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Economic evaluation of the manufacturing of 3D-printed wrist orthoses vs low temperature thermoplastic wrist orthoses

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Abstract

Background In recent years, three-dimensional (3D) printing has emerged as a new manufacturing technique of custom-fitted orthoses, showing comparable stability, and wearing comfort than traditional orthoses. However, there is a paucity of data on economic aspects of the manufacturing of 3D-printed orthoses (3DPOs). The aim of this study is to economically evaluate the manufacturing process of 3DPOs compared to conventional low-temperature thermoplastic orthoses (LTTOs) in a clinical setting.

Methods A prospective cost minimisation analysis from a healthcare provider perspective was conducted including 17 wrist orthoses (8 3DPOs and 9 LTTOs).

Results The mean cost per orthosis was significantly higher in 3DPOs (€ 46.54) than in LTTOs (€ 30.28). The main cost factors in 3DPOs were the labour (62.2%) and purchase cost (22.2%), while the material (69.4%) and labour cost (30.6%) were most important in LTTOs.

Conclusions The high initial investment might be a hurdle in the implementation of 3DPOs in hand rehabilitation, however, lower material cost and less waste is a benefit compared to LTTOs. Large-scale use of the infrastructure and developments in technology might reduce the investments needed in the future.

Trial registration : not applicable.

Keywords Orthosis, Patient-specific, 3D-Printing, Low-Temperature-Thermoplastics, Economic evaluation, Cost-Minimisation analysis

Background

In the treatment of injuries and conditions of the upper extremity, orthoses are used to immobilise a body part to facilitate healing, or to improve the function of the affected limb by correcting the alignment of joints [1, 2]. Over the last few years, a new manufacturing technique for custom-fitted orthoses using three-dimensional (3D) printing has emerged, and drawn a substantially growing interest in the area of upper extremity rehabilitation [2–4].

Hand therapists hold the expertise and skills to manufacture custom fit or patient-specific orthoses, however,

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the widespread implementation of 3D-printing in everyday hand therapy practice has not yet been achieved [5]. The costs and practicability of 3D-printing have been identified as a significant concern of therapists [6]. The high initial investment and availability of the needed infrastructure (e.g. space, printer, software, imaging) are considered a main barrier in the implementation of 3D-printed orthoses (3DPOs) [5, 7, 8].

However, there is a paucity of data on the economic aspects of the manufacturing 3DPOs [2–4]. Cost-effectiveness analyses in orthotic provision are generally scarce [9], and even more so in the emerging field of 3D-printing: The material costs of 3DPOs are only reported in a few studies [10–12], and the highly varying costs (ranging from € 20.00 to € 150.00 for wrist 3DPOs) reflect the lack of details about the included elements (e.g. labour-, overhead- and facility costs) and influencing factors.

Although some authors consider the costs and production time of 3DPOs [13, 14], their single case and laboratory setting impede on direct implementation into practice. A clinical setting, reflecting everyday situations of hand therapists while fabricating orthoses, is needed in order to provide realistic data on production costs and the evidence base necessary to promote the integration of 3DPOs in hand therapy practice [9, 15]. In the light of increasing health expenditures and economic pressure, the critical evaluation of therapeutic interventions is essential to ensure a cost-effective allocation of resources [16].

This study aimed to perform an economic evaluation of the manufacturing process of 3-dimensionally printed wrist orthoses compared to low-temperature thermoplastic wrist orthoses in a clinical setting.

Methods

We performed a prospective cost minimisation analysis (CMA) aiming to cost the manufacturing of 3DPOs compared to Low-Temperature Thermoplastic Orthoses (LTTOs) from a healthcare provider perspective. A convenience sample of consecutively referred wrist orthoses was collected over a period of 12 weeks from March to June 2023, aiming to include a minimum of 7 orthoses in each group, as required per preliminary sample size calculation based on estimates, in order to have an 90% chance of detecting a difference in means of € 10.00 (standard deviation (SD) = € 5.00) at the 5% level of significance.

Inclusion and exclusion criteria

All palmar wrist orthoses referred to the hand therapy unit during the period of data collection were included in the analysis, regardless of the underlying diagnosis and duration of wear, as the study focused solely on the

manufacturing process of the orthosis itself, excluding all additional treatment (such as change of dressing, patient education, exercise therapy, etc.). Circular (dorso-volar) wrist orthoses, as well as orthoses fabricated for patients under the age of 18, were excluded to ensure comparability of the results in terms of the size of the orthoses.

