Foot & Ankle Orthopaedics: Towards In Silico Clinical Trials in Prosthesis Wear Estimation

A. Stenti[1(*)], E. Morales[1], F. Giuliani[1], R. Desmet[1], T. Leemrijse[2], P-A Deleu[2], B. Ferré[3], and E. Lété[1]

[1] *Digital Orthopaedics, Belgium.* [2] *Foot & Ankle Institute, Belgium.* [3] *IM2S, Monaco*

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1. Introduction

Medical Device companies, which undergo strict regulatory procedures to put their products on the market are experiencing an increasing attrition rate towards the end of the device product cycle. In addition, the current standards used in certification often do not entirely reproduce realistic biomechanical conditions.
Computer modelling and simulation (CM&S), already a well-established tool in several industries (e.g. aeronautics, automotive), is just now beginning to be exploited in the healthcare sector. CM&S allows the generation of digital twins: deeper cause-effect investigations on specific pathologies; what-if patient specific surgical risk analyses; testing of medical devices on a virtual population in realistic biomechanical conditions.
The FDA efforts to promote the use of CM&S in the healthcare sector as an additional source of evidence are pushing towards the definition of a solid reglementary framework [1,2]. Although at a slower pace, Europe is also following the same direction, towards the adoption of the so-called In Silico Clinical Trials (ISCT) [3,4].
In the framework of ISCT, this study focuses on the total ankle-joint prostheses wear test certification standard: ISO 22622:2019 [5] . Test results are presented and reproduced virtually on a given prosthesis model. An ISCT approach is then proposed: a specific digital twin is developed, the prosthesis is inserted and its wear behaviour is estimated in realistic biomechanical conditions. Differences with the certification standards are discussed. The study closes with a more general discussion on the challenges involved in using an ISCT approach for predictive medicine.

2. Methods

2.1 ISO 22622:2019

The testing machine defined in the standard is originally designed for knee implants. The ankle-joint prosthesis and the corresponding loading conditions are therefore adapted. One of the consequences, and thus a limitation to be considered, is that the talar component of the prosthesis rotates along a mechanical fixed axis, which does not represent the real movement of the ankle joint.
6 samples of a given customer's prosthesis are tested. Figure 1 shows a virtual reproduction of the force driven ISO 22622:2019 wear test.

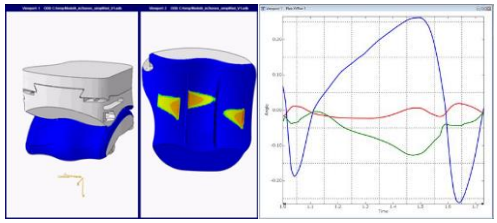

Figure 1 : Virtual ISO 22622.2019
The prosthesis of interest (left); polyethylene insert contact pressure (centre); relative movement (right)

2.2 ISCT Approach

A Digital Orhopaedics internal workflow is used to generate a digital twin of a healthy subject. In a multi-step process, the workflow uses as inputs the subject's CT-Scan and gait lab measurements; automatically generates a multi-body model used to identify the muscular activation scheme proper to the subject; finally injects the activation scheme into a detailed finite element anatomical model to simulate the subject gait.

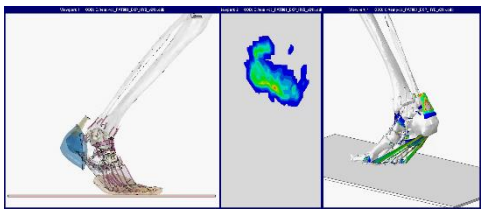

Figure 2 : Digital Twin
Plantar pressures (centre); ligaments & fascia stresses (right)

Figure 2 shows the digital twin model used in this study: healthy subject, age 45, 84Kg,

*Corresponding author. Email: astenti@01ortho.com

179cm. The anatomical axis of the twin's ankle joint is computed based on the talocrural joint shape of the subject and the prosthesis is inserted and aligned consequently. Typical surgical positioning variability is considered. Prosthesis wear map and mass loss are estimated during gait simulation.

3. Results and discussion

Figure 3 shows the simulated wear map (left) with respect to measurements (right) according to the ISO 22622:2019. A good qualitative agreement can be observed. Total weight loss of the polyethylene insert was measured on four samples and is in agreement with simulations.

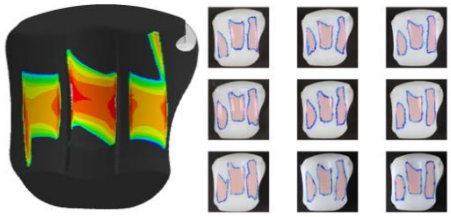

Figure 3 : ISO 22622.2019
Simulated wear map (left); measured wear map on 9 polyethylene samples (right).

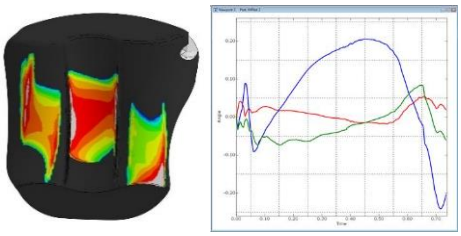

Figure 4 : Digital Twin
Simulated wear map in biomechanical conditions (left); relative movement (right).

The prosthesis is further inserted into the subject and the wear map and the mass loss are predicted in biomechanical conditions. When comparing the ISO 22622:2019 wear map (figure 3, left) and the biomechanical wear map (figure 4, left) the differences on the prosthesis are evident: while the central region is comparable, a clear difference is notable on the lateral and medial part of the prosthesis. Figures 1 (right) and 4 (right) show the differences in the prosthesis relative movement: blue dorsiflexion; red inversion/eversion; green adduction/abduction. When the typical surgical positioning variability is considered in the simulation, the spread on the wear map and on the mass loss clearly shows the limitations of the ISO 22622:2019.
It becomes apparent the interest in estimating the wear behaviour of a given prosthesis design in biomechanical conditions via an ISCT approach: the inclusion of biomechanical in-vivo loading conditions; a specific pathological population and its variability; prosthesis surgical insertion variability.

4. Conclusions

The study presented here shows the differences in the ankle joint prosthesis wear behaviour evaluated via the certification standard ISO 22622:2019 and the behaviour estimated via a digital twin in realistic biomechanical conditions. The limitations of the certification standards and the importance of adopting an ISCT approach are discussed.
It is clear that the results presented here represent just a first step towards the full exploitation of the ISCT concept in the foot & ankle prosthesis wear estimation. Although the ISCT set considered in this study involves only one healthy subject, the Digital Orthopaedic automatic workflow allows the development of a set of digital twins representative of a specific pathological population.
The choice of the pathology of interest, the definition of an ISCT digital twin set which is representative of the pathological population of interest and the evaluation of the impact on the wear map estimation is the natural follow up investigation to the study presented here.

5. Acknowledgements

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6. References

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