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Development of Adjustable Lower Extremity Abduction Apparatus

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Abstract

Background: Currently, devices and pillows are used to provide abduction between the lower extremities after total hip replacement. However, the pillows used are not individually adjustable, are too large for short patients, and are not large enough for tall patients. This can prevent hip abduction at the recommended angle of 15°-20°, leading to complications such as prosthesis slippage and delayed healing.

Aim: The Adjustable Lower Extremity Abduction Apparatus was developed as an innovative, adjustable device designed to prevent dislocation and assist with walking in patients who have undergone total hip replacement surgery.

Methods: A new apparatus was planned to improve the present system, increase patient comfort, develop a product that minimizes the risk of dislocation, and increase the effectiveness of post-operative care. A literature review was conducted, and the researchers created the Adjustable Lower Extremity Abduction Apparatus, a novel invention. The researcher then carried out the drawing and design phase of the device. Patenting procedures were completed (Patent Application No: 2021/021259). The prototype processes and evaluation stages of the designed device were also carried out.

Results: The research and development (R&D) process for the Adjustable Lower Extremity Abduction Apparatus was conducted. Following the evaluation of the extracted protopin on both healthy and sick individuals, it was determined that the apparatus is an innovative product that supports dislocation and walking, stabilizes the angle between the legs, mitigates risks to patient safety and financial losses, and enhances healthcare quality and patient satisfaction. This apparatus has not yet been commercially used either abroad or in Türkiye.

Conclusion: Upon evaluating the results of the R&D process, it was determined that an innovative product has been created to eliminate situations that may pose a risk to patient safety and financial loss, and to improve the quality of care.

Keywords: Abduction, dislocation, gait, lower extremity, total hip replacement

Introduction

Total hip replacement (THR) is surgery to replace a severely damaged hip joint with an arthroplasty prosthesis.[1] Dislocation can occur with excessive postoperative movements that exceed the limits of the prosthesis.[2] Dislocation is the most common complication after THR surgery.[3] After THR surgery, pillows are placed between the patient's legs to provide abduction of the hip at recommended angles.[4] The pillows used in clinics for this purpose are generally basic. Over the years, positioning pillows with different characteristics have been designed. Although the designed pillows are more effective in the hip abduction process compared to other pillows, they do not fully meet the requirements due to the lack of individual adjustment, ease of use, and ergonomics.[5-8]

Today, the number of total hip replacement surgeries is gradually increasing in parallel with the increase in life expectancy and musculoskeletal problems.[9] According to the data of the Turkish Statistical Institute's report for the year 2022, there are 8,451,669 million people over the age of 65, representing 9.9% of the total population.[10] According to the 2023 Organisation for Economic Co-operation and Development (OECD) health statistics in Türkiye, 55 out of every 100,000 people underwent THR surgery.[9]

The main aim of surgical treatment is to improve the functional level and quality of life by reducing pain, increasing stabilization, and increasing the range of motion.[1] However, patients can develop various complications after surgery. These include dislocation, thromboembolism, excessive wound drainage, infection, and heel pressure ulcers.[4] Dislocation is the most common complication following THR surgery.[3] Dislocation can occur with

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excessive movement beyond the limits of the prosthesis.[2] Healthcare professionals should help prevent dislocation by educating the patient on how to abduct the leg.[11]

Given the lack of standardization in the current range of pillows and the insufficient number of studies evaluating their efficacy, there is a need to develop a standard apparatus that can be adjusted according to the characteristics of each individual.

Innovations and changes in the health system directly affect human life and quality of life. Innovation involves the process of converting either existing or new information into a commercial benefit.[12] The healthcare sector is a key area where innovation is frequently applied. Hospitals, as providers of health services, should display novel approaches to adapt to change and sustainability, and to better meet the needs of health professionals and patients.[13]

In this study, the Research and Development (R&D) process of a novel adjustable lower limb abduction apparatus was evaluated, taking into account the importance of innovative approaches. This product is intended for use after total hip replacement surgery.

