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NANO-MICRO BIO-TRIBOLOGY OF ENDOCARDIAL LEADS IN HANKS' SOLUTION

Prepared by

Duanjie Li, PhD

6 Morgan, Ste156, Irvine CA 92618 · P: 949.461.9292 · F: 949.461.9232 · nanovea.com

INTRO

A pacemaker is a medical device used to regulate the heart beating and maintain an adequate heart rate. It is usually implanted in the chest or abdomen and sends tiny electrical impulses to the heart muscles through endocardial pacing leads. As pacemakers become a widely used standard treatment for many heart problems, the quality and service lifetime of the pacing leads become life-critical issues. Lead failures can severely jeopardize the life or health of the patients and cause significant pain and cost in the resulting surgical replacements[12345].

IMPORTANCE OF WEAR AND FRICTION FOR ENDOCARDIAL LEADS

The outer insulation material of the endocardial lead requires several vital properties: biological inertness, high flexibility, superior fracture toughness and long service life, etc. A low friction can reduce the interaction of the lead to the blood vessel so as to reduce vessel spasm. In addition, the constant movements of the heart and body muscles against the lead make the wear resistance of the insulation layer particularly critical. Due to the complicated corrosive environment of the body fluid, a monitored and controlled technique is in need to simulate the bio-tribological behavior of the lead insulation.

MEASUREMENT OBJECTIVE

In this study, we simulated and compared the nano friction and wear behaviors of endocardial pacing leads made of different materials in Hanks' Solution using Nanovea Mechanical Tester and Tribometer, respectively.

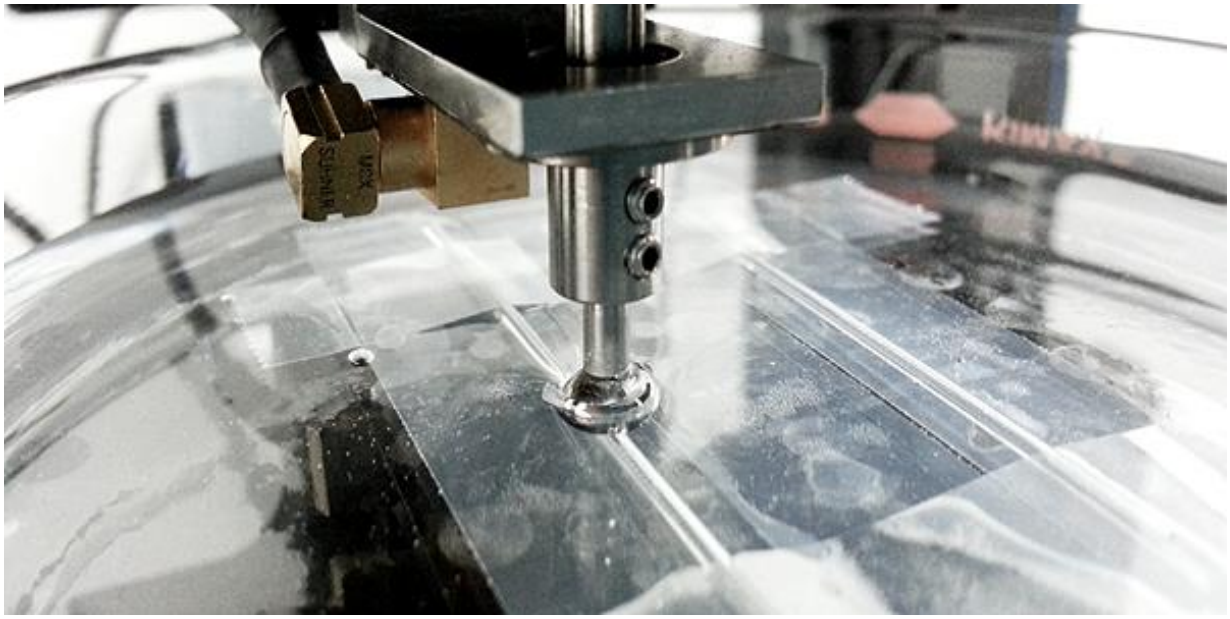

Fig. 1: Nano friction test setup.

