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Original Research

DESIGN FOR ASSEMBLY: WRIST ORTHOSIS DESIGN CONCEPTS PROPOSALS

PROJEKTOWANIE POD KĄTEM MONTAŻU: PROPOZYCJE KONCEPCJI ORTEZ NADGARSTKA

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Abstract

This study investigates the integration of modern engineering techniques, including 3D scanning and additive manufacturing, in the design and production of wrist orthoses. The research aims to enhance orthotic devices by proposing three innovative fastening methods - Velcro straps, screws, and magnets - designed for use with 3D-printed orthoses. The study outlines the entire process from patient hand scanning to the final orthosis creation, emphasizing the precision and customization afforded by these advanced technologies. The proposed designs are intended to improve the comfort, effectiveness, and usability of orthoses for patients with musculoskeletal dysfunctions. The findings demonstrate the potential for significant advancements in personalized medical devices, offering new avenues for rehabilitation and patient care.

Keywords: orthosis, 3D scanning, additive manufacturing, fastening methods

Streszczenie

Niniejsze badanie analizuje integrację nowoczesnych technik inżynieryjnych, w tym skanowania 3D i wytwarzania przyrostowego, w projektowaniu i produkcji ortez nadgarstka. Celem badań jest udoskonalenie urządzeń ortotycznych poprzez zaproponowanie trzech innowacyjnych metod mocowania – pasków na rzep, śrub oraz magnesów – przeznaczonych do użytku z ortezami wydrukowanymi w technologii 3D. Badanie przedstawia cały proces, od skanowania dłoni pacjenta po końcowe stworzenie ortezy, z naciskiem na precyzję i możliwość personalizacji, jakie zapewniają te zaawansowane technologie. Proponowane projekty mają na celu poprawę komfortu, skuteczności i użyteczności ortez dla pacjentów z dysfunkcjami układu mięśniowo-szkieletowego. Wyniki wskazują na potencjał znacznych postępów w dziedzinie spersonalizowanych urządzeń medycznych, oferując nowe możliwości w zakresie rehabilitacji i opieki nad pacjentem.

Słowa kluczowe: orteza, skanowanie 3D, wytwarzanie przyrostowe, metody mocowania

1. Introduction

Modern medicine requires innovative solutions to meet the growing expectations of patients in developed and emerging regions. The ongoing improvement of existing treatment methods is driven by advances not only in medicine but also in technology and engineering. Rapid prototyping (RP), particularly additive manufacturing (AM), has become popular in recent years as an alternative method for making prototypes. For example, in the automotive industry, AM prototypes are used to validate engineering processes (Jiménez et al. 2019).

AM techniques, due to their speed and cost-effectiveness, have attracted interest in various fields, including industrial design, automotive, manufacturing, as well as medicine, and biomedical and tissue engineering. In the medical field, 3D printing is used to create custom medical products such as prostheses, implants, surgical tools, and orthoses that are tailored to the anatomy of the patient (Jiménez et al. 2019; Kumar and Sarangi, 2021; Pathak et al. 2023).

Implants, prostheses, and orthoses are designed to correct and alleviate dysfunction and disability (Hailey, 1995). However there are some differences between them. An implant is an internal medical device placed in the body to replace or support a damaged structure, a prosthesis is a device that replaces a missing body part, and an orthosis is an external medical device used to stabilize, support, or correct musculoskeletal dysfunctions (Chen et al. 2016).

Using AM techniques for the production of medical devices allows them to be precisely tailored to each patient's unique anatomical characteristics, increasing comfort and effectiveness. Achieving these features is unlikely with universally mass-produced medical devices. Furthermore, this type of personalization leads to better patient outcomes and greater satisfaction (Pathak et al. 2023; Tserovski et al. 2019). Furthermore, as indicated by Boretti (2024), 3D printing reduces production time and costs while offering patients the same or better functionality. This is particularly beneficial in cases where traditional methods can cause discomfort due to bulkiness or poor fit (Oud et al. 2021).