Today, the devices and pillows used to provide an opening between the lower extremities of patients after surgery come in standard sizes and shapes and are not adjustable according to the height and weight of the patient. These products are not manufactured to a standard and cannot be customized. As they are not adjustable according to the patient's height and weight, they are difficult to use. McDonald[14] reported that the relative risk of suffering an acute hip dislocation was 2.25 times higher if the hip abduction pillow was utilized. Effective limb opening cannot be provided and complications such as prosthesis dislocation and delayed healing may occur.[8] The development of the Adjustable Lower Extremity Abduction Device was planned within all these requirements. In this article, the R&D process of the adjustable lower extremity abduction apparatus, which is an innovative product, was included.

Materials and Methods

Innovation is a procedure entailing the conversion of fresh, inventive ideas or inventions into outcomes that generate value by modifying and implementing them in economic domains while delivering them to the market.[12] This procedure consists of five successive phases from concept to product. The development of an innovative product involves a number of distinct stages. The first is defining the problem to be solved, followed by developing the product idea and conducting research to inform the development process. Visual drawings of the product are then created before beginning the prototype process. Certification in the form of either a patent or utility model marks the next stage, after which the product is brought to life. Finally, a brand is created and promotion is undertaken to bring the product to market.[12]

In this study, the research and development (R&D) processes of an innovative product were evaluated based on the steps of the innovation process. The study was conducted from April 2020 to July 2022, with the goal of developing an adjustable apparatus designed to prevent dislocation and assist with walking in patients who have undergone total hip replacement surgery. We took into account the current difficulties (Figure 1-3) when developing the Adjustable Lower Limb Abduction Apparatus (Figure 5-7), an innovative invention in its field.

A series of steps were followed throughout the innovation process of the Adjustable Lower Limb Abduction Apparatus.

The following outlines the development process of the Adjustable Lower Extremity Abduction Apparatus (ALEAA):

- Initially, the problems and defects in the current abduction apparatus system were identified following total hip replacement surgeries.
- In order to optimize the system, enhance patient comfort, prevent complications, and enhance patient satisfaction, it was proposed to develop the ALEAA following THR operations.
- A comprehensive literature review was conducted, and patents for the apparatus currently in use worldwide and in Türkiye were analyzed.[5-8]
- A new ALEAA, representing a novel invention, was designed with the objective of overcoming the limitations of existing products. The researchers were responsible for the conceptualization and design phases.

Firstly, a comprehensive similarity analysis was conducted on the product in question, both globally and within our own country. This revealed that the "Adjustable Lower Extremity Abduction Apparatus" is distinct from other products in the field—both internationally and domestically—due to its unique features. Consequently, it can be concluded that the product in question possesses a distinctive feature set within its respective market.

- The product, which had been developed, was named the Adjustable Lower Extremity Abduction Apparatus.
- A patent application (Patent application no: 2021/021259) was submitted to the Turkish Patent and Trademark Office with the intention of protecting the invention under the scope of the Intellectual Property Law.
- A grant application related to the ALEAA was submitted. The grant was subsequently supported (Grant no: BAP.2022.01.03).
- While the patent procurement process was ongoing, plans were formulated for the prototype development phase of the product. The prototype was created with the assistance of engineers.
- The required permissions and approvals for the utilization of the designed ALEAA prototype on healthy individuals and patients have been obtained.
- Once the required permissions had been obtained for the implementation of ALEAA, the initial trial was conducted on ten healthy volunteers, who subsequently agreed to participate in the study. Following the completion of the evaluation process, modifications were made to the apparatus.
- Following the revision, the preliminary application was conducted once more on ten healthy volunteers, who were subsequently approved. Expert physician coordination was provided throughout the implementation process. Final revisions were made to the prototype in accordance with the results of the implementation, suggestions from healthy volunteers, expert opinions, and the final version of ALEAA was provided.

Ethical Considerations

The research was conducted with the required permissions and was subject to evaluation and approval by Bahcesehir University Clinical Research Ethics Committee (Approval Number: 2020–11/07, Date: 2.9.2024)ç All principles of the Helsinki Declaration, Good Clinical Practices, and Good Laboratory Practices were followed throughout the study. Informed consent was read and signed by all participants.