MEASUREMENT PRINCIPLE

NANO-FRICTION MEASUREMENT PRINCIPLE

During the test, the indenter makes contact with the surface at a very low controlled load. The Nano Module uses a fast piezo electric system and a load cell to quickly adjust the ball position to keep a constant applied load. The sample is then moved at a controlled speed and the lateral force is plotted versus displacement. In general a steel ball of a large diameter (6 mm) is used but other materials/shape/size can also be used to measure coefficient of friction (COF).

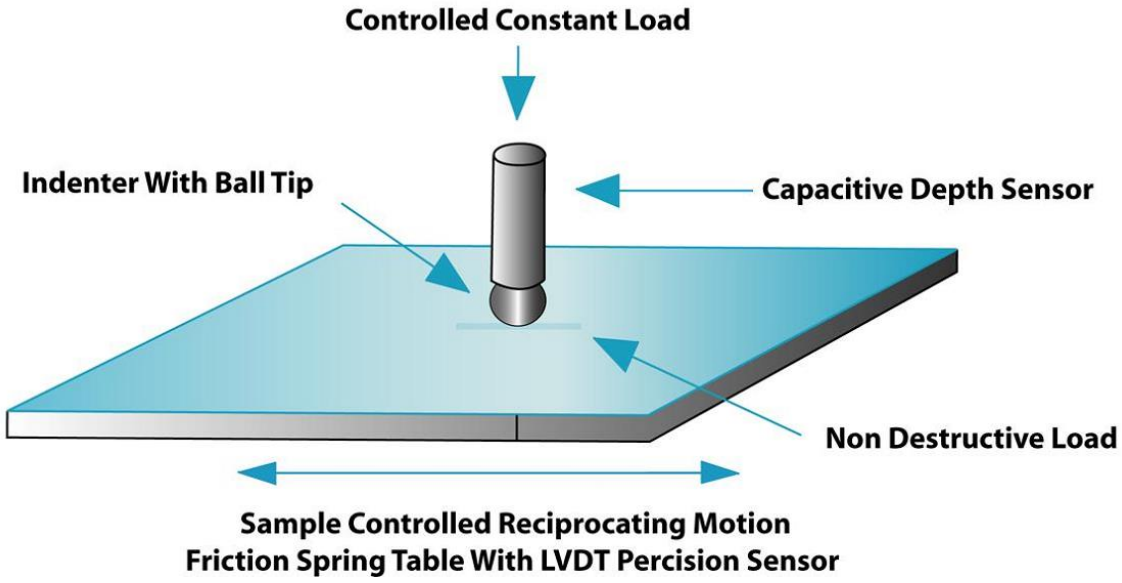

Fig. 2: Schematic of the nano friction measurement.

RECIPROCATING WEAR PRINCIPLE

A flat or a sphere shaped indenter is loaded on the test sample with a precisely known force. The indenter (a pin or a ball) is mounted on a stiff lever, designed as a frictionless force transducer. As the plate slides in a linear reciprocating motion, the resulting frictional forces between the pin and the plate are measured using a strain gage sensor on the arm. Wear rate values for both the pin and sample may also be calculated from the volume of material lost during a specific friction run. This simple method facilitates the determination and study of friction and wear behavior of almost every solid state material combination, with varying time, contact pressure, velocity, temperature, humidity, lubrication, etc.