Musculoskeletal disorders (MSDs) are prevalent conditions that significantly affect the quality of life and functional abilities of individuals. As indicated by Mohaddis (2023), the use of orthoses as a treatment modality for these disorders is common and well documented in clinical practice. Orthoses, commonly used to limit joint mobility, have been employedfor more than 150 years in the treatment of various musculoskeletal conditions (Mohaddis, 2023). However, they are not only useful for immobilizing fractured limbs; postoperative (Donato et al. 2023), and rehabilitative (Mohaddis, 2023) variants are also popular. They are routinely prescribed to improve mobility in children and adults with neurological disorders such as cerebral palsy, Charcot-Marie-Tooth disease, stroke, and multiple sclerosis (Haque et al. 2023); there is also potential to help with Patellofemoral pain syndrome (PFPS) (Smith et al. 2015).

Orthotic devices (orthoses) can be divided into three types based on the anatomical structure of the human body: spinal orthoses, upper limb orthoses, and lower limb orthoses. Names indicate the specific anatomical joints and body parts that each orthosis supports (Nouri et al. 2023). For example, one of the orthoses for the upper extremity is a wrist hand orthosis (WHO) that covers the wrist and hand, including fingers (Costa, 2024). A rehabilitative WHO, such as a dynamic splint, is used to aid in recovery of hand function after injury, surgery, or neurological condition (Gilanlıoğulları and Soyer, 2024; Zhou et al. 2024). This type of orthosis provides controlled movement and support to the fingers, wrist, and hand, facilitating the rehabilitation process by improving range of motion, reducing stiffness, and assisting in muscle re-education (Yang et al. 2021).

Different types of fastening are used in the design of orthoses. For instance, Poier et al. (2021b) used for their design of wrist orthosis velcro straps, Li and Tanaka (2018) used elements such as velcro straps and screws, whereas Paterson (2013) used a very unique fastening system that incorporates rubber bands. Moreover, the parts of orthosis could be also connected by a snap fit shape connection, such as in the project by Górski et al. (2020).

The choice of fastening plays a critical role in both the effectiveness and user comfort of the orthosis. According to the study by Ferrari et al. (2021), fastening systems significantly influence how well an orthosis fits the user. A popular option for fastening rehabilitative orthoses due to their ease of adjustment and user-friendly application are velcro straps, as confirmed by studies such as Poier et al. (2021b), Li and Tanaka (2018), and Cazon et al. (2017). 3D-printed orthoses offer significant advantages over traditional methods such as mass-produced ones or plaster casts (Oud et al. 2021; Zhou et al. 2024). These include superior customization, allowing precise tailoring to an individual's unique anatomical features, which enhances both comfort and effectiveness (Oud et al. 2021). Using AM to produce custom orthoses allows for rapid and cost-effective production (Pathak et al. 2023). Moreover, it allows for a more flexible approach to design (Zhou et al. 2024). The freedom of design enables the creation of highly specialized and personalized orthoses, including the incorporation of various fastening methods to meet the needs and preferences of the individual patient (Li and Tanaka, 2018; Jiménez et al. 2019).

The goal of this paper is to design a personalized 3D-printed wrist orthosis, while also exploring different fastening methods to enhance its adherence and effectiveness. To achieve this, a systematic product development process was followed, including concept generation, evaluation of various fastening options (such as Velcro straps, screws, and magnets), and final product specification. This paper will discuss the design process, the selection criteria for fastening methods, and the overall performance of the personalized orthosis.

2. Materials and Methods

2.1. Product Development

At the beginning of product development was to conduct a literature review to generate ideas for different fastening methods for wrist orthoses. Based on the literature, many options for fastening mechanisms were identified. The authors chose two of them: Velcro straps due to their popularity and screws, which were used in only one project. Screws were also considered due to their availability and low cost. Moreover, it was decided to use for fastening mechanism elements such as magnets. To the best of the authors' knowledge, the use of such elements for fastening mechanisms of wrist orthoses has not been described in the literature, and the authors believe it is worth considering due to the availability and low cost of magnets. The next step of product development was to design an initial model of orthosis.

2.2. 3D Model Creation and Processing Workflow

To obtain models of wrist orthoses, modern digital technologies such as 3D scanners and computer-aided design (CAD) were chosen, similar to the approach of Zhou et al. (2024). The creation of the orthosis can be divided into several key stages as shown on Fig. 1.

