FAILED	-
	Stator DLC-02	-	-	-	Passed: No damage	FAILED
	Stator DLC-03	-	-	FAILED	-	-

DLC, diamond-like coating; RA, Rotating Assembly.

that the blood film and journal bearing remain stable once the start-up period is over [5]. Because of this, damage to the bearing can occur only during starting and stopping; it is not a matter of total running time, but the number of start/stops that is critical. According to the test procedure, pump disassembly and component inspection was performed only after the 1^{st}, 5^{th}, 25^{th} and 100^{th} start/stop cycle. Generally, bearing damage occurred early on in the testing (within the first 5 start/stop cycles) for the DLC-coated parts and was progressive and cumulative. Representative bearing wear (**Figure 4**) for the commercial DLC-coated stator is compared to undamaged BMF-coated RA and stator parts post-bearing test; bearing wear was only on the stator post of the DLC-coated parts and not the RA.

With start/stop reliability demonstrated, endurance tests of indefinite duration in 37℃ saline and glycerin blood analog have been started to verify compatibility in a saline environment. After 275 and 70 days, respectively, there has been no bearing wear on two pump assemblies with BMF paired journal bearings undergoing mock circulatory *in vitro* endurance testing in an aggressive, pulsatile environment.

BMF was successfully deposited onto titanium pump surfaces and endured at least 100 start/stop cycles for each bearing pair without damage; over 57% of the commercial DLC-coated pairs failed at the same test parameters. Five of the BMF stators accumulated up to 800 start/stop cycles with no wear. Neither the testing duration nor number of start/stop cycles were increased, as the test was deemed to be adequately aggressive given the "failure" of the commercial DLC pairs. These tests demonstrated that BMF can provide a durable coating in our application, along with a viable solution to bearing FEP coating adhesion problems seen in the initial CorAide clinical trials.

Biocompatibility is being validated with ongoing *in vivo* studies of the performance of LVADs, RVADs, and biventricular assist devices in animals [6].

5. CONCLUSIONS

BMF has many qualities that support its significant advantages as an alternative journal bearing material in both Cleveland Heart pumps: 1) demonstrated bearing reliability, 2) a thin-film coating that still offers a depth of several micrometers, and 3) the capability for batch coating processing. To further test durability, BMF-coated pumps have been placed on mock circulatory endurance test with the pumps running and submerged in a saline/glycerin blood analog fluid at body temperature.

6. ACKNOWLEDGEMENTS

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