Following the routine treatment pathway, the attending hand surgeon referred the patient to the hand therapy department once the indication for immobilisation of the wrist was established. The type of orthosis to be manufactured was then determined depending on the individual's needs and preferences, either out of low-temperature thermoplastic material or by 3D-printing.

The manufacturing of both orthosis types was done by graduated occupational therapists and/or certified hand therapists, with experience in the manufacturing of LTTOs varying between 2 and 14 years, and approximately 6 months experience in the fabrication of 3DPOs since its implementation in the hand therapy department.

Manufacturing of the orthoses

To manufacture a 3DPO (Fig. 1), the affected limb was scanned by the therapist during the first appointment using an optical structure sensor (Mark I Structure Sensor®, Occipital Inc.TM, Boulder, Colorado, USA) rigged on a tablet. A purpose-built and CE-marked application (Spentys® Point-of-Care Solution®, Spentys SA/NV™, Brussels, Belgium) was used to design the orthosis based on the scan by semi-automated modelling. After converting the model of the orthosis into a Standard Tessellation Language (STL) file, the orthosis was printed in the in-house print lab using Digital Light Processing (DLP) technology with photosensitive resin (BASF Ultracur3D, ST45B, black). Post-processing after printing included manually wiping off residual resin with ethanol and curing the orthosis with UV-light in a vacuum chamber (atum3D Curing Station; atum3D, Gouda, The Netherlands). The structural supports were then removed, and edges smoothed with sandpaper. During the second appointment, the orthosis was fitted to the patient, adding the Velcro straps. All steps were performed by hand therapists, with an average active time of approximately 45 min, while the printing took around 11 h.

To manufacture an LTTO (Fig. 2), a pattern of the orthosis was drawn by the therapist on a spare plastic foil, using the hand and arm of the patient as template. The thermoplastic sheet (Klarity KS 3.2 mm, Klarity Medical & Equipment Co. Ltd., Guangdong, China) was then cut accordingly and heated for a few minutes in a water bath (WDB 6-100/4; Heuser Apparatebau GmbH, Haan, Germany) at a temperature of 70 °C. Once heated and softened, the material was adjusted to the patient's forearm and hand, and post-processed by cutting down overlaps, smoothing and correcting the edges using a heat gun, and



Fig. 1 3D Printed Wrist Orthosis (healthy volunteer)



Fig. 2 Low-Temperature Thermoplastic Wrist Orthosis (healthy volunteer)

adjusting the Velcro straps. The manufacturing of the orthosis was made in one therapy session, taking an average time of 14 min.

The manufacturing of both orthosis types is described in more detail in the Additional File 1.

Data collection

The time and material needed in the fabrication process of the wrist orthoses was recorded by the manufacturing therapists using a data collection sheet. The time needed for each step of the manufacturing process was measured using an electronic time clock, and the amount of material used was assessed using a scale or measuring tape for the thermoplastic material, Velcro, and padding, or the data provided by the 3D-printer (amount of resin needed in millilitres) and were accordingly recorded on the data collection sheet.

The costing of the materials and infrastructure was performed using up-to-date information relating to the time period of data collection, in order to allow for comparability. Given the short data collection period of 12 weeks, the material costs remained undiscounted [17].

Cost calculation

Based on existing cost models for additive manufacturing [18–20], the overall cost per orthosis was estimated as the sum of purchase cost of the equipment (P), operating costs (O), material costs (M), and labour costs (L), as described in Eq. 1.

$$Total\ Cost = P + O + M + L \quad (1)$$

The purchase cost (P) per orthosis was defined as the sum of the product of the entire production time (T_x) and the purchase cost (P_x) divided by useful operating time (UT_x) multiplied by useful life (Y_x) of each piece of equipment (x/y/...) needed for the fabrication of the orthosis, as shown in Eq. 2. In other words, the production time was multiplied by the purchase cost per hour, which was based on the assumed production capability during its useful life.

$$P = \frac{T_x \times P_x}{UT_x \times Y_x} + \frac{T_y \times P_y}{UT_y \times Y_y} + \dots \quad (2)$$

The assumed production capability per hour was based on the production of a single orthosis at a time and a utilisation rate of 0.5, due to the presence of the therapists during 8.5 h per weekday, however accounting for the possibility of printing outside of these times (e.g., overnight), or the time needed for heating up the water bath. A useful life of 5 years was determined based on usual depreciation rates, and in accordance with the manufacturers, to allow for comparability [21].

