FutureFeet

2. Dosage-response modelling

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1 Theoretical content

In order to better inform the clinical decision making of the foot health practitioner in the computer-aided design stage, some research investigated how the design of FO impact some biomechanical variables and Patient Reported Outcomes [1–11]. Some research has compared the results of a control intervention group to a FO intervention group [1,2,4–7]. However the design of these studies may fail to identify the effect of the FO intervention since it is highly probable that the control intervention also triggers the conditioned and unconditioned stimuli of FO intervention and thus have an effect on the outcomes evaluated [1,12–14].As mentioned above, the placebo and nocebo effects (secondary clinical strategy) depend indeed on the intervention [12,15] and the forces applied on the foot is the result of its interaction with the device with which it interacts [16–18]. Based on this, it seems evident that the effect allocated to the FO intervention actually depends on the effect of the control intervention and that it is consequently hard to quantify the real effect of the FO intervention.

To better quantify the effect of FO intervention, some studies have analysed how incrementally modifying certain geometric features of the design of a FO (dose of stimulus) impact a variable observed (response) [3,8–11]. Whereas analysing the dose-response relationship of an intervention is originating from the pharmaceutical industry [19], it has been newly introduced in the domain of FO and has gain interest with the development of Computer-aided design (CAD) [1,3,8–11,20]. Advances in CAD facilitates the incremental change of the dosage of the stimulus thanks to their ability to generate a FO geometry with a set of parameters to which values are assigned [21–26]. These values are an integral part of the design whose incremental change modify the FO geometry and consequently the dose of the stimulus [3,8–11,21–26].

In addition, how the FO geometry behave with incremental changes is defined by a mathematical foundation [21–26] which can be exchanged between different CAD Systems [21,25]. This ability to exchange the information which determine how the geometry behave when the dosage is changed seems to be a great opportunity to promote a more accurate replication of a FO geometric feature modification. To date, all the studies which investigated the dose-response relationship of FO intervention incrementally change the dosage of the geometric features while the incremental change of a feature related to the visual and physical properties has never been investigated yet. Among other things this could be explained by the fact that current CAD systems are developed to allow the design of geometries but are not efficient to take the physical and visual properties into considerations [27–29].

Beside the use of CAD systems, computational simulation are used to evaluate synergistically the geometrical and material designs of a device while assessing its mechanical behaviour in a specific loading condition [30]. In other words, these simulations allow to analyse how the stress and strain of a specific tissue are affected by a specific loading condition [30–39]. The process consists of importing a FO model into a computational simulation system in which the material properties, the loading and boundary conditions will be applied [30–39]. By repeating this process various times before manufacturing the FO, the user is able to optimize the geometric feature and physical features of the FO (dose of stimulus) in regards to its mechanical effect (response) [30–39]. While the computational simulations are a great tool to better understand the mechanical effect of FO [30–39], its utilization is probably not suitable for clinical practice at the time being due to its time-consuming procedure and its complexity [31]. This is even more true when we know that to be more accurate, this process should ideally be based on patient-specific data such as an MRI and a 3D gait analysis [39]. It can therefore be speculated that this kind of simulations mainly provide basic science information while knowledge transfer has yet to be done.

To date the literature which has investigated the dose-response relationship in the domain of FO focused on the analysis of biomechanical responses and mainly highlighted that the geometric feature of FO can incrementally alter the foot biomechanics until a desired degree [3,8–11]. Future research could eventually promote other practices in the field of FO by analysing if the geometric feature, physical properties or visual properties of FO can incrementally alter the tissue and cells, the patient perception and other responses related to the placebo effect[12,40–52]. These research could guide practitioner in the dosage of FO dosage-response model which should be considered in light of the primary and secondary clinical strategies[3,8,43,45–53,9–12,15,40–42]. Notably, practitioners should be aware that increasing the dosage of FO mechanical stimulus can affect the comfort perceived by the patient[11,53] which is itself related to the compliance to FO[54].

2 Task

After having consulted the PowerPoints related to the design, please answer the following questions:

- Which feature or properties of the FO design are determined in those PowerPoints. Please adopt the terminology reported in the following publication [15].

- How could you incrementally increase the dose of the design illustrated in the PowerPoint "Example 2" and what would be the expected response(s)?

- How could you incrementally increase the dose of the design illustrated in the PowerPoint "Example 3" and what would be the expected response(s)?

3 Reference

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