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IDENTIFICATION OF THE PARAMETERS THAT INFLUENCE THE UNCERTAINTY SOURCES IN ORTOPHAEDIC IMPLANTS FATIGUE TESTS

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Abstract – Orthopaedic implants should be designed and manufactured in such a way to protect the patient and user against imperfections and damages. These medical devices require specific tests to evaluate their performance like: tensile strength, resistance to wear and fatigue, among others. These tests represent a way to ensure that the implants are both reasonably safe and effective for their intended use. Due to design requirements dictated by the anatomy, and physiology of the skeletal structure of the human body, these devices present complex geometric forms and so fatigue tests often involve applying complex load profiles under multi-axial conditions using specialized test fixtures. In this context, the uncertainty evaluation of the fatigue test assumes a relevant role to ensuring that the mechanical qualification of the orthopedic implant is been performed in agreement with the metrological requirements. This study presents an inter-institutional working plan to evaluate the testing machine performance and the uncertainty associated with fatigue tests of orthopaedic implants, including the identification and quantification of uncertainty sources and the first steps leading to the development of a methodology for dynamic force calibration.

Keywords: dynamic force calibration, fatigue tests, orthopaedic implants, uncertainty evaluation.

1. INTRODUCTION

The present work is part of a large project that has been under development in the last few years, which the main purpose is to support the Brazilian institutions that perform tests and conformity assessment of orthopaedic implant, with procedures and standards that are traceable to National Metrology Institutes (NMI) recognized worldwide, aiming further accreditation of these institutions by the National Institute for Metrology, Standardization and Industrial Quality (Inmetro) based on the ISO/IEC 17025 standard [1].

In 2005, a partnership between the Brazilian Health Ministry and the Science and Technology Ministry established an Orthopaedic Implants Evaluation Network-REMATO involving 13 Institutions and Universities and more than 20 laboratories, with recognized expertise in tests and conformity assessment of orthopaedic implants. The Brazilian Government sponsored projects of these Labs aiming the increase of the national infra-structure to support the demand for the large range of tests related to the quality evaluation of orthopaedic implants. These institutions and universities are working on the development of methodology, procedures and traceability for the tests performed on these products, aiming further certification process related to orthopaedic implants commercialized in Brazil due the large number of premature failures of related (informed/observed) in the last decades.

In the first step of the network, these Labs were involved with acquisition of equipments, accessories and infrastructure facilities, necessary to develop the tests according to the international procedures. At the moment these Labs are working to adjust their methodologies according to the requirements of the ISO/IEC 17025 standard [1], and harmonizing the technical procedures.

Special attention has been given to the mechanical evaluation of these medical devices. According to the biomechanical requirements of orthopaedic implants in clinical applications, fatigue behaviour is one of the most important properties to be evaluated. In this way, mechanical fatigue performance is priority for a product certification process.

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Also, according to the ISO/WD 4965-1 [2], the dynamic errors of the force experienced by the test-piece and the intended force indicated by the testing system (fatigue machine) come from the result of the inertial forces acting on the force transducer and any dynamic errors in the electronics of the force indicating system.

For a given frequency range, and over a given force range, different combinations of compliance values could result in different amplitudes of motion.

For the purpose of the uniaxial dynamic force calibration, a linear relationship between the applied force and the displacement of the actuator must be established. In this content, this work presents a methodology to calibrate a dynamic testing system (fatigue machine) by applying a Dynamic Calibration Device (DCD), using the Replica Test-Piece Method.

This method, specified on the ISO/WD 4965-1[2], was used in the present work aiming to calibrate a dynamic testing system (fatigue machine) with a DCD and a correction factor was calculated relating the indicated force range(ΔFi) to the test-piece force range (ΔFt). This factor could be applied to adjust the results and to modify the force applied by the testing system, reducing the dynamic force error bellow 10 % of the indicated force range, in case of necessity. These correction factors are dependent on the test frequency, and therefore have to be determined over the entire range of anticipated test frequencies. The accreditation process based on ISO/IEC 17025 [1], item 5.4.6, demands that the Labs have a procedure to evaluate the uncertainty associated with each test performed and all measurements traceable to a national metrological chain, where the traceability of the fatigue testing machine is a well known as big challenge [3].

Considering the difficulties in identifying and quantifying the uncertainty sources associated with the dynamic mechanical tests, a partnership between four Brazilian research institutions was established, with the support of Brazilian government, to study this subject. The institutes involved in the present study are:

- Inmetro - National Institute for Metrology, Standardization and Industrial Quality.
- INT - National Institute of Technology.
- ITUC/PUC-Rio - Technological Institute of the Catholic University of Rio de Janeiro.
- HU/UFSC - University Hospital of the Federal University of Santa Catarina.