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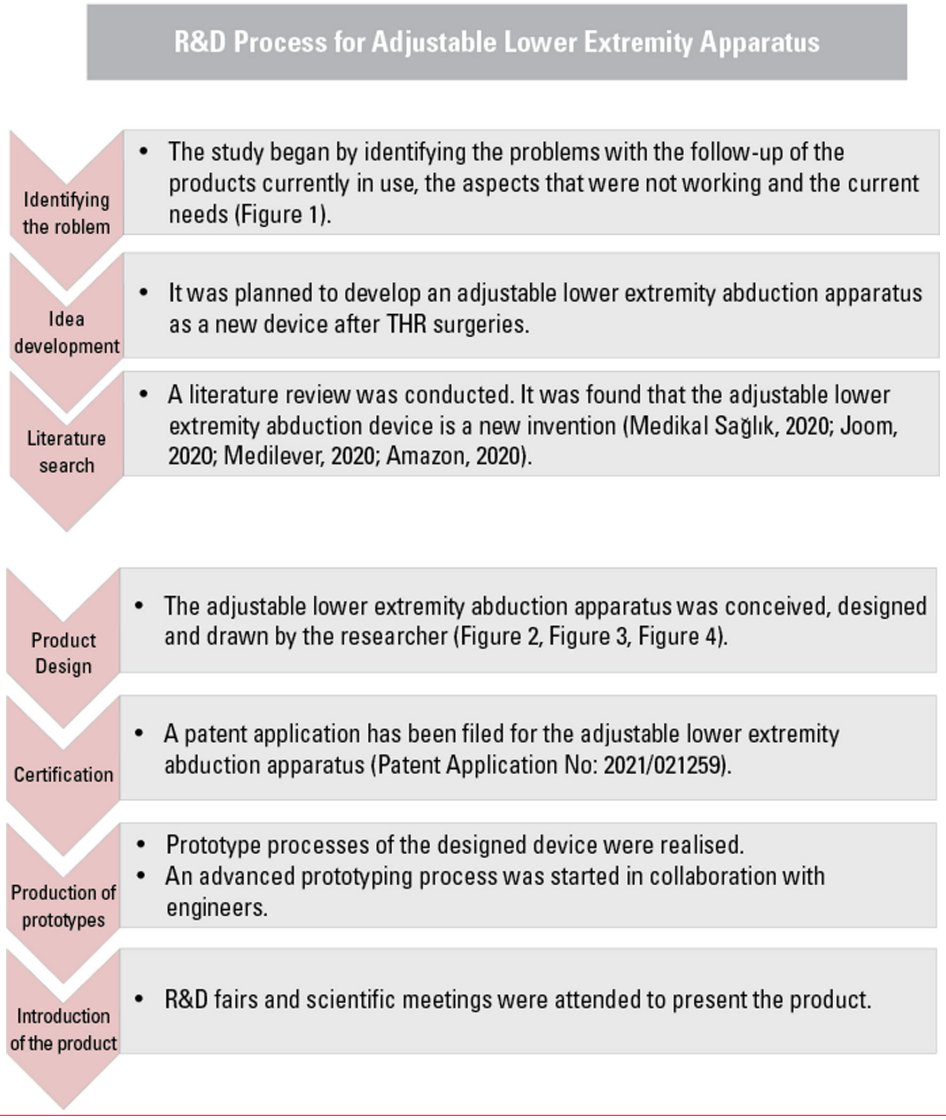

Figure 1. Research and Development (R&D) process of the Adjustable Lower Extremity Abduction Apparatus.

