Acta Materialia Transylvanica 6/2. (2023) 84–89.
DOI: Hungarian: https://doi.org/10.33923/amt-2023-02-04
English: https://doi.org/10.33924/amt-2023-02-04

Medical Device Design to Support Hand Movement

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Abstract

After accidents, neurological disorders, and cerebrovascular diseases, patients must learn to perform their daily tasks with their new, changed life situation, in which they can be helped by various ergotherapy aids. In the course of my work, I aimed to develop an aid that not only tries to correct the errors of products found on the market, but also a multifunctional aid that serves several types of disability, and which can be worn by individuals with upper limb involvement and living with locomotor diseases/locomotor disorders/changes. An important aspect in the design of the aid was, among other things, that it can be used in any environment and during any activity and that it should be comfortable to wear.

Keywords: *special design, 3D modelling, product design, ergotherapy.*

1. Introduction

In some countries ergotherapy and ergotherapist terms are used instead of occupational therapy and occupational therapist. The hieroglyphic sign of life (𓋹) from ancient Egyptian writing was chosen as the symbol of the profession [1].

Occupational therapy helps to treat hand dysfunction caused by rheumatic diseases. The main anatomical area of therapeutic interventions for the hand is the wrist and finger joints, and the task is the postoperative or conservative treatment of these parts of the body. The aim of occupational therapy is to maintain joint mobility, strengthen muscles, correct deformities, relieve pain or treat inflammation [2].

In Hungary, the first publication on occupational therapy was published almost 80 years ago [3], and the most recent just a few months ago [4]. Szilvia Mogánné Tölgyesy gives a detailed account of the development of the field in Hungary [5], and describes treatments specifically used to improve mobility in a study with her co-author Adél Bartos [6].

Rehabilitation has been an independent Hungarian-language journal of the profession for more than 30 years.

2. Selection of topics, definition of users

I have chosen to design a medical device that facilitates the daily activities of people with upper limb musculoskeletal disorders or neurological disorders. My aim is that the medical device I design will help users to live their lives from the simplest tasks to the most complex ones.

In selecting the users, I have chosen people with severe disabilities who suffer from one of the musculoskeletal disorders listed below:

- hemiplegia (paralysis of one side),
- hemiparesis (weakness of the opposite side of the body),
- cerebral palsy,
- rheumatoid arthritis.

Another target group is the so-called intermittent users, who need to use certain assistive devices due to an injury or trauma, such as a broken hand.

When defining the user group, it was important to include as many groups as possible, as the main objective of the design task was to design a device that would provide a complex solution.

To determine the dimensions of a medical device of the type designed, it was not sufficient to examine the geometric characteristics of the analogues. I reviewed the relevant chapters of the PeopleSize catalogue to determine the dimen-

sions of the adult human hand, and examined the ranges of reach for specific cases. Data that were not included in the catalogue, such as wrist size determinations, were determined by a thirty sample measurement.

After evaluating the results, I also determined the mean and percentile values, broken down by gender.

3. Testing the standard

All products on the market are subject to different rules and standards that they must comply with. In my work, the standards to be respected were those relating to universal design, including accessibility rules.

The ISO 9999:2007 standard [7], also published in Hungarian, defines the classification of assistive devices manufactured specifically for or generally available to people with disabilities. It also includes assistive devices that require the assistance of another person for use. Currently, the most recent standard for the product I am developing is MSZ EN ISO 9999:2023 [8] which has been significantly revised in its title.

4. Material selection

My product has to meet a number of hygienic, mechanical and physiological criteria, of which the biocompatibility property is key. Since I have tried to cover a very wide range of disorders when identifying the user group, I have also had to take into account the diseases that may occur with the disorders, such as skin diseases in which the skin of the patient concerned becomes ulcerated and the protective function of the skin is not complete.

To meet these requirements, I chose a silicone suitable for use as a medical device as the material for the strap.

In terms of its hygienic properties, silicone is the easiest to keep clean, as it does not soak through, is water-repellent and easy to disinfect. In terms of physical characteristics, it is impact resistant, stretchable, yet soft to the touch. It is non-irritating to the skin, making it safe to wear for extended periods.