For the software, the cost per orthosis was calculated based on time it was used during the manufacturing process (scanning and designing time).

The operating costs of the infrastructure (O) are expressed in Eq. 3, and comprised the energy consumption costs, assessed as product of the cost of electricity (P_e) and the sum of the power consumption (C_x) during the production time (T_x) of each piece of equipment (x/y/...).

$$O = P_e \times (T_x \times C_x + T_y \times C_y + \dots) \quad (3)$$

The material costs (M) were given by the sum of the products of the price of each material (mat1/mat2/mat...) per unit (P_{mat}) and the number of units used (Mat), as displayed in Eq. 4.

$$O = P_{mat1} \times Mat1 + P_{mat2} \times Mat2 + \dots \quad (4)$$

Finally, the labour costs (L) were expressed as the product of the average hourly wage of a hand therapist (C_l), multiplied by the total active working time used for each orthosis (T_l), as shown in Eq. 5.

$$L = C_l \times T_l \quad (5)$$

Further overhead costs, such as room cleaning or rent, as well as societal costs were not incorporated in this cost evaluation, as they were considered comparable for both manufacturing techniques, which were taking place in the same hospital under equivalent circumstances, thus inducing similar costs.

Statistical analysis

We summarized the fabrication time and manufacturing costs using descriptive statistics for numerical data, as outlined in the preceding section. This included calculating the average cost for each type of orthosis, along with its range and standard deviation (SD) where relevant. Due to the low number of cases, the data was expected to be non-parametric, leading to the application of the Mann-Whitney U test for the comparison of the means of two independent groups.

Results

During the 12 weeks of data collection, 21 patients needing a palmar wrist orthosis were referred to the hand therapy department. Seventeen orthoses were included in the data analysis. Reasons for dropout were incomplete data collection in three cases, and one patient below the minimum age criteria. Therefore, the data of eight 3DPOs and nine LTTOs were analysed.

The mean size of the orthoses, calculated as length multiplied by width, measured at the farthest point, was

Table 1 Prices of main items (in €)

Item	Price (in €)
Purchase Costs	
Structure Sensor (Scanner)	929.35
3D-Printer	19'359.13
Curing Station	15'364.39
Designing Software (Spentys)	3652.65 per year
Printer Software (atum3D)	1272.53 per year
Water Bath	2636.85
Heat Gun	175.10
Operating Costs	
Electricity	0.22 per kWh
Material Costs	
Resin, 1 L	106.08
LTT (Klarity), 46×61 cm	134.70
Labour Costs	
Mean hourly wage	38.98

Table 2 Cost per orthosis (in €)

	LTT0 (range)	3DPO (range)	Sig.
Purchase Cost	0.01 (0.00–0.01)	10.34 (9.49–11.63)	$p < 0.001$
Operating Cost	0.003 (0.00–0.00)	0.11 (0.10–0.12)	$p < 0.001$
Material Cost	21.01 (17.20–28.31)	7.12 (5.83–8.35)	$p < 0.001$
Labour Cost	9.26 (6.87–11.45)	28.96 (20.16–36.87)	$p < 0.001$
Total Cost	30.28 (26.23–36.41)	46.54 (36.42–54.93)	$p < 0.001$

LTT0 = Low-Temperature Thermoplastic Orthosis; 3DPO = 3D-Printed Orthosis

350.35 cm² (range: 255.85–513.00; SD: 70.74). There was no statistically significant difference between the two groups (Mann-Whitney U: 27.0, $p = 0.386$), allowing for a direct comparison of both types of orthoses.

Cost calculation

The prices of the main items used for the costing of the manufacturing process are summarised in Table 1.

The mean cost per orthosis was € 30.28 (range € 26.23–36.41) for LTTOs, and € 46.54 (range € 36.42–54.93) for 3DPOs. The Mann-Whitney U test showed a statistically significant difference between the groups ($p < 0.001$).

Table 2 shows the mean of the purchase cost of the equipment, the operating cost (energy consumption), material cost and labour cost for both groups. The costs for 3DPOs were statistically significantly higher in all categories except for the material costs, which were statistically significantly lower in 3DPOs.