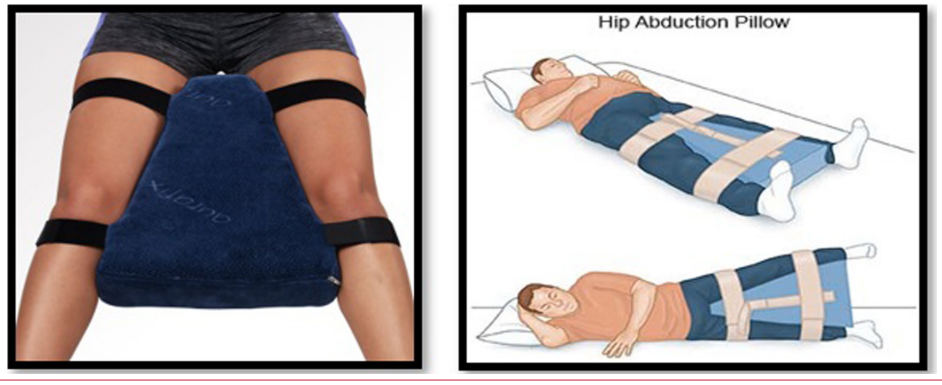

Figure 2. Current pillows used for hip support [Link to hip pillows on Amazon] (https://www.amazon.com/slp/hip-pillows/ujuyjx84ce8t5xz) (Accessed: May 26, 2020).

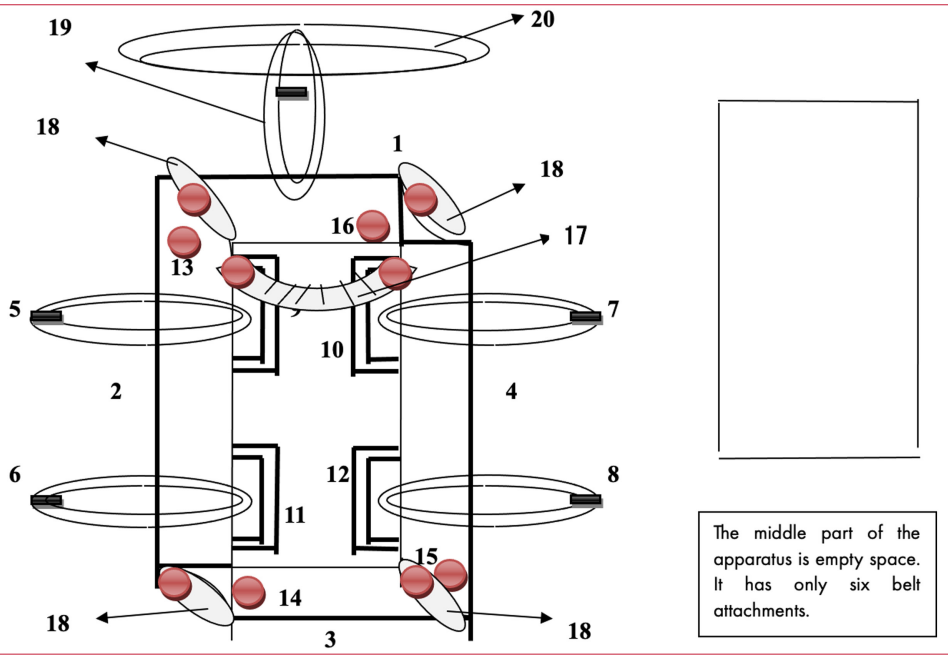

Figure 3. Compact configuration of the Adjustable Lower Limb Abduction Apparatus.