Of the two-component mouldable silicones, I chose the RTV two-component material. As I am using it for the preparation of a skin contact product, I have considered the use of a catalyst suitable only for food applications.

Among the Hungarian based manufacturers, Bondex Ltd.'s peroxide silicone product Rubosil SR-30 meets the above criteria as it is one of the few materials that are approved by OÉTI (National Institute of Food and Nutrition). The main characteristics of the product are shown in Table 1. [9].

Table 1. *Material properties of Rubosil SR30*

Processing time, pot life	20 min
Binding, curing time	30 min
Hardness	30±5 ShoreA
Heat resistance	–55–200 °C
Viscosity	26 500 ± 1500 m·Pas (or cP)
Density	1.40 g/cm^3
Resistance to splitting	4.86 N/mm
Tensile strength	1.88 N/mm^2
Elongation at break	140 %

For the Rubosil SR-30 silicone, the manufacturer recommends the Rubosil K Food catalyst, for which the manufacturer has also obtained OETI approval. To 1kg of silicone, 50 mL of catalyst is added. The most typical applications for the chosen silicone are in food and confectionery moulds. In addition, skin contact products such as toe separators and spacers and other prostheses can be made from it.

For the 3D printed parts - functional heads, staples - I used a polyamide filament: a white 3D Printer Tough Resin from the manufacturer 3D JAKE. This is a high hardness photopolymer resin that can be used with SLA printers. The composition of the material has not been made public by the factory, the choice of material being justified by previous prototyping processes. First, parts were made of docamide material using the FDM process variant of the fibre compression [10] additive manufacturing process. Due to the manufacturing process, the surface roughness of the elements is high and the spherical elements are separated from their base by tensile stress. The manufacturing method was then changed to SLA; a high hardness but inelastic resin [11].

The parts became brittle due to the choice of material, the snap-in joint suffered a permanent deformation on the third snap-in and then broke. These experiences justified the use of the modified product. The hardness and wear resistance of the parts were found to be better, and the intact

bond did not deform, despite more than twenty cycles of connection and disconnection.

5. Definition of the product concept

In my information gathering work, I analysed a number of competing products. I examined the strengths and weaknesses of these products in order to adapt and adapt the positive features and eliminate the negative ones to create a product proposal that would meet as many user needs as possible. After processing the information, a list of requirements was drawn up.

During the market research, I tested several holders and handles, and the idea of a silicone strap (**Figures 1** and **2**), with a 3D-printed base to which, on request, a detachable snap-on bandage can be attached to some multifunctional heads that help to grip specific objects and perform specific activities; e.g. holding cutlery, toothbrush, writing utensil, buttoning a button, zipping a zipper.

The plastic insert is located on the palm side of the strap, built into an increased thickness silicone pad (the so-called core) so that only the part that can be snapped in protrudes from the strap. This way, the user is not disturbed even when not in use.

I have placed anti-slip ribs on the palm side of the silicone strap, next to the core, to ensure a secure grip and hold.

Perforations should be made on the back of the hand to allow the skin to come into contact with the air and reduce the amount of material used, which in turn affects the weight and price of the product.

I have designed heads and straps for the product that can be used in as few but as many ways as possible, and that can fit in a pocket or a small bag. I wanted to design a fashionable, inconspicuous, compact and discreet product to help users who want to distract themselves from their changing situation.

