

TRANSFORMING ORTHOPAEDIC FOOT AND ANKLE SURGERY THROUGH SIMULATION

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ABSTRACT

In daily practice, the identification of the mechanical pathogenesis of foot diseases mostly relies on observation, patient history, clinical assessment, medical imaging, and in rare cases on gait analysis. Based on the results of this plethora of tests, orthopaedic surgeons use a variety of treatments with respect to clinical guidelines to restore and maintain proper bony alignment and muscle balance. Despite improvement of clinical and radiographic parameters, a growing body of evidence finds that one-type-surgery-suits-all approach does not ensure a restoration of function. Inter-subject anatomical heterogeneity, the complexity of the foot and the inability to assess the internal foot loading conditions preclude one-type-surgery-suits-all approach.

To limit the uncertainty, Digital Orthopaedics' platform has developed a subject-specific computational model of the human foot incorporating clinical reasoning and expertise in clinical decision making in the field of foot and ankle surgery. This platform integrates Dassault-Systèmes technologies (Simpack, Abaqus, CATIA) and clinically oriented data management providing orthopaedic surgeons efficient, outcome-driven and patient-specific diagnostic and treatment tools to deliver effective patient-care. Through Digital Orthopaedics' virtual surgical solution developed in CATIA, orthopaedic surgeons can virtually plan, design, perform and adjust their surgery until they achieve the desired clinical outcome before entering the operating room. This solution offers surgeons a tool to reduce the surgical outcome variability by directly predicting clinical outcomes in relation to their actions. This technology offers the opportunity to create new surgical guidelines built on effective data analytics and to demonstrate the value of predictive analytics in transforming orthopaedic surgery.

INTRODUCTION

In daily practice, common methods of assessment in patients suffering from foot and pathologies are observation, patient history, clinical assessment, medical imaging and in rare cases on gait analysis. Based on the results of this plethora of tests, orthopaedic surgeons use a variety of treatments (surgical or conservative) with respect to the latest evidence-based recommendations in conjunction with their clinical expertise to restore and maintain proper bony alignment and muscle balance. Despite the strict application of evidence-based interventions that emerge from science to clinical practice, our current treatment approach does not guarantee the complete resolution of our patient's symptoms and functional limitations.(Canseco et al., 2012, 2011, 2009; Kernozek and Sterriker, 2002; Schuh et al., 2009; Wang et al., 2010) Inter-subject anatomical heterogeneity is one of the main reason why this may be the case and thus precludes one-type-treatment-suits-all approach to treat foot and lower limb diseases. A growing body of evidence points out the existence of anatomical foot variations in terms of joint surfaces and geometries, muscle insertions, presence of accessory muscles or ligaments, ligament insertions and their potential impact on the mechanical behaviour of the foot and the lower limb.(Alonso-Vázquez et al., 2009; Bonnel et al., 2013, 2011; Guiotto et al., 2013) This further supports that the “one-type-treatment-suits-all” approach could potentially induce different contact pressure at the joints due to the large existence of inter-subject anatomical heterogeneity. Therefore, rather than continue to apply a poorly founded surgical / conservative model of foot type whose basis is to make all feet criteria for the anatomical / radiological ‘ideal’ or ‘normal’ foot, clinicians should incorporate anatomical variation between feet and identify the patient's proper biomechanics. Significant inter-subject anatomical variation exists and question any surgical and/or conservative notion that is based on the concept of a single ideal anatomical / radiological foot type and alignment.

However, there is no well quantified consensus on the appropriate magnitude of surgical corrections required nor a full understanding of its biomechanical effect for each pathology while at the same time respecting the subject's unique anatomy. For example, in the correction of a flatfoot deformity some patients undergo bony reconstruction which consists of changing the alignment of the heel bone (calcaneus) wherein the back half of the heel bone is cut and slid back underneath the leg. By doing so, the entire back half of the heel where the Achilles tendon has its insertion, is translated medially, which in turn has the effect of moving the gastrocnemius/soleus complex line of action medial of the subtalar inversion/eversion axis, thereby enabling the inversion of the mid- and hindfoot while simultaneously disadvantaging the everting power of the peroneus brevis.(MH et al., 2003; Spratley et al., 2015) Also, sliding the back half of the heel will induce changes in soft-tissue strain and in joint contact forces which today can not be measured in vivo. To reduce the surgical outcome variability, there exists a need to develop subject-specific computational foot models that will better predict clinical outcomes in relation to the magnitude of the surgical corrections. This technology offers the opportunity to create new surgical guidelines built on effective data analytics and to demonstrate the value of predictive analytics in transforming orthopaedic surgery.