This working group configuration covers the various levels of the national metrological system, including the Inmetro, calibration and tests Institutes (ITUC/PUC-Rio and INT) and a final user(Biomechanical Engineering Lab from the HU/UFSC).

The results obtained in this partnership will be disseminated to all the Labs that are member of the Ortophaedic Implants Evaluation Network-REMATO.

2. METHODS AND PROCEDURES

The main problem concerning with the uncertainty evaluation of the fatigue test is the methodology applied to certificate the dynamic test machine. Until now, the procedure commonly used to evaluated the machine performance is the methodology described on the Brazilian Standard NBR NM-ISO 7500-1 [4], similar to the ISO 7500-1 [5], and both performs static verification of testing machines. On this approach the evaluation of important aspects that must be analyzed when discussing dynamic force calibration in fatigue test, as frequency and strain gage displacement, are not considered by now.

Figs. 1 and 2 illustrate two different medical devices, Hip Femoral Steam and Straight Plate (test-piece considered in this work) used in different clinical applications, being tested in order to evaluate the mechanical properties and biomechanical behavior [6-7]. These products have a large range of geometries which require specifically devices and test conditions.

Fig. 1. Picture illustrating a test configuration of the hip femoral steam, according to ASTM F 1440 [5] .The arrow indicates the implant being tested.

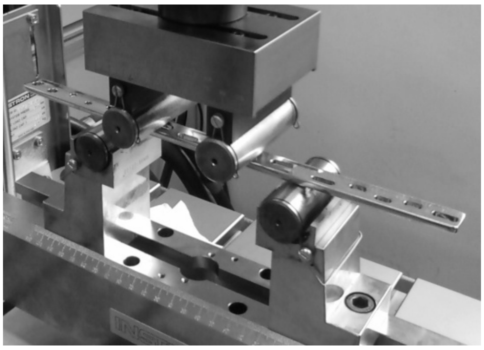

Fig. 2. Picture illustrating the four points flexure test configuration of the straight plate used in this work, according to ASTM F 382 [6].

According to International Organization for Standardization (ISO), the procedure that describes the dynamic verification of testing machines (ISO 4965 "Metallic materials - Fatigue testing - Uniaxial dynamic force calibration - Part 1: Testing systems") is being revised in the field of the TC164/SC5, where is being included a Replica strain-gauge technique [8], and a formal document should be published soon.

Based on the standard draft ISO/WD 4965 parts 1 and 2 [2] and [9] respectively, the group is organizing a working program that consider in this first moment, that the uncertainty associated with the force transducer calibration is one of the major contribution to the combined uncertainty related with the fatigue implant test. In accordance with this approach, special attention is being consumed on understanding the process, and the error sources, that may affect the calibration of this device [10]. The follows activities are programmed:

- Identification of uncertainty sources of force transducer calibration.
- Estimation of the sensitivity coefficients for the system calibration process.
- Definition of a preliminary methodology for dynamic force calibration.

According to B.F. Dyson et.al, [11], for each type of test-piece to be tested dynamically an instrumented standard test-piece, known as Dynamic Calibration Device (DCD) or a Replica Test-Piece, have to be used to calibrate a dynamic testing system indicator (fatigue machine).

The DCD used in this work, Fig. 3, was fabricated considering the previous mechanical properties data, compliance and mass, that means 47,73 N/m^2 and 50,04 g, obtained from the test-piece to be tested (straight plate used in clinical applications), Fig. 2.

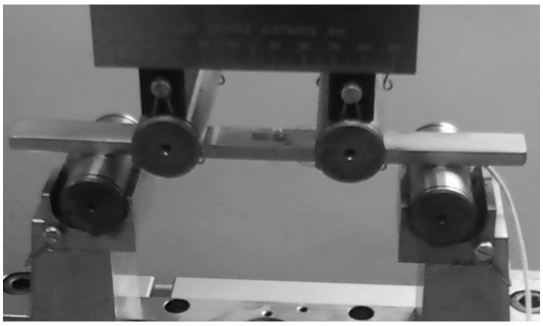

Fig. 3. Replica strain-gage (Dynamic Calibration Device), installed on the fatigue machine.

In the Fig. 3 is possible to see the elastic strain-gages (two in each face of the middle plate), with 120 Ω in full bridge, capable to do dynamic measurements.