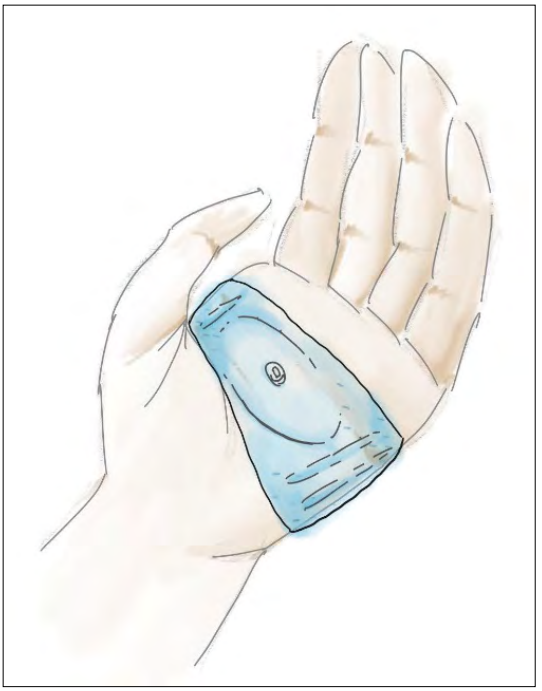

Figure 1. *The front of hand side of the first product concept.*

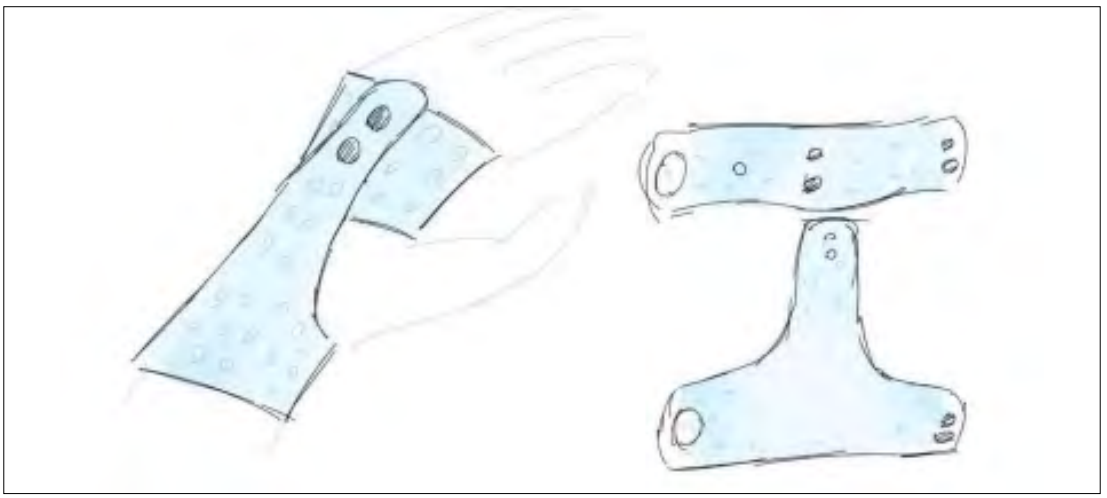

Figure 2. *The back-of-hand side of an improved product concept.*

6. Developing the product concept

6.1. Evaluation of the first product concept

To conduct the interviews, I visited rehabilitation centres. During my visits, I consulted stakeholders and specialists on the product concept. I received many comments from these people, which allowed me to improve my product proposal accordingly.

The first criticism concerned the donning and doffing of the strap: the hand wrapping is not an appropriate method for a person with limited upper limb mobility. It is therefore necessary to replace the strap with a strap-like geometry, which can be adjusted to several sizes by means of a buckle. It is also important that a ring-shaped perforation is provided at one end of the strap to allow users with limited finger mobility to put it on independently. They can then hook their finger into the ring and pull the strap to the correct size. In addition to all these aspects, I have also identified the need to design several accessories to ensure that the concept, which is evolving into a product family, can meet as many user needs as possible.

During the visits I also examined the geometry of the functional heads. The feedback showed that the heads should be able to hold small and large diameter products, as well as assist with dressing. Users have the most problems with buttoning, putting on socks and tying shoes. Some users also need help with typing and using touch screen phones. This requires the design of a head that allows accurate tapping even for people whose fingers do not allow it due to a restricted range of motion.

The analysis of complex workflows has also highlighted the flaws in the head-strap connection. During everyday activities, gripping and using certain tools requires a different direction of movement, which is not always possible depending on the user's condition. For this reason, the connection must be able to rotate so that these actions can be carried out by everyone, and therefore users are not hindered by possible shortcomings in the product design. Therefore, the geometry of the snap-in connection has been modified. It thus behaves as a ball joint in a given range, ensuring the right amount of rotation and bending.