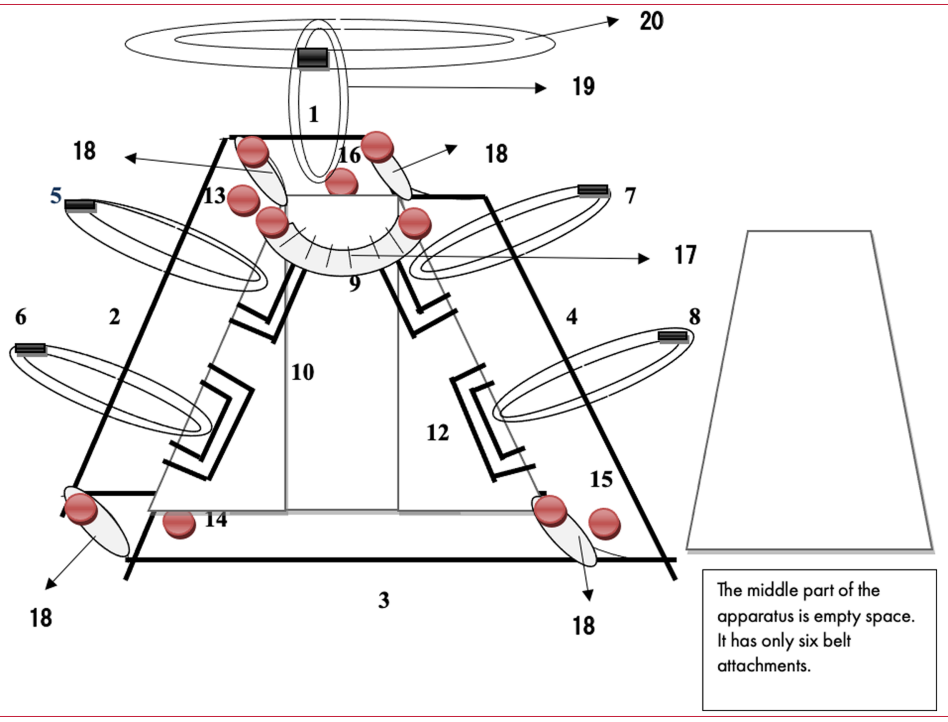

Figure 4. Expanded configuration of the Adjustable Lower Limb Abduction Apparatus.

An agreement on confidentiality was established with the engineering teams involved in the R&D processes to ensure product safety.

Discussion

One of the most common complications following total hip replacement surgery is dislocation.[3] A study conducted in the United States between 2017 and 2019 revealed that dislocation was the second most common reason for revision surgery, accounting for 18.3% of cases. The financial impact of revision surgeries on the healthcare system was estimated at $100,191.[15] In a retrospective cohort study of patients undergoing total hip replacement by Müller et al.,[16] the mortality rate after one year of follow-up was 9% in patients who underwent revision surgery after dislocation.

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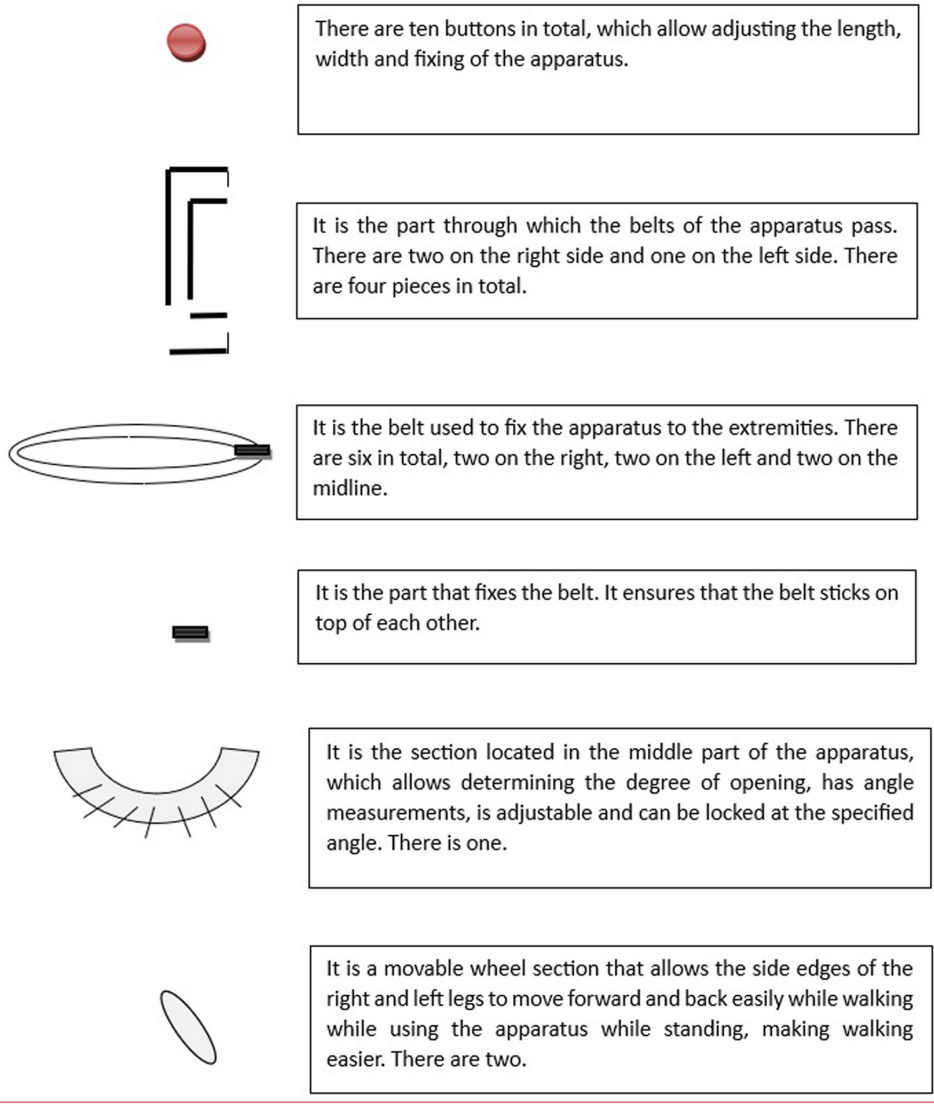