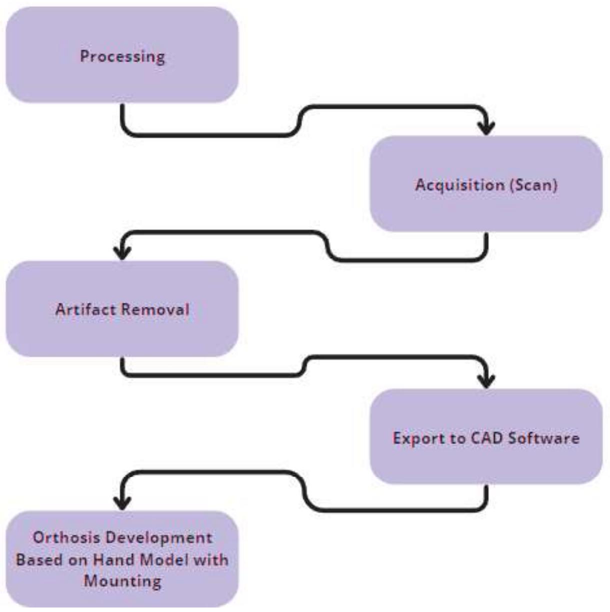

Fig. 1. Process for model creation

Initially, detailed requirements for the orthosis and scanning parameters are established. The patient's hand is then scanned with an 3D scanner to create an accurate digital anatomical model. Preliminary data processing follows to remove any unwanted artifacts and noise, which is crucial for maintaining the model's accuracy. The cleaned model is then exported to specialized CAD software for further processing and customization of the orthosis design. Finally, the orthosis is designed based on the hand model, incorporating appropriate fastenings such as Velcro straps, screws, or magnets, and is thoroughly analyzed for ergonomics, user comfort, and functionality.

2.2.1. Initial model of wrist orthosis

The development of the orthosis began with establishing detailed requirements and scanning parameters. The patient's hand was then scanned using an advanced 3D scanner, creating a digital anatomical model that captured even the smallest details (Kumar and Sarangi 2021; Silva et al. 2024). In this project, a detailed scan of the left hand was performed using the Shining 3D Einstar scanner. This device is equipped with three infrared VCSEL structured light projectors, which are safe for the eyes. The scanning process began with preparing the subject's hand, which included positioning the hand correctly and ensuring optimal lighting conditions to achieve the best results. The entire scanning procedure took less than thirty minutes, demonstrating the efficiency and advanced technology of the device.

Upon completing the scan, an initial 3D model of the hand was obtained, as shown in Fig. 2A. Unfortunately, this model contained several artifacts, which could have resulted from various factors such as hand movement during scanning or light reflections. Preliminary data processing using tools available in the dedicated scanning software (EXStar Software) removed those artifacts and noise to ensure the model accurately reflected the patient's anatomy. This involved using filtering algorithms that automatically identified and eliminated unwanted elements.

The next step was model segmentation, which involved isolating the selected area from the rest of the scanned object. This was achieved by cutting the model with a suitably positioned cutting plane (Fig. 2B). This step was crucial to obtain a model encompassing only the part of the arm and hand where the orthosis would be applied (Fig. 2C). Isolating just this section of the scanned model reduced the file size, which in turn made further processing of the model require less computational power.

The obtained model contained various irregularities, including gaps in the scanned surface. Therefore, it underwent further corrections. The repair of the model was carried out using the same software by employing available editing tools. One of these tools allowed for the reconstruction of missing parts of the model.

As a result of the implemented corrections, a digital model of the upper limb was obtained. The 3D model of the hand was not only free from disturbances but also accurately reflected the real proportions and anatomical structures. This model served as a reference during the modeling of the final orthosis, ensuring the orthosis would meet the requirement of being customized.

