Foot & Ankle Orthopaedics: Towards the use of In Silico Clinical Trials in Prosthesis Placement Criteria

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Foot & ankle orthopedic surgeons are daily confronted with surgical decisions based on geometrical realignment criteria. Studies show that the mid to long term success of these surgeries is not always guaranteed [1,2]. The need to enlarge the perspective is evident. Understanding the impact of a specific proposed surgical treatment to the ligaments, the cartilages, the gait performance of a specific pathological population of interest becomes crucial.

Computer modelling and simulation (CM&S), already a well-established tool in several industries (e.g. aeronautics, automotive), is 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 [3,4]. Although at a slower pace, Europe is also following the same direction, towards the adoption of the so-called In-Silico Clinical Trials (ISCT) [5,6].

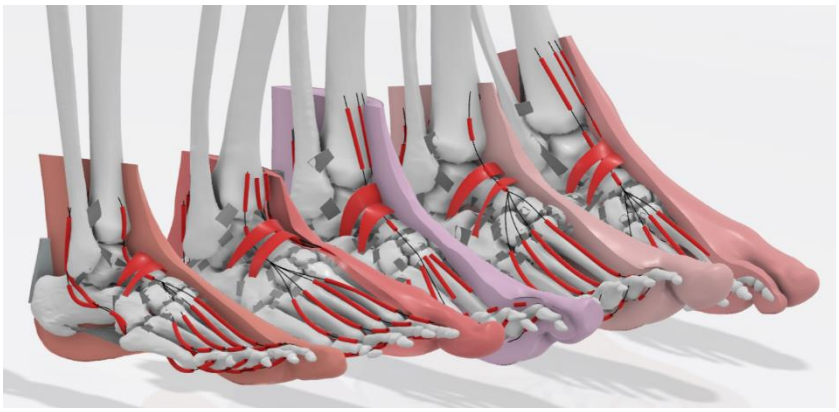

Figure 1 : The Twin Factory

In the framework of ISCT, this study focuses on the evaluation of the total ankle-joint prostheses placement criteria in realistic biomechanical conditions. The work is divided into two steps:

- A virtual population set is generated and the reference prosthesis inserted.
- Surgical variability is introduced and prosthesis performance is evaluated.

In the first step, a Digital Orhopaedics internal workflow is used to generate the virtual population set: The Twin Factory (see figure 1). 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. The anatomical axis of the twin's ankle joint is then computed based on the talocrural joint shape of the subject and the prosthesis is inserted and aligned consequently. Figure 2 shows one of the digital twin models used in this study: healthy subject, age 45, 84Kg, 179cm.

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A second workflow is used to identify an equivalent mechanical anatomical axis of the twin's ankle joint from the joint shape of the subject and insert and align consequently the prosthesis of interest. Figure 3 shows the identified talus dôme kinematic rotation axis and the reference prosthesis aligned consequently.

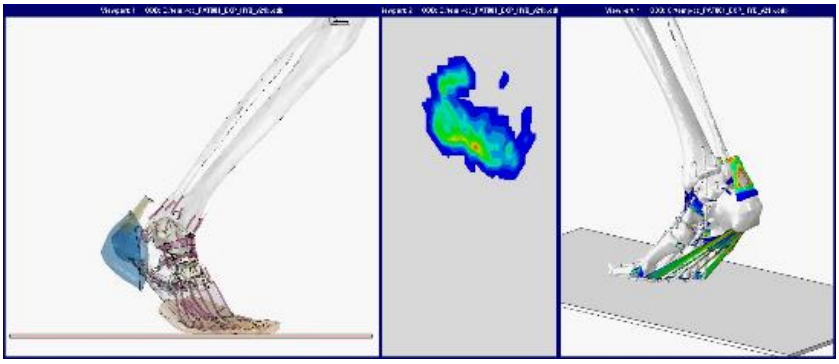

Figure 2 : One Digital Twin of the population set.
Plantar pressures (centre); ligaments & fascia stresses (right)

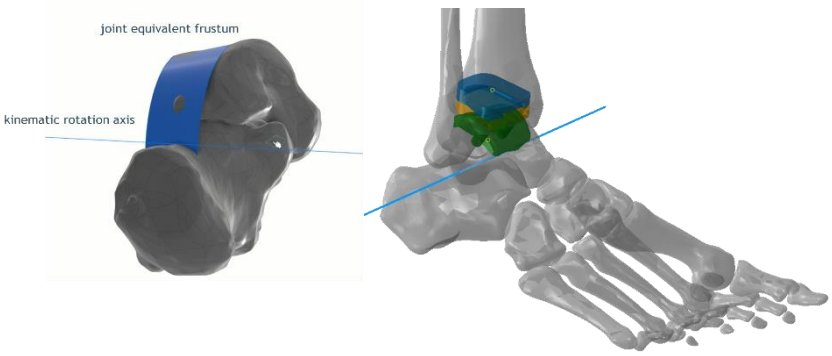

Figure 3 : Talus dôme equivalent axis of rotation (left); aligned reference prosthesis (right)

In the second step, a design of experiment (DOE) approach is followed to investigate the correlation between the prosthesis position and several metrics of interests. The prosthesis is initially aligned along the computed talus dôme equivalent mechanical anatomical axis: reference position. In this study a 5° and 10° valgus/varus perturbation is considered according to the DOE summarised in table 1. The positioning impact is monitored via several output metrics involving: plantar pressure, cartilage contact pressure, ligaments strain and stress, joint ankle range of movement (ROM)(see figure 4).

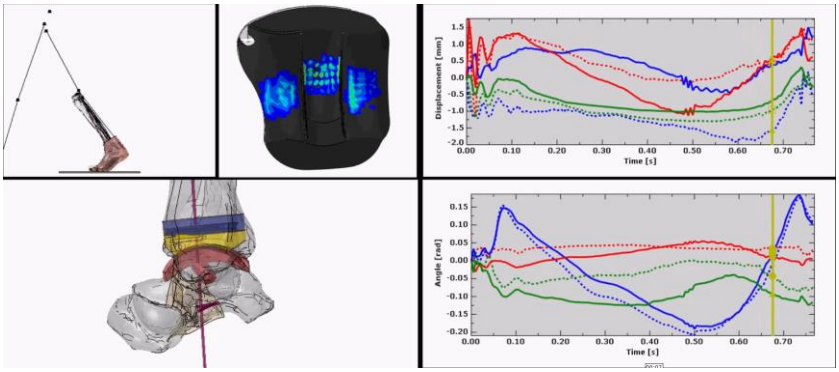

Figure 4 : Prosthesis insert contact pressure and joint ankle ROM during stance phase : with prosthesis (full lines) and without prosthesis (dotted lines).

experiment #	description
-2	varus -10°
-1	varus -5°
0	0°
+1	valgus +5°
+2	valgus +10°

table 1 : the DOE set

KPI #	description	definition
1	ROM delta	max-min value, focus on tibio-talar, sagittal plane
2	medial ligaments strain energy	focus on anke joint
3	lateral ligaments strain energy	focus on ankle joint
4	prosthesis volume loss	

table 2 : the KPI set

A subset of output metrics is defined in terms of objective key performance indicators (KPI). Table 2 shows the definition and the description of the KPI of interest in this study.
The correlations identified is further evaluated on two additional digital twins. The study closes with a more general discussion on the challenges involved in using an ISCT approach for predictive medicine.

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