To limit the uncertainty, Digital Orthopaedics' platform has developed a subject-specific computational model of the human foot incorporating clinical reasoning and expertise in clinical decision making in the field of foot and ankle surgery. This platform integrates Dassault-Systèmes technologies (Simpack, Abaqus, CATIA) deployed on the 3DExperience platform to provide orthopaedic surgeons efficient, outcome-driven and patient-specific diagnostic and treatment tools to deliver effective patient-care. The current paper describes a workflow that has been developed by Digital Orthopaedics to generate the biomechanical and anatomical data required to provide orthopaedic surgeons a tool for planning, designing, performing and adjusting virtually their surgery until they achieve the desired clinical outcome before entering the operating room.

METHODS AND DESIGN

Subject

One male healthy adult volunteer (age 34 years, height 1,70m, weight 75kg, BMI 25,95 kg/m², shoe size 42) will be recruited. A participant will be considered healthy and included if he 1) is able to walk barefooted independently, without support, 2) has no history of major trauma and/ or surgery of the lower limb, or 3) presents no systemic or neurological disorder involving the musculoskeletal system directly.

Imaging studies :

Computed Tomography (CT)

A computed tomography (CT) scan of the right leg (shank and foot) of a healthy subject will be performed in an unloaded condition. The subject will be positioned with the right foot approximately 90° to the leg in a customized boot. The following parameters will be used to acquire the scan on a Siemens slice scanner (Siemens, Munich, Germany) at the Clinique du Parc Léopold (Brussels, Belgium): 130 kVp, 0,6mm effective slice thickness, 512x512 matrix.

Magnetic Resonance Imaging (MRI)

Due to the limitations of soft tissue information that can be provide from the CT-scan, the subject will also have a MRI taken from his right foot. For the MRI, the foot will be placed in a suitable imaging foam padding placed around the foot and the leg to prevent movement during the scan. MRI images will be acquired using Optima MR450w (GE Medical Systems). Three scans (T1,T2 and DP FAT SAT) will be taken in total covering the full foot and ankle with the following scanning parameters : 0,8mm slice thickness and 512x512 matrix. MRI will be used for the identification of soft tissue insertion and via points.

Gait analysis

Gait analysis will be performed in the Laboratory for Clinical Motion Analysis of the Foot & Ankle Institute (Brussels, Belgium) using an advanced clinical examination platform. It is composed of a passive motion capture system, a plantar pressure platform and a force platform to obtain the simultaneous assessment of kinematics, kinetics, and plantar pressure measurements of each subject. This platform can provide further insight into the

biomechanics of the foot and the lower limb.(Giacomozzi et al., 2014, 2000; MacWilliams et al., 2003; Sawacha et al., 2012)

The motion analysis system (MAS) (Qualysis, Sweden) is composed of 8 Miquis cameras in order to track the kinematic data (200Hz) of all participants while walking over a 10 meter walkway at a self-selected speed.(Caravaggi et al., 2010) Residual errors of < 1mm are deemed acceptable for the system.(Oosterwaal et al., 2011)

In the middle of the aforementioned walkway, a Footscan® pressure plate (dimensions 0.5m x 0.4m, 4096 sensors, 2.8 sensors per cm², RSscan International, Paal, Belgium) is mounted on a custom made AMTI-force plate (dimensions 0.5 x 0.4m, Advanced Mechanical Technology, Inc., Watertown, MA, US). The current set-up allows the detection of specific gait events as well as for a continuous calibration of the pressure plate with the force plate using a Footscan® 3D interface box (RSscan International, Paal, Belgium). Data from the pressure and force platforms are measured at a sampling rate of 200Hz. The adequate integration and synchronization of the different hardware devices will be achieved by connecting all the hardware devices with the synchronisation unit (Qualysis, Sweden). Data from the pressure, force plate and MAS will be measured at a sampling rate of 200Hz.

Surface electromyographic signals (sEMG) will be collected from the tibialis anterior, peroneus longus, medial gastrocnemius and soleus muscles on both sides by means of a 16 channel wireless Zerowire system (Cometa, Italy) at a sample rate of 1500Hz.

