Design and Development of a Specialised Footrest for Foot Restriction During Epiphysiodeses - *Public Summary*

Antony Radstake, BSc Industrial Design Engineering
University of Twente, The Netherlands

This thesis details the development of a footrest designed to properly position and fixate patients' feet during an epiphysiodesis. This assignment was issued by orthopaedic surgeons at the Medisch Spectrum Twente (MST).

INTRODUCTION

In 2023 the Netherlands is the country with the tallest people in the world [1]. Although a tall stature can prove advantageous, in extreme cases it can have a negative impact on a person's life. Excessive growth can lead to both psychological and physical problems, such as difficulties finding fitting clothing, shoes, and modes of transportation [2].

Each year, approximately 150 children are treated for excessive growth in their feet in the Netherlands [3]. The projected growth is reduced through a procedure called an epiphysiodesis, where the epiphyseal plates in the metatarsals are fused.

Although this surgery is conducted globally, the Netherlands is the only country that performs it with the express purpose of stunting excessive growth [4]. Because of this there has been a lack in the development of specialised medical instruments, such as those capable of restricting the feet during an epiphysiodesis. Consequently, the surgeons currently have to position and stabilise the foot manually using one hand, while performing the surgery with the other. This onerous method makes the surgery needlessly impractical to perform and increases the amount of radiographs required throughout the surgery, which in turn increases the risk of radiation related diseases for both the patient and the surgeon.

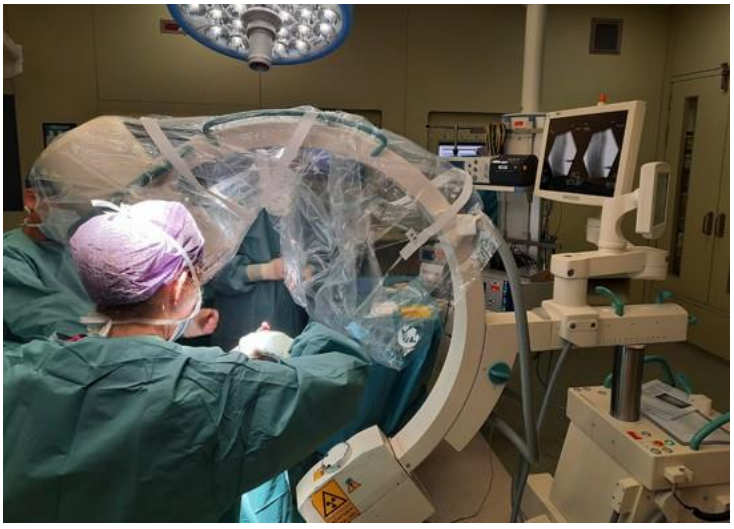

Figure 1: Image of the operating room during an epiphysiodesis

RESEARCH

In order to design a footrest that is capable of remedying this problem, the context in which the footrest will be used needs to be researched. Firstly, multiple epiphysiodesis are attended to better understand the challenges that the orthopaedic surgeons are currently facing. Following this, the main research question is developed:

How can a footrest be designed to fix the metatarsals of the patient's foot (relative to the operating table) during an epiphysiodesis surgery, while retaining the required access to the foot and the ability to identify the metatarsals using radiographs, in order to make it easier to perform the surgery and minimise the required amount of radiographs.

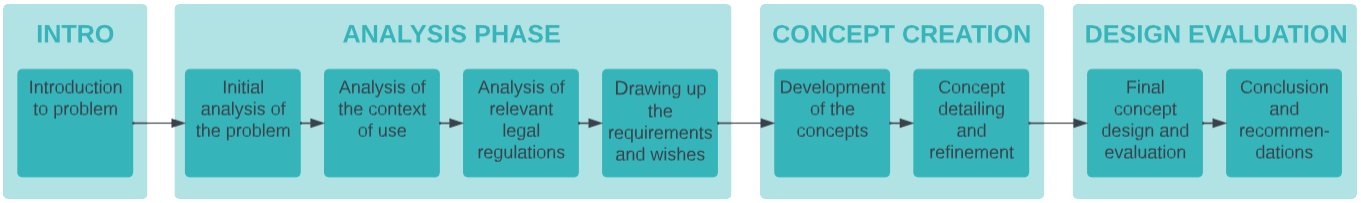

Figure 2: Overview of research structure

In order to answer this question, the operating room and operating table are analysed. Following this, research is conducted concerning the storage, transport and sterilisation of medical instruments at the MST (Figure 3). Lastly, to ensure that the development of the footrest adheres to all legal standards, the medical device regulations (Regulation (EU) 2017/745) concerning the in-house development of medical instruments is perused. Based on this analysis, the requirements pertaining to the footrest are developed.

Figure 3: Operating room (left), operating table (middle) and sterilised medical equipment for ab epiphysiodesis (right)

RESULTS

Following this research, three concepts are developed and evaluated together with the orthopaedic surgeon that issued and guided the development of the footrest. Based on the results of the evaluation, one of the concepts is adapted, resulting in a fourth concept. A first iteration prototype of this concept is developed to assist during the evaluation of the fourth concept. This evaluation culminates in a final concept, leading to the construction of a functional, full-scale prototype. This prototype is used to assess the functionality of the final concept in its context of use.

Figure 4: Digital renders of the final concept design

This prototype evaluation test identified several necessary design adaptations, most notably that the angle that the footrest places the patients foot in should be reduced. This likely negates the need for the elastic bands around the forefoot to adequately restrict the patient's foot.

Figure 5: Testing the usability of the final concept design using the prototype in the OR

CONCLUSIONS

Although the final concept requires some design adaptations, significant progress towards the development of the issued footrest has been attained.