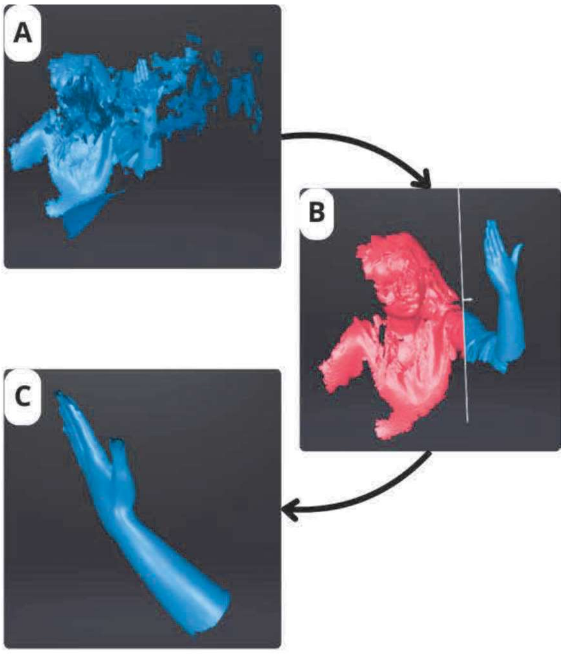

Fig. 2. Three stages of processing the 3D model of the left hand: (A) Raw scan with artifacts, (B) Segmentation and extraction of the hand, (C) Final, corrected 3D model of the hand

The cleaned model was exported to CAD software for further processing and customization. However, the import required file format conversion, as the initial model was a point cloud. This conversion was performed in SpaceClaim software by approximating spline curves. The process involved covering the point cloud with elementary NURBS (non-uniform rational B-spline) surface patches. The resulting model was saved in STEP format.

After importing the model into Autodesk Inventor, the first step was to divide it along the axis of the hand using planes. The model was divided into several parts, where hand outlines were created. Then, the loft function was used, allowing these outlines to be selected and a figure to be formed based on them. This resulted in a model of the hand based on the previous scan, which could be further refined (Fig. 3).

The next step was to create an offset, which involved forming a new solid offset 5 mm from the hand. Another offset was created on this offset model, also offset by 5 mm, which formed the orthosis skeleton. After performing these operations, the hand model and the first offset could be turned off, allowing direct work on the orthosis skeleton.

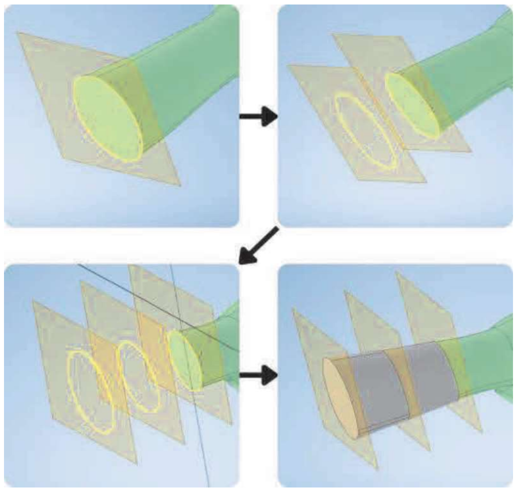

Fig. 3. Shows the stages of creating the model in Autodesk Inventor. The process starts with setting up reference planes (top-left) that define the cross-sectional profiles of the object. More planes are added (top-right) to capture different sections along the length of the model. These cross-sections (bottom-left) guide the creation of the final 3D shape (bottom-right), resulting in a solid model ready for further processing

Cutouts for the fingers and a cutout at the back of the hand, which allows easy insertion of the hand into the orthosis, were added to the orthosis skeleton. The next step was to round all parts to eliminate potential sources of discomfort. As a result, a 3D model of the wrist orthosis without the fastening mechanism was obtained. The next step was to incorporate suitable fastenings, such as Velcro straps, screws, or magnets.

2.2.2. First design - Velcro Fastenings

The first and simplest concept implemented was the use of Velcro fastenings. This straightforward, yet innovative idea offers an exceptional ease of application and removal, particularly important for individuals with rheumatological conditions or those who need to wear an orthosis intermittently. Velcro fastenings provide several advantages, including simplicity and adjustability. They are incredibly user-friendly, allowing quick and effortless fastening and unfastening of the orthosis, greatly facilitating daily use (Bader and Pearcy 1982). Additionally, the adjustability of Velcro enables a customized fit to the individual's specific needs, enhancing comfort and minimizing any discomfort associated with wearing the orthosis, which is crucial for individuals with limited mobility.