Forty-two retro-reflective markers will be mounted over the described anatomical landmarks according to the 3D Multi-Segment Foot Model of Leardini et al. (2007)(A. Leardini et al., 2007) and of the 3D Lower Limb Model of Leardini et al. (2007).(Alberto Leardini et al., 2007) The skin markers will be attached over the anatomical landmarks using double-sided adhesive tape. After marker placement, two standing trials will be recorded in a relaxed standing position. After checking for a successful acquisition of all marker positions in static way, the participants will be asked to walk barefoot, walking at a self-selected speed until five valid trials are recorded.(Schwartz et al., 2004) A trial will be considered valid when the following criteria are met: walking speed within the outlined boundaries, no visual adjustment in gait pattern to contact the pressure plate and a clear pedobarograph contact with the foot.(Willems et al., 2006)

Data processing

Imaging data

CT-scan data will be segmented into the individual bones of the foot using ScanIP (Simpleware, Exeter, UK) image processing software. The same software will be used to create the surfaces and volume meshes of the bones. Based on the subject-specific imaging data and data from the literature,(Kelikian and Sarrafian, 2011) individual soft tissues of the foot will be segmented using ScanIP (Simpleware, Exeter, UK) image processing software. Soft-tissue segmentation is divided in two phases: first reconstruction of skin, muscle, heel pad and plantar pad volumes from literature(Kelikian and Sarrafian, 2011) and adapted to the current patient-specific model; a second reconstruction of ligaments and tendons insertion and reflection point coordinates from the MRI and from literature(Kelikian and Sarrafian, 2011) and adapted to the current patient-specific model. Fourteen anatomical landmarks on the patient's CT-scan will be placed by the clinician over the described anatomical landmarks

according to the 3D Multi-Segment Foot Model of Leardini et al. (2007)(A. Leardini et al., 2007). Their respective coordinates will be used afterwards in the multi-body model.

Motion capture data

The kinematic data, the kinetic data, surface EMG data will be processed by using Visual3D (C-Motion, Germantown, US) software and saved in the C3Dformat.

Three-dimensional rotation angles and planar angles and joint moments will be calculated according to the 3D Multi-Segment Foot Model of Leardini et al. (2007)(A. Leardini et al., 2007) and of the 3D Lower Limb Model of Leardini et al. (2007)(Alberto Leardini et al., 2007) using Visual 3D (C-Motion, Germantown, MD, US). Inter-segment 3D rotations will be calculated following ISB recommendations.(A. Leardini et al., 2007; Wu et al., 2002)

Plantar pressure data

The plantar pressure data will be processed by using Footscan 7.97 (RsScan International, Paal, Belgium) and saved in the ASCII-format. The semi-automatic total mapping procedure (SATM) will consist of determining ten anatomical pressure areas, called region of interest (RoI) on the peak-pressure footprint. These RoI are medial heel (HM), lateral heel (HL), midfoot (MF), metatarsal heads I to V (M1 to M5) and the hallux (T1). The RoI will be determined by using the free-mapping method of the total mapping technique. It involves the manual circumscription of RoI using graphical tools of the Footscan® 7.97 software (RSscan International, Olen, Belgium). The protocol for each SATM of each peak-pressure footprint will consist of (Kevin Deschamps et al., 2013): 1) positioning a pre-determined foot last, 2) delimitation of the complete forefoot and toe regions using the aforementioned graphical tools, 3) manual adjustment of the pre-established vertical oriented lines in order to determine the five metatarsals RoI, 4) manual adjustment at a sensor level to fine-tune the limits of the RoI.

Plantar pressure variables (e.g. peak pressure, average pressure, force-time related ratios, ground reaction forces and total contact area) for each RoI of the peak pressure footprint will be calculated within Python with the program made by the consortium of authors.

Gait events and subphases

The adequate integration and synchronization of the plantar pressure plate with the MAS and the force platform will allow the detection of subject specific gait events.(De Cock et al., 2005; K Deschamps et al., 2013)

The stance phase will be divided in three sub-phases:

- Forefoot Contact Phase (FCP) starts with the First Foot Contact (FFC) and ends when all the metatarsal heads are in contact with the ground.
- Foot Flat Phase (FFP) is the time between the Forefoot flat (FFF) and Heel Off (HO).
- Forefoot Push Off Phase (FFPOP) is defined as the duration between Heel Off and Last Foot Contact (LFC).

The division of the stance phase into the sub-phases described in the current study is based on

studies of De Cock et al. (2005)(De Cock et al., 2005) and Deschamps et al. (2013)(K Deschamps et al., 2013) and referred to the evolution of the plantar pressure distribution during roll-over. The time between the gait events First Foot Contact and Last Foot Contact will be used to define the stance phase, whereas the duration between the gait events Last Foot Contact and the Second Heel Strike (collected with the motion capture system) will be used to define the swing phase. The complete gait cycle will be defined as the duration between the First Foot Contact and the Second Heel Strike.

