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STUDY PROTOCOL

3D-PRINTING AND ACCES TO TELE REHABILITATION (IMP&ACTE3D)

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Lieven De Maesschalck

THOMAS MORE Kleinhoefstraat 4, 2440 Geel

Protocol Imp&Acte3D

1. BACKGROUND

This study will investigate whether 3D printing of orthoses (night splints and AFO/KAFO for walking, further named as dynamic AFO/KAFO) for the lower limbs can help to improve the limited accessibility to orthopaedic devices in developing countries. The 3D printed orthoses will be assessed for effectiveness, cost and feasibility. Measurement and manufacturing of the orthoses will also be supported remotely via video conferencing.

Specifically, the study is being conducted in 3 West African countries: Togo, Niger and Mali. A total of 4 orthopaedic centres are involved, whereby an equal number of patients are recruited each.

There are 2 groups of patients, those who need a (knee) ankle-foot orthosis to move around (dynamic AFO/KAFO) and those who need a night splint to correct the ankle or knee position. All patients in the study will have a treatment path involving fitting of a new traditional orthosis and fitting of a new 3D printed orthosis. The order of application of both treatments is randomised in a crossover design. Patients are measured at baseline after the first treatment period (3 weeks) and after the second treatment period (6 weeks). The primary outcome measures are different for both groups of patients: the walking speed when performing the 10-metre walk test in the patients wearing the dynamic AFO/KAFO, and the measured angle (of knee or ankle) in the patients wearing a night splint.

There are recent scientific studies showing that the functional clinical parameters in patients wearing lower leg orthoses are the same in traditional and 3D printed orthoses. These studies were conducted using the manufacturing techniques available in the Western world. The potential for the use of 3D scanning and 3D printing in developing countries is great since in many places the traditional means of production are not available [5]. Apart from a few case studies or pilot projects, there are few large-scale studies on the use of 3D printing for lower leg orthoses in developing countries. This study hopes to fill some of this gap.

The study will be conducted in accordance with the proposed protocol and good clinical practice guidelines.

The study will be conducted in up to 105 healthy adults.

2. GOALS

The study has 3 objectives:

1. To find out if the clinical impact of traditional and 3D printed lower leg orthoses differs

2. To evaluate patient satisfaction with traditional and 3D printed lower leg orthoses

3. To inventory the cost of 3D printed lower leg orthoses, and to evaluate the impact of the implementation of the new sizing and production workflow

3. STUDY DESIGN

A member of staff from the local orthopaedic centre will go through the information and consent form with the test subject and submit it for signing.

Within the research project 3 main groups of treatments will be investigated:

- orthoses for patients with drop foot and knee instability that are used while walking (further mentioned as dynamic orthoses)

- night splints (static orthoses) for genu varum and foot stance deformities (e.g. talipes equinus, talipes valgus)

- seating shells for children with e.g. CP

For all target groups, patients are recruited separately and checked for specific outcome measures.

The first group are patients who wear their orthosis to move around. There is primarily an immediate effect (the effect of wearing the orthosis) and less of a therapeutic effect (which improves the patient in the long term).

The second group of patients wear the orthosis at night to reduce ankle or knee joint deformity. Here, the therapeutic effect is particularly important; the orthosis helps to correct the position of the foot or leg with a lasting effect.

Dynamic ortheses

The primary outcome measure here is the measured speed in the 10 metre walk test (10MWT), in metres per second. A secondary outcome measure is patient satisfaction, measured using the OPUS/CSD scale (Orthotics and Prosthetics Users' Survey - Satisfaction with Devices) [6], which surveys patient satisfaction with the orthosis.

Patients meeting the inclusion and exclusion criteria are recruited from existing patient lists. The patients are all already wearing dynamic orthoses.

The patients will be fitted with both a new traditional orthosis and a new 3D printed orthosis. The study is designed so that all patients are fitted with both types of orthosis in a crossover design [3].

The 2 conditions included and patients recruited also give rise to 2 different types of orthoses: an ankle-foot orthosis (AFO) for the drop foot patients, and a knee-ankle-foot orthosis (KAFO) for the patients with knee instability.

Patients are measured while wearing the orthosis, and while not wearing the orthosis (3 times each, and in a randomised order). The first baseline measurement is taken at the start of the measurement campaign (T0). For each type of orthosis, the patient is given 3 weeks to walk with the orthosis before being checked for a new measurement. After the first phase with the first orthosis (traditional or 3D printed), the patient is measured again (T1), with and without the orthosis. After the second phase with the second orthosis (3D-printed or traditional), the patient will be measured again (T2), with and without the orthosis.

The statistical analysis will be done with repeated measures analyses of variance (RM-ANOVA's), with the 2 within-subject factors: the 2 phases (phase 1 and phase 2), and the wearing or not of the orthosis (with and without), and 2 between-subject factors: the orthosis/pathology (AFO for drop foot, KAFO for knee instability), the treatment group (group A and group B).Sample size

Sample size

As indicated above, the primary outcome measure is the measured speed during the 10m walk test. A secondary outcome measure here is patient satisfaction, calculated from the OPUS-CSD scale. Our sample size is not adjusted for multiple testing.