Implementation:

1. **Cutout Creation**: Initially, a suitable cutout is made at the back of the orthosis (see photo Fig. 4.) to create the required space for mounting the Velcro.
2. **Velcro Attachment**: The next step involves attaching the Velcro in the designated area,

which required sewing it onto the orthosis. This step required precision and skill to ensure that the Velcro was securely attached and would perform effectively in regular use.

Fig. 4. Back (left photo) and front (right photo) of the 3D model for velcro fastenings

2.2.3. Second design - Screws

The second concept involved the use of screws. In this approach, the orthosis is divided into two parts and printed separately. Special protruding areas were added to allow the orthosis to be screwed together. This method is particularly suitable for individuals who use an orthosis as a substitute for a cast and do not remove it by themselves. The use of screws makes the orthosis more secure and robust, ensuring that it remains in place and functions effectively without the risk of being accidentally removed.

Implementation:

1. **Design Modification:** The orthosis is divided into two parts and printed separately, with special protruding areas to enable it to be screwed together.
2. **Square Nut Integration:** Cutouts are added inside the back half of the orthosis to accommodate a square nut (Fig. 5.) This square nut, printed along with the orthosis, provides a more stable and stronger base for the screws.

Fig. 5. Front (left photo) and close -up of the place for square nut (right photo) of the 3D model for screws

2.2.4. Third design - Magnets

The third concept involves dividing the orthosis into two parts, similar to the previous designs, but using neodymium magnets to join them. This approach is particularly suitable for people who need a secure and easy-to-use fastening method without the complexity of screws or the manual effort required for Velcro. Neodymium magnets provide a strong and reliable connection, ensuring that the orthosis remains firmly in place while also being easy to detach when necessary. This option is ideal for people who require frequent adjustments or need to remove the orthosis quickly and effortlessly, such as children, the elderly, or people undergoing physical therapy.

Implementation:

1. **Design and Integration**: The orthosis is divided into two parts, with neodymium magnets embedded within the material to join them (Fig. 6.).
2. **Magnet Placement**: Internal placement of the magnets ensures that the orthosis remains lightweight and maintains its aesthetic appearance.

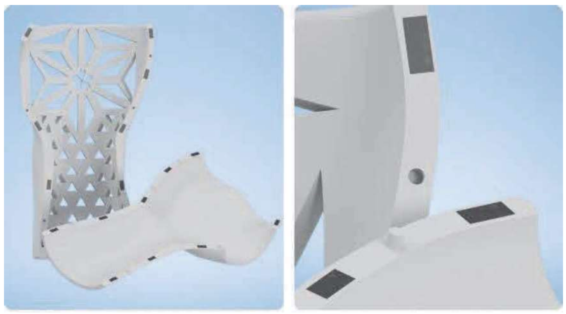

Fig. 6. Two elements of the orthosis (left photo) and close-up of the place for magnets (right photo) of the 3D model for magnets

2.5. Material Selection for 3D printing

For FDM printing, materials such as PLA, ABS, PA (nylon), PETG, TPU, HIPS, and PVA can be used, offering diverse physical and chemical properties. For printing an orthosis mostly three materials are used ABS, PA, and PLA (Jaworska and Podsiadło 2019; Kumar and Sarangi 2021; Steck et al. 2023).

ABS (Acrylonitrile Butadiene Styrene) is characterized by high strength, rigidity, and durability. It is resistant to heat and chemicals, making it suitable for applications requiring high mechanical resistance. Its printability is also high, allowing for precise models. However, ABS is less environmentally friendly compared to PLA and requires a higher printing temperature, which can affect energy costs (Poier et al. 2021a).

PA (Polyamide, Nylon) is distinguished by exceptional strength and durability, as well as resistance to chemicals and heat. It is flexible and abrasion-resistant, making it ideal for applications requiring high resistance to mechanical stress (Kumar and Sarangi 2021). However, printing with nylon can be more demanding due to its hygroscopic nature, which means that it absorbs moisture from the environment.