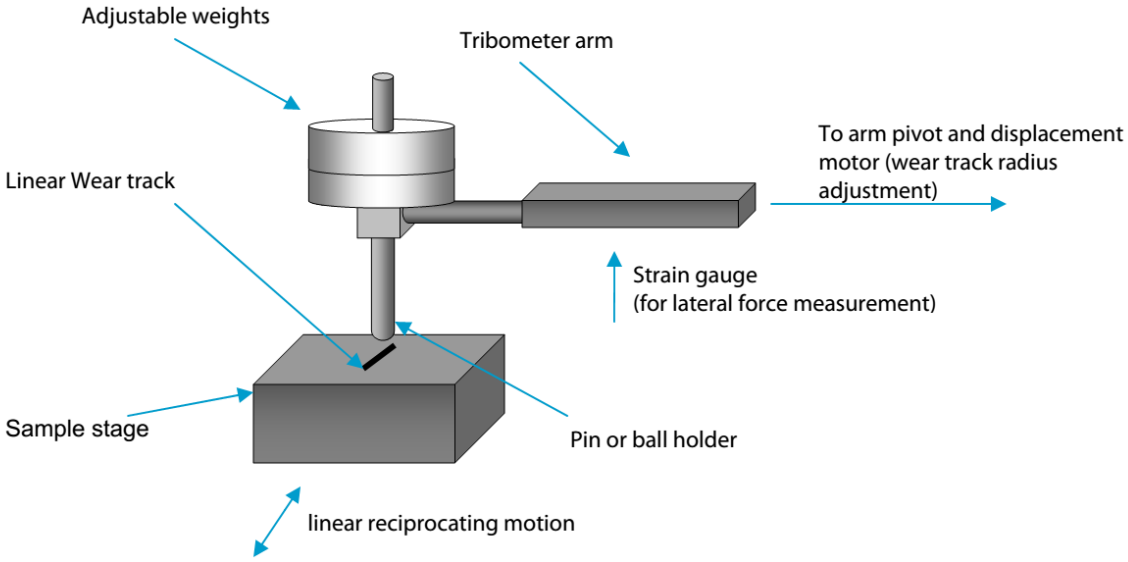

Fig. 3: Schematic of the linear wear test.

TEST PROCEDURE

The coefficient of friction, COF, of the leads against a stainless steel 440 ball (SS440, 6mm diameter) was measured using the Nano Module of the Mechanical Tester. The sample was immersed in Hanks' Solution and the applied load was kept constant at a low value of 50 mN to simulate the application environment. The ball slid on the lead at a constant speed of 20 mm/min. The total sliding distance is 10 mm.

The wear resistance of the leads was evaluated by Nanovea Tribometer using Linear Reciprocating Wear Module. The evolution of COF, of a stainless steel 303 (SS303) block (10 × 10 mm^2) on the lead surfaces was recorded in situ with a time interval of 0.1 s. The wear track was examined under an optical microscope after the tests. The test parameters are summarized in Table 1.

Please note that the stainless steel as a counter material was used as an example in this study, any solid material with different shapes can be applied using custom fixture to simulate the actual situation.

Sample	Leads made of Silicone or Polyether-Polyurethane (PP)
Normal force	1 N
Speed	200 cycles/min
Duration of test	5 h
Environment	Hanks' Solution

Table 1: Test parameters of the wear test.

RESULTS AND DISCUSSION

NANO FRICTION TEST

The nano friction of the Silicone and PP leads was first investigated using the Nano Module of Mechanical Tester. As shown in Fig. 4, The Silicone and PP leads exhibit different COF in Dry and Hanks' Solution environments. The Hanks' Solution here was utilized for simulating body fluid conditions, while COF measured in the dry environment is for comparison. The Silicone and PP leads exhibit low COF of ~0.15 and ~0.05, respectively, in Hanks' Solution, compared to substantially higher values of ~0.6 and ~0.5 in a dry environment. This clearly demonstrates the significant effect of the test environment to the COF measurement – proper test settings are essential in simulating the bio-tribological behaviors of materials under their application conditions. Thanks to the combination of the precise force measurement of the load cell and the fast piezo electric system, the ball position can be promptly adjusted to keep a constant low applied load of 50 mN, allowing us to simulate the low contact force of the lead to the blood vessel.