The DCD used as reference to calibrate a servo-hydraulic fatigue machine, INSTRON model 8872, was previously calibrated statically, following the ISO 376 [12] standard against a 10 kN HBM, C3H2 force transducer, class 00. At this moment, the Instron 8872 machine was used only as a force generator. It wasn't considered in this study, the uniaxial dynamic calibration by applying a DC sinusoidal voltage (electrical measurement), as described in ISO/WD 4965-2[6].

Continuing the measurements required by the ISO/WD 4965-1[2], the same 10 kN force transducer was the reference used to calibrate statically the force application of the Instron 8872 fatigue machine by following ISO 7500-1 standard[5].

In order to maintain the same consistency of compliance and mass from the fatigue calibration machine by DCD and from the straight plate four points flexure testing, the load-train (force transducer, adaptors, grips, and other fixtures) didn't moved up neither changed along the whole process of calibration and testing.

The processes of calibration included the dynamic and the static measurements of the fatigue machine by using the DCD as following.

2.1. Static measurements procedure

The DCD was measured statically and compared against the dynamic testing system indicator (fatigue machine), using the force range defined by the compliance of the straight plate to be tested, that means from 80 N to 800 N, by cycling the force between the selected upper (800 N) and lower (80 N) force levels at three times (known as pre-load testing) and then the force was holding constant on the machine at each force level and the DCD indication was read. The readings were taken at the four following static force values, according to ISO/WD 4965-1:

- peak force + 5 % of the force range (840 N).
- peak force – 5 % of the force range (760 N).
- valley force + 5 % of the force range (84 N).
- valley force – 5 % of the force range (76 N).

2.2. Dynamic measurements procedure

The DCD was measured dynamically and the peak and valley readings were compared with the force indicator of the dynamic testing system at each of five increasing test frequencies that means 2 Hz; 4 Hz; 6 Hz; 8 Hz and 10 Hz and at four decreasing test frequencies in the midway between these test frequencies that means 9 Hz; 7 Hz; 5 Hz and 3 Hz.

3. RESULTS AND DISCUSSION

3.1. Static calibration with DCD

To calibrate statically the fatigue machine with DCD, the force values of the indicated force machine, F_i(p) as well the indication of the DCD force F_i(v), were determined considering the peak force 840 N (+5 %) and 760 N (-5 %)

of the force range (80 N to 800 N) and the valley force 84 N (+5 %) and 76 N (-5 %) where the results are described in the Table 1 and 2 for frequency range from 2 Hz to 10 Hz.

Table 1. Verification of the increasing frequencies.

	2Hz	4Hz	6Hz	8Hz	10Hz
i_{DCD} (p)	0,00114	0,00114	0,00114	0,00114	0,00113
i_{DCD} (v)	0,00059	0,00059	0,00059	0,00059	0,00059
F_i (p)	799,1	798,1	798,6	798,8	798,8
F_i (v)	82,3	81,0	80,1	81,9	82,1
F_{DCD} (p)	803,4	804,8	804,8	806,3	802,0
F_{DCD} (v)	55,3	53,9	58,1	56,7	59,5
ΔF_i	716,8	717,1	718,5	716,9	716,7
ΔF_{DCD}	748,1	751,0	746,7	749,5	742,5
C	1,04	1,05	1,04	1,05	1,04

Table 2. Verification of the decreasing frequencies.

	9Hz	7Hz	5Hz	3Hz
i_{DCD} (p)	0,00113	0,00113	0,00113	0,00114
i_{DCD} (v)	0,00059	0,00059	0,00059	0,00059
F_i (p)	798,2	798,5	799,3	800,9
F_i (v)	83,7	81,1	80,3	80,7
F_{DCD} (p)	802,0	800,6	802,0	809,1
F_{DCD} (v)	59,5	60,9	59,5	53,9
ΔF_i	714,6	717,4	719,0	720,2
ΔF_{DCD}	742,5	739,6	742,5	755,2
C	1,04	1,03	1,03	1,05

From both peak (p) and valley (v) force levels (F_{DCD} (p) and (v)), (1) and (4) respectively, it was calculated the coefficients of the peak and valley straight line, m_p and c_p (2) and (3) respectively and m_v and c_v (5) and (6) respectively. These coefficients joins the two adjacent values to give the static force relationship between the DCD indication and the fatigue machine using the averaged values of the machine peak and valley force indication (F_i (p) and (v)), the DCD peak and valley indication (i_{DCD} (p) and (v)), previous determined, according to ISO/WD 4965-1.