PLA (Polylactic Acid) is a biodegradable and easy-to-print material, making it environmentally friendly and suitable for less experienced users. PLA offers moderate strength and rigidity, which are sufficient for many medical applications, such as orthoses (Poier et al. 2021b). Its heat and chemicals resistance is lower than ABS and nylon, but its ecological potential and ease of processing make it an ideal choice for this project [9].

2.6. Printing of the chosen design

The first design, which incorporated a fastening mechanism using Velcro straps, was chosen for 3D printing. As shown in Fig. 7B, the model was imported into PrusaSlicer 2.7.4.

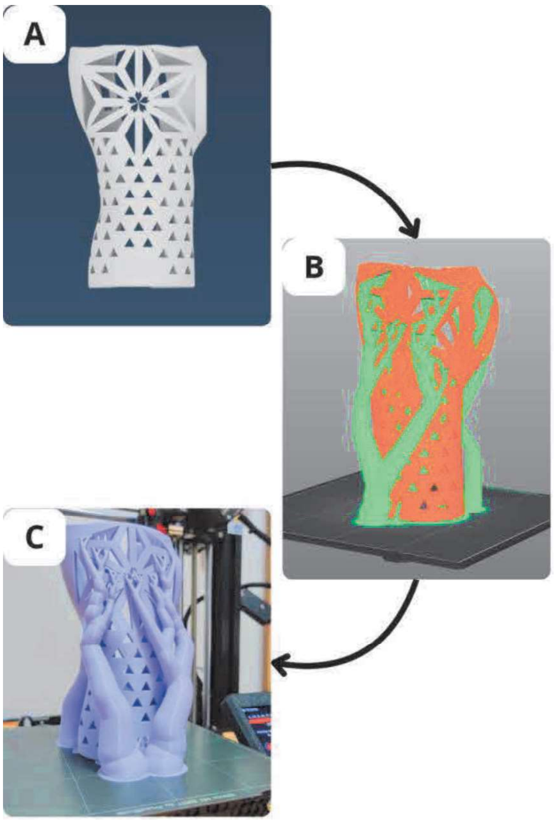

Fig. 7. Stages of the printing process. A - model in Autodesk Inventor. B - model imported into a dedicated Prusa slicer program to prepare it for 3D printing. C - printed model on Prusa Mini 3D printer

The model was positioned on the build plate without internal infill, as its geometric design provides sufficient structural support. Supports were added for overhanging sections to ensure an accurate reproduction of complex geometries. The printing settings included a layer height of 0.2 mm, a nozzle temperature of 210°C, and a bed temperature of 60°C. PLA was the material used for the print. Fig. 7C shows the model after printing on the Prusa Mini, still attached to the build plate with supports intact. The total print time was approximately 5.5 hours, with a material consumption of 90 grams.

After printing is completed, the model is removed from the printer and the supports are removed. Organic supports used in this process allow for easy and quick removal. A special open-cell foam was adhered to the inside of the orthosis.

This particular type of foam was chosen for its properties that allow for better skin breathability, reducing hand sweating, and minimizing the risk of skin irritation. However, several alternatives can also be considered depending on the specific needs of the user.

An alternative to open-cell foam is the use of silicone gel. It is often used because of its ability to evenly distribute pressure, which is beneficial for users with more sensitive skin. Silicone gel also provides excellent cushioning and is very durable, making it an ideal choice for orthoses requiring long-term use.

In the pre-planned locations, fastening elements were placed to ensure proper fit and stability of the orthosis on the patient's limb. In this case, Velcro straps were sewn in which can be seen in Fig. 8. This fastening method allows the user to easily and quickly adjust the orthosis to their individual needs and ensures that the orthosis stays in place.

Fig. 8. Front and back view of the finished wrist orthosis

3. Results and Discussion

The primary objective of this study was to create personalized 3d printed wrist orthosis. The secondary goal was to prepare concepts of three distinct fastening methods for 3D printing orthosis with: Velcro, screws and neodymium magnets. This process started with precise 3D scanning of the patient’s hand. The scanned data were then utilized to create accurate digital anatomical models using advanced CAD software, allowing for the customized design of the orthoses. Each orthosis design incorporated one of the three fastening methods.