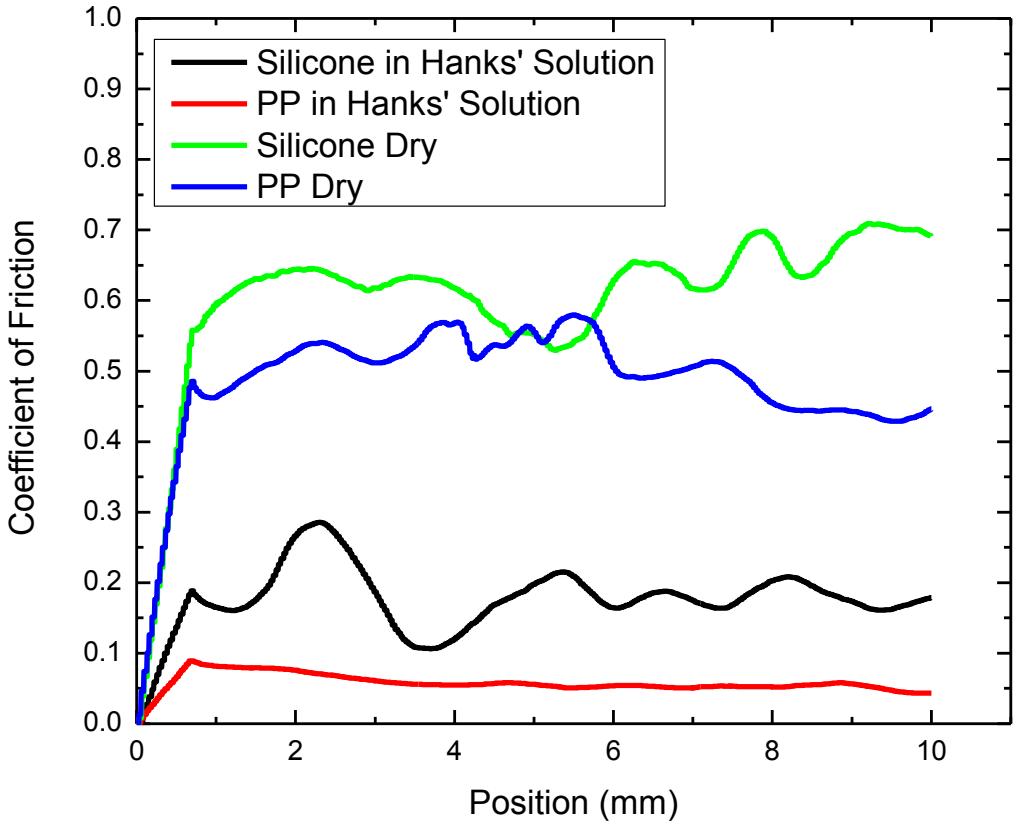

Fig. 4: COF of Silicone and PP leads in Dry and Hanks' Solution environments.

WEAR TEST

Nanovea Tribometer was employed to evaluate the wear behavior of the Silicone and PP leads in Hanks' Solution. Fig. 5 displays the Silicone and PP lead before and after the wear tests. The Silicone lead shows a large wear scar with a width of ~1.2 mm, compared to ~0.6 mm for that of the PP lead. It can be observed under the microscope that severe wear took place on the Silicone lead, creating parallel deep grooves along the movement direction of the rubbing

block. In comparison, the wear on PP lead is mild, exhibiting only several small scratches on the shallow surface.

The wear of the lead outer insulation could result in pacing and sensing abnormalities[6], and in turn become a threat to the patient's health and life. A wear resistant insulation can increase the service life of the lead, and make it possible to design a thinner lead body to ease lead installment for the physicians and reduce the pain and vessel spasm of the patients.