The shape of the footrest, in combination with the memory foam included around the ankle, provides a comfortable and secure fit for the different foot sizes that the footrest is intended for (EU 39-46). The elastic band around the ankle is easy to install and pulls the foot into the footrest; it provides the required fixation of the foot, while retaining the comfort of the patient.

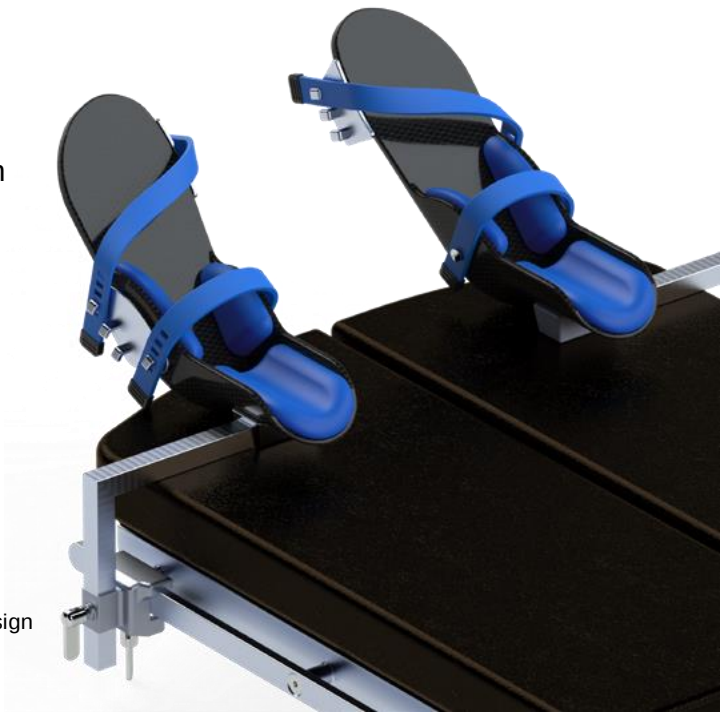

Figure 6: Digital render of the final concept design

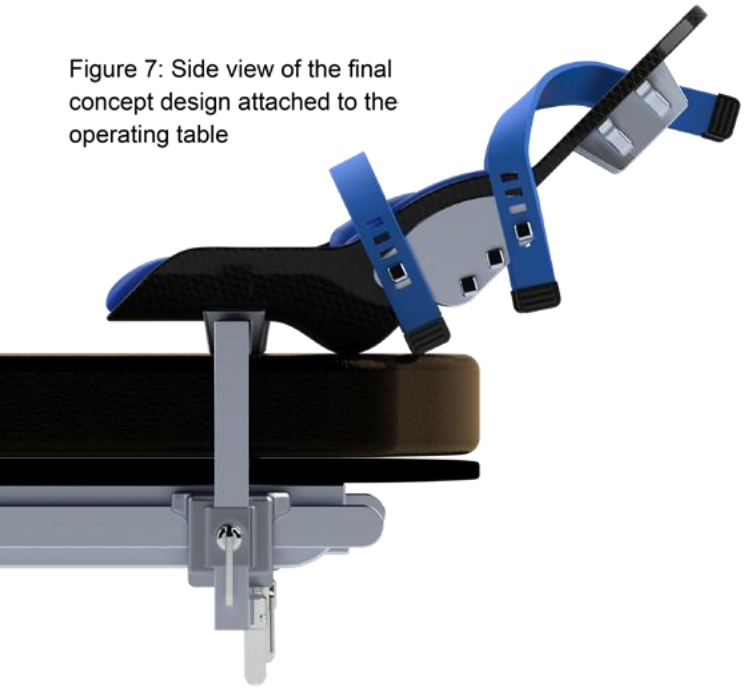

Figure 7: Side view of the final concept design attached to the operating table

The system included on the footrest that allows it to be installed on operating tables employs components very similar to those already in use at the MST. This makes the installation process easy and intuitive; the surgeons and surgical assistants were able to install the prototype of the footrest without the need of any instructions or guidance.

In addition to this, carbon fibre has been found to be a very suitable material for the body of the footrest. Although expensive, making the body out of carbon fibre ensures that the footrest does not interfere with any of the radiographs required throughout the epiphysiodesis. It is furthermore a very light and durable material, that has been shown to be biocompatible and chemically resistant to the disinfectants used on similar medical instruments.

In order to continue the development of this footrest, a new prototype that features the required design adaptations should be manufactured and used to evaluate the usability of the footrest. After the design is finalised using this method, a more detailed material and production analysis should be conducted. Following this analysis, medical instrument manufacturers can be approached, and the required legal procedures should be initiated.

REFERENCES

[1] World Population Review, “Average Height By Country 2020,” Worldpopulationreview, 2023. https://worldpopulationreview.com/country-rankings/average-height-by-country (accessed Sep. 12, 2023).

[2] R. J. Odink, W. M. Gerver, M. Heeg, C. W. Rouwé, W. M. Bakker, and P. J. Sauer, “Reduction of excessive height in boys by bilateral percutaneous epiphysiodesis around the knee,” European Journal of Pediatrics, vol. 165, no. 1, Oct. 2005, doi: https://doi.org/10.1007/s00431-005-1722-z.

[3] I. Ghanem, J. A. Karam, and R. F. Widmann, “Surgical epiphysiodesis indications and techniques: update,” Current Opinion in Pediatrics, vol. 23, no. 1, pp. 53–59, Feb. 2011, doi: https://doi.org/10.1097/mop.0b013e32834231b3.

[4] Y. den Hartog, “Epiphysiodesis Attendance and Interview,” Oct. 03, 2023.