Velcro fastenings significantly enhance user-friendliness, especially for those who need to use such medical equipment regularly. Moreover, those are among the most popular methods (especially commercial wise) (Aranceta-Garza and Ross 2021; Coppard and Lohman 2020). This method is so common due to its cost-effectiveness. Velcro straps are inexpensive and readily available, making them an economical choice for orthosis fastenings. Furthermore, the ease of replacement ensures that the orthosis can maintain its functionality over a long period, even if the Velcro wears out. However, one of the challenges associated with Velcro is its tendency to lose grip over time, especially with frequent use and exposure to dirt and moisture (Bader and Pearcy 1982). This requires regular inspection and maintenance to ensure that the orthosis remains effective. Additionally, visible fastening elements can sometimes affect the aesthetic appeal of the orthosis, which may be a consideration for some users.

Using screws for fastening could offer superior stability and durability. Screws are believed to provide a tight and secure connection, ensuring that the orthosis remains in place and does not shift or become loose during use. This is particularly important for patients who require a high level of support and immobilization (Haje and de Podestá Haje 2009). However, the use of screws also presents some challenges. The assembly and disassembly of screws require tools, which can be time-consuming and complex for some users. This can be a disadvantage for patients who need to adjust or remove their orthosis frequently. Additionally, protruding screw heads can sometimes cause discomfort or irritation, especially if they are not adequately cushioned or covered.

Using neodymium magnets to fasten the orthosis could offer several significant advantages. One of the primary benefits is the elimination of external visual changes to the orthosis, as the magnets are embedded within the material and do not alter its appearance, maintaining a discreet and aesthetically pleasing look. Additionally, the internal placement of the magnets would ensure that the orthosis remains lightweight and comfortable to wear. Neodymium magnets also could provide a unique advantage in terms of ease of use. They require minimal effort to fasten and unfasten, making them an excellent choice for individuals with limited hand strength or dexterity. This can significantly enhance the user experience, particularly for elderly patients or those with conditions affecting their motor skills. However, there are some drawbacks to using neodymium magnets. These magnets are brittle and can easily crack or become damaged if handled carelessly. They are also prone to corrosion in humid conditions, which can affect their longevity and performance. Additionally, neodymium magnets are more expensive to produce than other fastening methods, which can increase the overall cost of the orthosis (Kapustka et al. 2020). The overall summary of the three concepts is presented in Table 1.

Table 1. Specification of the designs

	First design	Second design	Third design
Fastening type	Velcro	Screws and nuts	Neodymium magnets
Orthosis	Single part	Two parts	Two parts
Fastening mounting	Sewing	Nut inside orthosis	Magnets inside orthosis
Appearance	Velcro straps under orthosis	Screw visible on both sides	No visual indication
Suggested usage	Universal	Fractures	For kids
Bonding strength	Medium	High	Low
Degree of difficulty	Medium	Hard	Easy

4. Conclusions

This study presents valuable insights into the practical application of various fastening methods for wrist orthoses, providing preliminary guidance for their development. This may prove helpful to engineers involved in the development of orthoses.

This study represents a novel application of neodymium magnets for fastening wrist orthoses, to the best of the authors' knowledge. Although magnets are easy to use, they appear brittle, prone to corrosion, and expensive. Further development is needed to enhance their suitability for orthotic applications. Magnets may be suitable for low-load or supplementary uses, possibly in combination with other fastening methods.

Velcro straps emerged as a user-friendly and cost-effective fastening option. It is recommended for wrist and hand orthoses due to its ease of use and adaptability. However, Velcro may wear out over time and has some aesthetic drawbacks that should be considered in design.

Screws as a fastening mechanism offer stability and durability but require tools for adjustment and may cause discomfort. They are best suited for applications where high stability is essential.

Overall, while Velcro is currently the most practical and popular choice, ongoing innovation in fastening technologies is crucial for advancing orthotic solutions. The research highlights the importance of continuing to explore and develop new fastening methods to enhance the functionality and user experience of orthoses.

4.1. Future research directions

The study underscores the need for further research to explore advances in magnetic fastenings and hybrid methods. Long-term user studies are also recommended to refine these fastening technologies and improve orthosis design, ensuring greater effectiveness and user comfort.

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