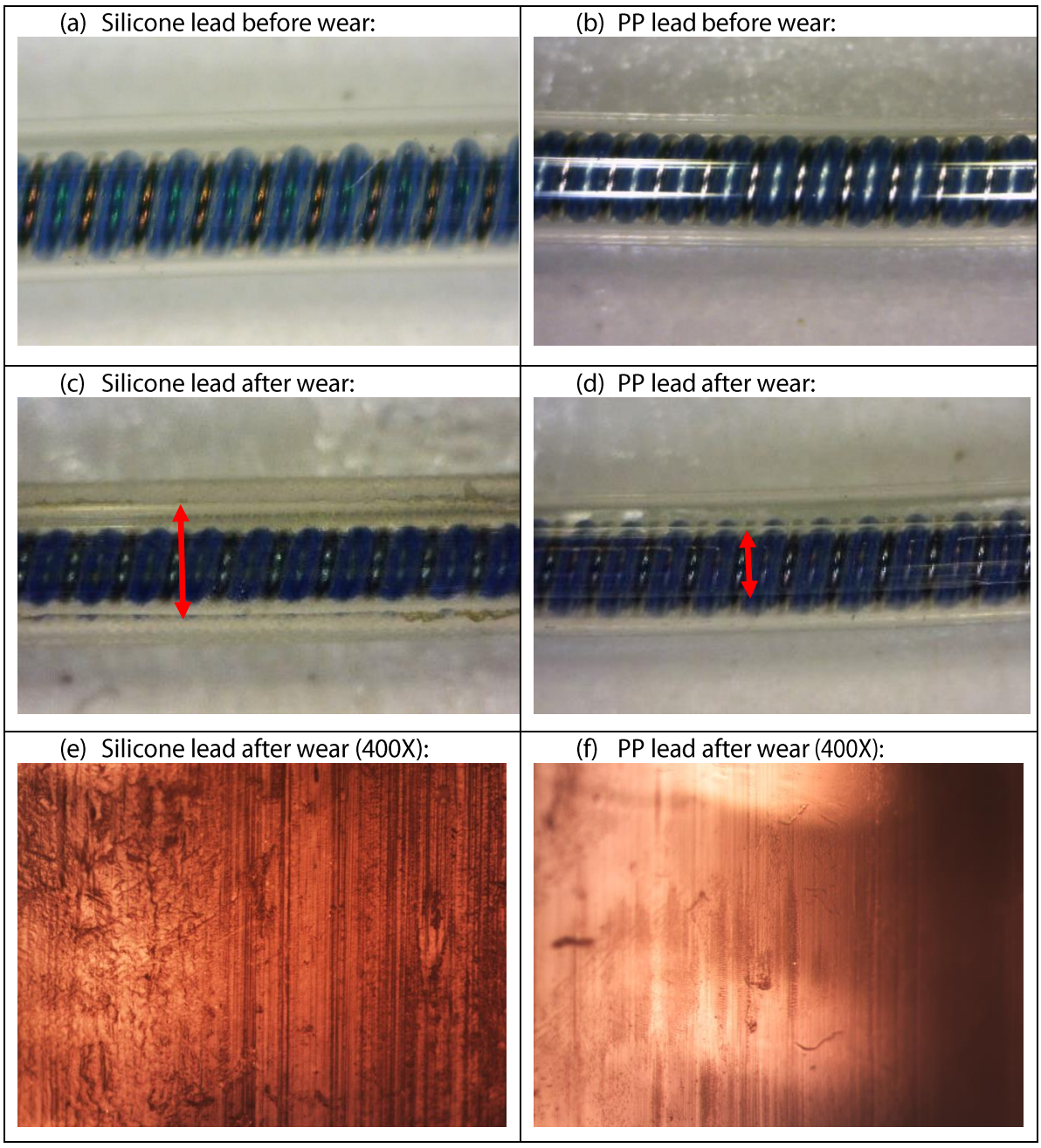

Fig. 5: Silicone and PP leads before and after wear tests.

CONCLUSION

In this study, we showcased the capacity of Nano Module of Nanovea Mechanical Tester in measuring the coefficient of friction of small endocardial leads at a very low load in a controlled and monitored manner. This nano friction measurement allows users to quantitatively assess the COF of the materials in the environment where low contact loads are applied and select the best candidate for the applications. In addition, wear tests in Hanks' Solution by Nanovea Tribometer simulated the wear behavior of the endocardial leads in human body fluid. Polyether-polyurethane (PP) shows a lower friction and better wear resistance compared to Silicone, making it a better choice as a biomedical material for the outer insulation of endocardial leads.

The Nano, Micro or Macro modules of the Nanovea Mechanical Tester all include ISO and ASTM compliant indentation, scratch and wear tester modes, providing the widest and most user friendly range of testing available in a single system. Nanovea Mechanical Tester provides comprehensive measurements of various mechanical properties, including hardness, Young's modulus, fracture toughness, adhesion, wear resistance and many others.

Nanovea Tribometer offers precise and repeatable wear and friction testing using ISO and ASTM compliant rotative and linear modes, with optional high temperature wear, lubrication and tribo-corrosion modules available in one pre-integrated system. Nanovea's unmatched range is an ideal solution for determining the full range of tribological properties of thin or thick, soft or hard coatings, films and substrates.

Learn More about the Nanovea Mechanical Tester, Nanovea Tribometer and Lab Service

REFERENCES

[1] Magney JE, Flynn DM, Parsons JA, Staplin DH, Chin-Purcell MV, Milstein S, Hunter DW. Pacing Clin Electrophysiol 1993; 16:445–457

[2] Jacobs DM, Fink AS, Miller RP, Anderson WR, McVenes RD, Lessar JF, Cobian KE, et al. Pacing Clin Electrophysiol 1993; 16:434–444.

[3] Gupta K, Villareal RP, Rasekh A, Massumi A. Tex Heart Inst J 2003; 30:84–85.

[4] Magney JE, Parsons JA, Flynn DM, Hunter DW. Pacing Clin Electrophysiol 1995; 18:1509–1517.

[5] Kazama S, Nishiyama K, Machii M, Tanaka K, Amano T, Nomura T, Ohuchi M, et al. Jpn Heart J 1993; 34:193–200.

[6] Andrzej K, Barbara M, Agnieszka K, Marcin G. Pacing Clin Electrophysiol. 2013; 36(12):1503-1511.