Figure 5. Components of the Adjustable Lower Extremity Abduction Apparatus: (1) Upper Part: Minimum width is 15 cm; can expand up to 20 cm via a control button. (2) Right Side Part: Minimum length is 45 cm; can extend up to 70 cm via a control button. (3) Lower Part: Minimum width is 15 cm; can expand up to 46 cm via a control button. (4) Left Side Part: Minimum length is 45 cm; can extend up to 70 cm via a control button.

Currently, the apparatus that creates an opening between the lower extremities of patients after surgery is only available in standard sizes and formats and is not adjustable to suit the individual's height and weight. These products are not manufactured according to a specific standard and are not customizable. The lack of customizability may result in insufficient limb opening and complications such as prosthetic slippage, which may impede recovery.

Due to the lack of standardization of pillows for each individual and insufficient studies evaluating their effectiveness, a standard apparatus that could be adapted according to each individual's characteristics was essential.

A cohort study conducted by Lemme et al.[17] examined 1,940 patients between 2015 and 2020 to assess complications and re-operation risk after total hip replacement and found a dislocation rate of 1.56%. In a study by McDonald[14] investigating the effect of abduction pad use on dislocation after total hip arthroplasty, it was reported that the use of an abduction pad increased the risk of acute dislocation by 2.5 times.

The study, conducted by Yuan et al.,[18] determined that THR surgery had an impact on the patients' daily activity, even though there was no significant difference in the Barthel scores of the control group prior to and one month following surgery. In this randomized controlled trial examining the influence of pain, movement, and fear of falling on the daily activity of patients who underwent total hip replacement, the Barthel score was 54.86 ± 5.64 at the first month after surgery.[18]

One of the most significant challenges following total hip replacement surgery is the limitation of mobility. This, in turn, results in the development of complications. The present study encompassed the entire process, from the initial concept to the final product, and evaluated the opinions of both healthy individuals and patients

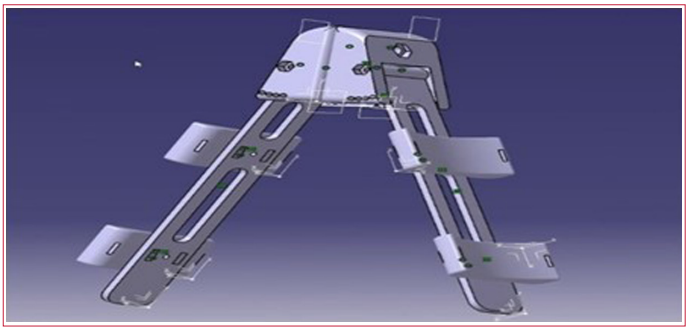

Figure 6. 3D illustration of the Adjustable Lower Extremity Abduction Apparatus.

throughout the development phase. During the evaluation process, it was determined that users expressed satisfaction with the apparatus during both lying and walking. They also indicated that the apparatus was comfortable, particularly due to its individual-based adjustment feature. In this regard, it was demonstrated that the use of the "Adjustable Lower Extremity Abduction Apparatus" with its individual-based adjustable feature, movement feature in the walking process, and soft and comfortable structure is efficacious in augmenting daily life activities (intra-pedestrian movements, sitting, walking, etc.) in patients.