For peak force levels,

$$F_{DCD}(p) = m_p . i_{DCD} + \tag{1}$$

where,

$$m_p = \frac{F_i[p+5] - F_i[p-5]}{i_{DCD}[p+5] - i_{DCD}[p-5]} \tag{2}$$

and

$$c_p = F_i[p+5] - m_p . i_{DCD}[p + \tag{3}$$

For valley force levels,

$$F_{DCD}(v) = m_v . i_{DCD} + \tag{4}$$

where,

$$m_v = \frac{F_i[v+5] - F_i[v-5}{i_{DCD}[v+5] - i_{DCD}[v} \tag{5}$$

and

$$c_v = F_i[v+5] - m_v . i_{DCD}[v + \tag{6}$$

3.2. Dynamic calibration with DCD

To calibrate dynamically the fatigue machine with DCD, the peak and valley readings were taken from the force indicator of the fatigue machine (F_i) and from the DCD (i_{DCD}), at each of five increasing test frequencies that means 2 Hz; 4 Hz; 6 Hz; 8 Hz and 10 Hz and at four decreasing test frequencies in the midway between these test frequencies that means 9 Hz; 7 Hz; 5 Hz and 3 Hz.

In order to calculate the DCD force range (ΔF_{DCD}), (7), and the indicated force range (ΔF_i), (8), it was considered the calculated DCD force values (F_{DCD}) at each dynamic peak and valley from the DCD indications (i_{DCD}).

$$\Delta F_{DCD} = F_{DCD}(p) - F_{DCD}(v) \tag{7}$$

$$\Delta F_i = F_i(p) - F_i(v) \tag{8}$$

The correction factor was then calculated according to the (9), where the results are showed on the Table 3 and expressed as a curve by plotting it against frequency over the calibrated frequency range, Fig. 4.

Table 3. Calculated values used as the parameter to the curve of the figure

m_p	1415929,204
c_p	*-803,7*
m_v	1411764,706
c_v	-777,6
m_p	1415929,204

$$C = \frac{\Delta F_{DCD}}{\Delta F_i} \tag{9}$$

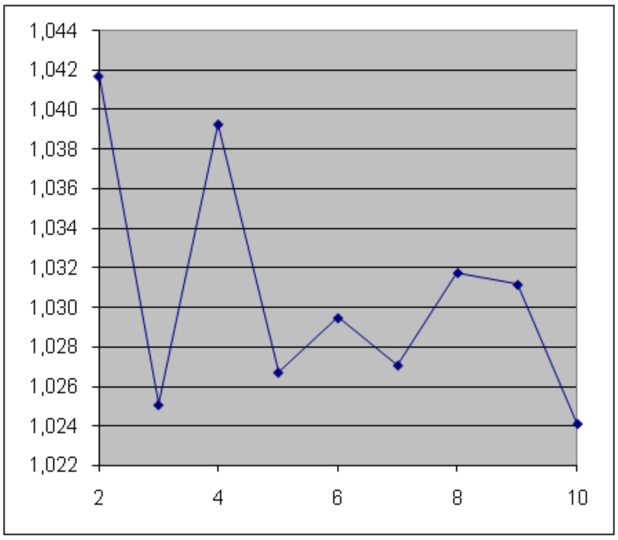

Fig. 4. Results of the fatigue machine calibration by using a Replica Test-piece method.

4. CONCLUSIONS

The knowledge, and control, of all stages involved on the performance of mechanical test on ortophaedic implants is a critical step on the development of innovative concepts into reliable medical devices. To ensure the safe and efficient performance of a medical device, in its biomechanical application, the fatigue tests of the component must be performed according to metrological requirements, which impose the need of evaluating the machine's performance.

This work aimed to cover two main aspects: the development of methodology for dynamic force calibration and the study of the parameters that influence the uncertainty sources in implants fatigue test. Even not performing the electrical calibration of the Dynamic Calibration Device (DCD), the final results of the fatigue machine calibration showed a low error, around 1 % for the indicated force range (80 N to 800 N) with frequencies varying from 2 Hz to 10 Hz.

Despite the no-workable procedure, where one has to have a large number of DCDs, by using the studied method, once it is necessary to had one DCD for each type and configuration of test-piece to be tested, this work has proofed that, in this way, it is possible to calibrate dynamically the dynamic testing system (fatigue machine) and to have the required traceable metrological chain to National Metrology Institute.

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