The sample size was calculated based on an effect size estimate of 25%, and an α equal to 5%, and a power of 80% (β = 0.20). In total, there are 4 groups (2 between-subject factors with 2 levels each), and we compare at 2 measurement points, T1 and T2. We expect that measured patient parameters (the speed) do not change that much over time and with the orthosis, so we take a correlation of 0.6.

This gives a total of 40 patients, or 10 patients per group. With a margin of 20% for drop-out, we arrive at 12 patients per group (total of 48).

Night splints

The primary outcome measure here is the measured angle of the knee or ankle (in the sagittal plane) in degrees [2, 4]. A secondary outcome measure is patient satisfaction, measured using the OPUS/CSD scale, which questions the patient's satisfaction with the orthosis, and the range of motion (ROM) of the ankle or knee in degrees.

Only new patients are recruited for this target group, as there is a therapeutic effect of the orthosis that was worn.

The patients will be fitted with both a new traditional orthosis and a new 3D printed orthosis. The study is designed so that all patients are fitted with both types of orthosis in a crossover design.

The two pathologies that are included and for which patients are recruited, also give rise to two different types of orthosis: an ankle-foot orthosis (AFO) for patients with foot stance disorders, and a knee-ankle-foot orthosis (KAFO) for patients with genu varum.

The patients are only measured without wearing the orthosis (2 times each time). The first baseline measurement is taken at the start of the measurement campaign (T0). For each type of orthosis, the patient is given 3 weeks to wear the orthosis before being checked for a new measurement. After the first phase with the first orthosis (traditional or 3D printed), the patient is measured again (T1) without the orthosis. After the second stage with the second orthosis (3D printed or traditional), the patient is measured again (T2) without the orthosis.

Sample size

Here, the primary outcome measure is the measured angle of the ankle or knee. A secondary outcome measure here is patient satisfaction, calculated from the OPUS-CSD scale and measured ROM. Our sample size is not adjusted for multiple testing.

The calculation of the sample size is similar to that of the first patient group. However, there are now 3 moments where we will compare the angles (T0, T1, T2), and a lower value for the correlation is expected, since an influence of the treatment is expected, and the correlation at successive measurements may be smaller. The correlation is estimated here at 0.4. This gives a patient number of 12 per group (48 in total).

4. PATIENT SELECTION

The recruitment of the maximum of 105 subjects will be done on the one hand by contacting patients who are already in the contact details of the orthopaedic centres involved, and this specifically for patients who will be fitted with the dynamic orthoses. On the other hand, the patients receiving the night splint will be new patients.

Patients and parents of patients in this second target group will be given information about the research project by means of a visual information sheet when they check in at the centre. The doctor or staff member will inform the patient and parents in detail about the research project. They can then decide whether or not to take part in the study.

The patients from the first target group will be contacted by a staff member of the centre who will explain the research project. The patient has the time to make a voluntary decision whether or not to take part in the research project. If the patient is interested in participating, he/she is invited to come to the centre, where the visual information sheet will explain the project once more. The information and consent form will be presented for signing before entering the project.

Patient selection

Patients with foot stance deformities

- Inclusion

o Age: >= 2 years, <= 6 years

Gender: any gender

Pathology: foot stance deformity

o Unilateral as well as bilateral orthoses were included

- Exclusion

o Patient is already wearing a night splint

Patients with genu varum

- Inclusion

Age: >= 2 years, <= 6 years

Gender: any gender

Pathology: genu varum

o Both unilateral and bilateral orthoses are included

- Exclusion

o Patient is already wearing a night splint

o The patient cannot stand upright

Patients with drop foot

- Inclusion

Age: >= 18 years

Gender: any gender

Pathology: drop foot

Patient is already wearing foot orthosis for drop foot

Patient is able to walk at least 10 meters with or without the assistance of an aid (such as a cane)

- Exclusion

Wearing bilateral orthosis

Wearing other orthosis (such as corset)

Having a mental disorder

The patient is pregnant

Patients with knee instability

- Inclusion

o Age: >= 18 years

Gender: any

Pathology: knee instability

Patient is already wearing an orthosis for knee instability

Patient is able to walk at least 10 meters with or without the aid of an aid (such as a cane)

- Exclusion

Wearing a bilateral orthosis

Having a mental disorder, neurological disorder

o The patient is pregnant

All subjects may decide to withdraw from the study at any time without giving a reason.

5. EVALUATION OF SECURITY

Previous studies [1, 7] have shown that there are no particular risks associated with wearing orthoses that are 3D printed as a whole, or with parts that are 3D printed. In particular, in this study the customised parts will be printed, while the parts that will be subjected to the greatest mechanical stress (such as the hinges and straps) are standard orthopaedic parts. This makes the risks as high as with traditionally designed orthoses. Subjects will not be exposed to unacceptable risks.

6. DATAMANAGEMENT

The data entered in the local orthopaedic centres remain on site in the patients' medical files, as is done in the regular course of business, and are only accessible to the doctors on site.

The encrypted patient data are digitally entered into a platform that is specifically used for conducting patient surveys, is shielded and only accessible to the researchers working on this project. At the latest 2 years after the end of the project, the data will remain accessible only to the local orthopaedic centres, as the patient data are included in the patient files there.

7. REFERENCES

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