Model creation (Finite element and Multi-body)

Multi-body model (MBS)

The main purpose of the multibody model is to reconstruct the patient-specific muscular activation scheme which will serve as input for the finite element model. Using all the information previously described, a multi-body model will be automatically generated using an in-house Python script. A 23 degrees of freedom 3D multi-body model (MBS) will be created in Simpack (Dassault Systèmes, France) based on the CT-scan and the MRI of the subject. MBS model includes all intrinsic foot joints, nine extrinsic foot muscles ((Tibialis Anterior, Tibialis Posterior, Peroneus Brevis, Peroneus Longus, Achilles tendon, Extensor Hallucis Longus, Extensor Digitorum Longus, Flexor Hallucis Longus, Flexor Digitorum Longus) and all foot ligaments. The joints or kinematic links between the bones of the foot and the ankle will be simulated using a combination of revolute (one rotation allowed), universal (two rotations allowed) and spherical (three rotations allowed) joints. The Number of rotations allowed per joint will be based on previous kinematic 3D multi-segment foot models and results of bone pine studies.(a Leardini et al., 2007; Lundgren et al., 2008; Nester et al., 2007, 2014; Westblad et al., 2002) The interaction between the ground and the skin will be simulated using independent discrete contact elements attached to each element of a triangular mesh of the foot surface. The contact elements will be modeled as spring-damper system.(Aerts et al., 2017) Muscles and ligaments will be represented using connectors between the origin, via points (for the muscles) and insertion. Material properties will be assigned for each element from the literature.(Athanasίου et al., 1995; Behforootan et al., 2017; Lemmon et al., 1996; Morales-Orcajo et al., 2016; Pai and Ledoux, 2012; Siegler et al., 1988) A forward dynamic gait simulation will be generated by combining Simpack and Isight (Dassault Systèmes, France) based on 3D motion capture data (markers and ground reaction forces) and used to reconstruct the patient-specific muscular activation scheme. The orientation of the foot from the pro-active phase just before heel strike obtained from experimental data will be used as initial condition of the model.

Finite element model (FE)

Using all the information previously described, a finite element model will be automatically generated using an in-house Python script. Material properties will be assigned for each element from the literature.(Athanasίου et al., 1995; Behforootan et al., 2017; Lemmon et al., 1996; Morales-Orcajo et al., 2016; Pai and Ledoux, 2012; Siegler et al., 1988) Muscle insertions will be identified using the subject-specific MRI and data from the literature.(Kelikian and Sarrafian, 2011) Muscles and ligaments will be represented using connectors between the origin, via points and insertion. The same nine extrinsic muscles as described in the MBS model will be implemented in the FE model. The patient-specific

muscular activation scheme identified in the MBS simulation will be used as input for the FE model. The plantar fascia will be represented by multiple connectors to evenly spread the loads.

Modelling of surgical corrections

Through Digital Orthopaedics' virtual surgical solution developed in CATIA, orthopaedic surgeons can virtually plan, design, perform and adjust their surgery until they achieve the desired clinical outcome before entering the operating room. In order to analyze the effects of the surgery, the patient-specific model will be investigated in four states : 1) Uncorrected model state , 2) post-operative model state with magnitude of correction A, 3) post-operative model state with magnitude of correction B, 4) post-operative model state with magnitude of correction C. All material properties will be held constant across each of the four states.

Validation

Initial validation of the multibody model will be carried out by comparing predicted and measured (via surface EMG) muscle timings. Formal validation of both models will be carried out by comparing plantar pressure measurements (e.g. peak pressure, average pressure, force-time related ratios, ground reaction forces and total contact area) taken during the stance phase to those predicted by the model. Comparison of the plantar pressure data between the experimental and the simulation will be performed for each region of interest of the peak pressure footprint.

Analysis of the surgical corrections

The uncorrected state will serve as control to evaluate the effects of the surgical corrections. This analysis will be carried out by comparing plantar pressure measurements (e.g. peak pressure, average pressure, force-time related ratios, ground reaction forces and total contact area) of the uncorrected model state to the three post-operative model states taken during the stance. Changes in soft-tissue strain will also be analysed across the four testing states. Finally, changes in joint contact force will also be recorded across the different states.

CONCLUSION

An innovative aspect of this project is the evaluation of the effects of four hypothetical surgical states in our subject-specific computational model of the human foot incorporating clinical reasoning and expertise in clinical decision making. Through Digital Orthopaedics' virtual surgical solution developed in CATIA, orthopaedic surgeons can virtually plan, design, perform and adjust their surgery until they achieve the desired clinical outcome before entering the operating room. The present solution offers surgeons a tool to reduce the surgical outcome variability by directly predicting clinical outcomes in relation to their actions. This technology offers the opportunity to create new surgical guidelines built on

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