Failure to ensure adequate limb opening after total hip replacement surgery can result in prosthesis slippage (dislocation), leading to suboptimal surgical outcomes, the need for a second operation, increased care costs, extended hospital stays, and heightened morbidity and mortality. The use of the Adjustable Lower Extremity Abduction Apparatus we have developed will eliminate this healing problem, situations that may pose a risk to patient safety and financial losses. The quality of healthcare will improve with this product, which is in high demand worldwide, thereby reducing our technological dependence on foreign countries.

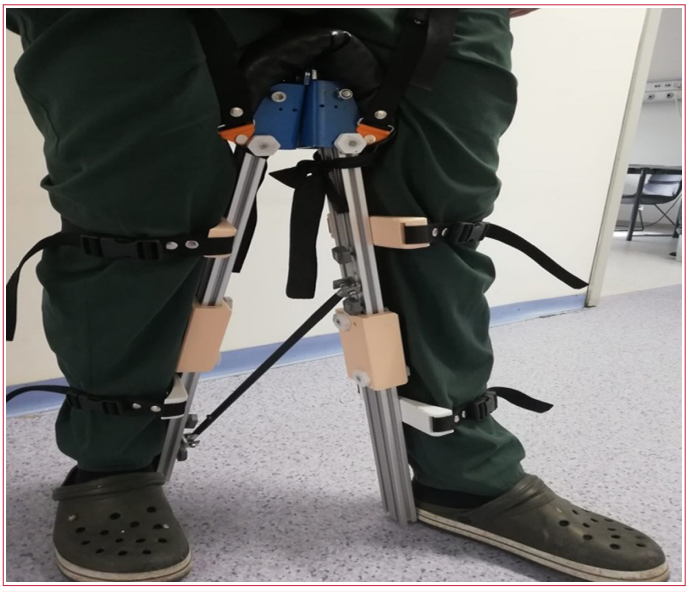

Figure 7. Adjustable Lower Extremity Abduction Apparatus.

Upon the completion of the research and development process for the adjustable lower extremity abduction apparatus, it can be observed that the apparatus possesses the following characteristics:

- The adjustable lower extremity abduction apparatus is equipped with features designed to facilitate the patient's positioning in bed, controlled movement in bed, and walking process.
- The mechanism of the knobs is integrated with wheel and rail systems and boasts a locking feature to adjust the "Adjustable Lower Limb Abduction Apparatus" as per the patient's characteristics and prevent inadvertent changes of the dimensions and degrees. It can be adjusted to vary the width or length of the area in which it is situated.
- The central part includes angle measurements and enables the determination of the degree of separation between the legs. This can then be locked securely at the chosen angle, thereby providing the recommended level of abduction to prevent dislocation. The central part includes angle measurements and enables the determination of the degree of separation between the legs. For added safety, it includes a locking feature.
- It is also designed for patient comfort, featuring a soft-filled, leather-coated surface.
- It can be disinfected due to its leather surface coating, thus eliminating the risk of transmission of infections from one patient to another.

Conclusion

Upon evaluating the results of the R&D process, it was determined that an innovative product has been created to eliminate situations that may pose a risk to patient safety and financial loss, and to improve the quality of care.

Acknowledgement: We thank R&D team for their support and all patients for their collaboration.

Ethics Committee Approval: Ethics committee approval was obtained from Bahcesehir University Clinical Research Ethics Committee (Approval Number: 2020–11/07, Date: 2.9.2024).

Informed Consent: Informed consent was read and signed by all participants.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – T.T., F.E.A., Y.D.M.; Design – T.T., F.E.A., Y.D.M.; Supervision – F.E.A., Y.D.M.; Materials – T.T.; Data Collection and/or Processing – T.T.; Analysis and/or Interpretation – T.T.; Literature Review – T.T.; Writing – T.T.; Critical Review – F.E.A., Y.D.M.

Conflict of Interest: The authors have no conflicts of interest to declare.

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