Research and Studies

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Imp&Acte3D project: Introduction of 3D printing technology for manufacturing of orthoses in West Africa - Clinical aspects

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About the project

The IMP&ACTE 3D Project (3D Printing & Access to Telerehabilitation) was implemented between November 2017 and April 2019 in 3 countries, namely Togo, Mali and Niger. The objective of the study was to see how innovation and, in our specific case, the use of 3D printing technology in orthotics in West Africa can improve access to physical rehabilitation services for the most vulnerable and isolated people in low-income countries and in fragile humanitarian contexts.

About this brief

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About this study

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A. Context of the study

The use of additive manufacturing or so-called 3D printing has seen a strong development in recent years, due to the increase in various new materials and techniques that are becoming available, and also due to the ever-decreasing cost price. There have also been developments in orthopedics for many years concerning the application of digital measurements, digital corrections and 3D printing.

This study examines whether 3D printing of orthoses (night splints, referred to as postural orthoses and AFOs/KAFOs for walking, further referred to as dynamic AFOs/KAFOs) for the lower limbs can help to improve access to orthopedic devices in developing countries. It is investigated whether the 3D printed orthoses are equally effective, and also the costs and feasibility of implementation are also evaluated. Remote support is also provided via videoconferencing.

Specifically, the study is conducted in 3 West African countries: Togo, Niger and Mali. A total of four orthopedic centers are involved, where a proportionate number of patients is recruited everywhere.

There are 2 groups of patients, those who need an (knee) ankle foot orthosis to walk (dynamic AFO / KAFO) and those who need a night splint to correct the ankle or knee position. All patients in the study received a treatment program in which a new traditional orthosis is fitted, and where a new 3D printed orthosis is fitted. The order of application of both treatments is randomized in a crossover design. The patient is measured at the start of the trajectory (baseline) after the first treatment and after the second treatment period. The primary outcome measures are different for both groups of patients: the walking time when performing the 10 meters walk test in the patients wearing the dynamic AFO / KAFO, and the measured angle (knee or ankle) in patients with a postural orthosis.

There are recent scientific studies showing that the functional clinical parameters in patients with lower-knee orthoses are similar in traditional and 3D-printed orthoses. These studies have been carried out with the production techniques that are available in Western countries.

The potential for the use of 3D scanning and 3D printing in developing countries is large. There are few larger-scale studies on the use of 3D printing for lower leg orthoses in developing countries. This study hopes to fill this gap to some extent.

B. General and specific objectives

The research part of this study has 3 goals:

1. Check whether the clinical impact of 3D printed lower leg orthoses is similar to traditional orthoses,
2. Evaluating patient satisfaction with traditional and 3D printed lower leg orthoses,
3. Investigating the cost of 3D printed lower leg orthoses, and evaluating the impact of the implementation of the new measurement and production workflow.

C. Methods

Adult patients (>18 years) with ankle instability (e.g. due to drop foot), or knee instability (e.g. as a result of polio) were recruited and fitted with a dynamic AFO and KAFO, respectively. Children (between 2 and 8 years) with a deformity of the ankle joint or genu varum/valgum were recruited and fitted with a postural AFO and KAFO, respectively.

All patients received a conventional and 3D printed orthosis in a crossover design. After they were equipped with an orthosis, they went back home and wore the device a home during 2 weeks (dynamic orthosis) or 25 days (night splint). When returning to the center, they were clinically tested, and interviewed.

From a clinical perspective, the 10 meters walk test was performed by patients fitted with a dynamic orthosis, and the ankle or knee angles were measured by patients fitted with a postural orthosis. All patients filled in the OPUS Satisfaction with Devices questionnaire to evaluate the patient satisfaction. All different production steps were timed and the costs of the material and components were registered, to be able to compare the production process of the conventional and 3D printed orthoses. Lastly, the implementation process of the study was evaluated.

A repeated measures analysis of variance was performed to test for significant differences in measurements at different time points. To compare paired data, which did not include different time points, paired t-tests or Wilcoxon signed rank tests were performed, depending on the type of data.

D. Findings

When comping the walking times between walking with a conventional and 3D printed orthosis of the 40 patients who completed all evaluations, we observe a statistically significant walking improvement when wearing a conventional orthosis compared to all three evaluations when walking without orthosis (baseline, first evaluation, second evaluation). Similarly, we observe a statistically significant improvement while wearing a 3D printed orthosis versus the three evaluations when walking without orthosis. Furthermore, there is no significant difference between walking with a conventional or 3D printed orthosis.

The improvement of the angles of the 44 patients equipped with a postural orthosis is statistically significant. When investigating the patients fitted with an AFO and KAFO separately, we observe that patients treated for genu varum/valgum (KAFO) showed a statistically significant improvement of the

angle after the first evaluation and second evaluation. The improvement when wearing a conventional or 3D printed was also significant. There was no difference between the conventional and 3D printed orthosis. The improvement of patients treated for a deformity of the ankle joint was not significant.

In patient satisfaction, there was a significant difference on the satisfaction of the durability and managing the weight between the two types of orthoses in favor of the conventional device. Patients find the 3D printed orthosis significantly better looking.

The cost and time of production was in favor of the 3D printed orthosis, mainly due to the longer manual manufacturing of the conventional device, and the lower cost for the filament compared to the material for the production of the conventional orthosis. But for the dynamic orthoses the difference in time is less pronounced and the cost is similar.

When patients had to express a preference for one of both devices, the patients equipped with a postural device were more in favor of the 3D printed one whereas the patients equipped with a dynamic orthosis had a preference for the conventional one. Furthermore, a large majority (82.35%) of the patients preferred the 3D scanning over plaster casting as measurement technique.

E. Conclusion

The 3D printed orthoses seem clinically equivalent to the conventional orthoses.

The weight and durability are points for improvement of the printed devices.

Especially patients fitted with a dynamic 3D printed orthosis indicated that the weight is high. Several fractures of the 3D printed dynamic orthoses were the cause of the lower perceived durability of the 3D printed devices.

Some steps are already taken to improve these two issues, by changing the type of filament (to polypropylene).

If these issues are solved, the way for a broader implementation of 3D printing of orthoses is open, as some other advantages are clear. There seemed to be a certain reduction in cost and time for production, patients like the 3D scanning better than the plaster casting, and the fact that measuring the patient with a scanner is possible, can enable treating patients that live on a remote location, far away from an orthopedic center.

The complete study is available.
To access it, please click here

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