When discussing aesthetic features, the perforation of the strap was supported by the respondents. So I was tasked with designing a pattern that would not tear when pulled, would be aesthetically pleasing and would leave as much skin surface area free as possible. In addition, it had to provide the necessary conditions for fastening: it had to fit the fastener precisely and allow for adjustability.

6.2. Design the perforations

When designing the pattern, I tried to keep the aesthetic features in mind and to cover as little skin surface as possible, so that the strap can still hold the tool holder head and the tool inside. This requires a ratio between the wall thickness and the area of the perforations, which should not be less than 1:2.

The patterns were evaluated using the Copeland method on the basis of various criteria: aesthetics, wall thickness, novelty. The scores obtained were summed up to select the right pattern for the perforations (**Figure 3**).

7. Conclusions: presentation of the final design of the instrument

The range of occupational therapy aids for hand movement that I have designed is a range of aesthetic, multifunctional devices to help people with upper limb impairments, musculo-skeletal disorders or neurological disorders to carry out their daily activities.

All frequently used parts of the products can be replaced separately, making them cost-effective for both the manufacturer and the customer, and extending product life. The different strap geometries allow specific users to select and use the right tools for their condition and reach, reflecting their individual needs.

The skin-contact straps are made of a two-component bio-compatible silicone with a unique pattern that not only provides aesthetic function but also ensures air contact with the skin, preventing

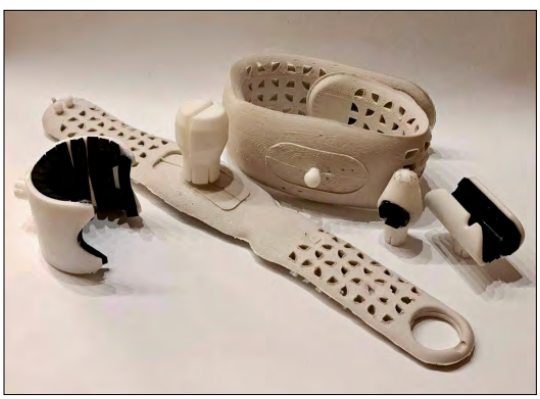

Figure 3. *The prototype of the product line.*

skin irritation due to penetration. In addition, the perforations help to connect the two ends of the strap so that the right size can be easily adjusted, ensuring a proper fit.

Due to the choice of materials, the product does not need to be put on and taken off when in contact with water, as all its components are waterproof. It is easy to keep hygienic, as it is not sensitive to commercial skin and tool disinfectants. It allows the grip of many tools used for everyday activities. Easy to adjust to size, it can be used not only on the palm side but also on the palm side.

I considered this feature of transformability important to include because the identified user group includes a large number of individuals with a high degree of hand lesion. The presence of these lesions - contactures, ossified cartilage - does not allow the user to insert anything into the palm of the hand. I believed that by fixing them to the back of the hand, they would also be able to access a number of functions that were previously inaccessible.

In designing the special device heads, I focused not only on the proper performance of the functions, but also on the fit of each accessory, its secure connection and its interchangeability without causing difficulties for the user.

In terms of securing the utensils, I looked at the easiest way to secure them so that they do not move during use. To solve this problem, I have designed a number of designs, some of which include proposals for additional fasteners made of compressible material depending on the type and geometry of the utensils to be captured.

I also tested the validity of the working principles in practice with a hemiplegic patient who survived a stroke and with occupational therapists. The results of the study clearly demonstrated the validity of the concept. The positive feedback and the suggestions on the individual elements have led me to continue the development of the project.

My product is niche and meets the objective set at the beginning of this work, i.e. to provide a complex solution without compromises for the specific user group identified. These people are all hand or palm mobility impaired, which makes it very difficult for them to carry out their daily activities. During hospital rehabilitation they learn how to adapt to their changed living situation, but after rehabilitation almost all of them need to use some form of assistive device. My product range is designed to meet their needs.

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Figure 4. *Photorealistic image of the final product range proposal.*

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