The main cost factors in LTTOs were material costs, accounting for 69.4% of the total cost, followed by labour costs (30.6%). The purchase and operating costs were negligible (0.03% and 0.01%, respectively). In 3DPOs, the labour cost accounted for 62.2% of the total costs, followed by the purchase costs (22.2%). The material costs amounted to 15.2%, while the operating costs were again marginal (0.2%).

Discussion

Purchase and material cost

In 3DPOs, 22.2% of the total cost is engendered through the purchase cost of the equipment needed for 3D-printing, amounting to € 10.34 per orthosis. This is significantly higher than the costs reported in other studies, which are below € 1.00 per orthosis [13, 14], however using a Fused Deposition Modelling (FDM) technique.

The prices used for this economic evaluation are list prices from the year 2023, and are subjected to significant variations depending on the provider and evaluation of prices over the years. As this study was performed in a clinical setting, a printing and manufacturing system conforming with the Medical Device Regulations (MDR) and Swissmedic was needed, explaining the high pricing of the equipment. Assuming that free software was used, and the purchase cost of the printer could be reduced by 50% or 75% of the listed price, the mean total cost of a 3DPO could be reduced to € 41.27 (-11.1%) or € 37.75 (-16.7%), respectively. However, the use of a different printers or open-source scanning and designing software would imply an off-label use without engineer feedback or standardized processes.

The investment, however, could be amortized when using the equipment on a large scale and with a diverse patient population [2, 22], or by printing multiple orthoses at once [11]. In DLP, the printing time is dependent on the size of the orthoses, as the resin is hardened layer by layer, thus the length defines the duration of printing. The width of the orthosis, in contrast, is irrelevant, as all points of one layer are polymerized at once. Therefore, multiple orthoses could be fitted on the same building platform without prolonging the printing time. This represents one advantage of the DLP compared to other techniques such as FDM, where only one object can be printed at a time, or rather the printing time is increased according to the number of objects.

The material cost is the only part of the costing in which 3DPOs were less expensive than LTTOs. As the size of the orthoses in both groups was comparable, the material cost represents an important aspect, especially once the initial investment of the equipment is amortised. The lower expenses for the material used in the production of 3DPOs are further enhanced by the fact that only very little excess material is needed, as the resin which is not hardened can be reused for the next print. Conversely, in LTTOs there often are leftovers which are too small to reuse, even when the patterns are arranged as space-savingly as possible on the sheet. Due to the price of the thermoplastic material, this might be a clear disadvantage of LTTOs compared to 3DPOs.

Labour cost and production time

The labour cost was the main cost factor of 3D-printed orthoses, established on an active working time of the therapists of approximately 45 min, compared to 15 min in LTTOs. The labour cost was calculated based on the average hourly wage of a hand therapist in Switzerland, however, they are undoubtedly dependent on the location of the study, the facility in which the orthosis is printed, as well as the profession and experience of the operator. They are further influenced by the production time of orthoses. LTTOs can be manufactured in one therapy session within approximately 15 min, whereas the total production time of a 3DPO in the present study comprised over 12 h, thus requiring two separate appointments. The production time and general practicability of 3DPOs and LTTOs in a clinical setting was compared and discussed in a separate article [23].

Limitations

This study has several limitations, principally the aforementioned expenses for the equipment, which may vary significantly between countries and over the years with the rapid development of the technology. This study was performed in the hand therapy department of a regional hospital in Switzerland, with the equipment and material accessible and MDR-conform at the time of study. It is therefore a snapshot of 3D-printing at a specific point of care during a specific timeframe, and the results might not be directly transferable to other settings. However, the relation of the total costs of both groups enables an appraisal of the cost distribution and might inform future practice.

Additionally, the value of a CMA approach is debated, as only the cost of an intervention are compared, based on the assumption that the outcomes of an intervention are equivalent [24, 25]. However, the wrist orthoses compared in this study achieve the same purpose, and the characteristics of both types of splints are equal and comparable (patient-specific, volar design). Furthermore, the literature has shown comparable stability and wearing comfort of different types of wrist orthoses, including 3DPOs, LTTOs and casting [4, 8, 26–28], the outcomes of the intervention can thus be considered comparable, allowing for the use of a CMA approach. Nevertheless, future studies should consider cost-effectiveness analyses in order to further emphasize the results.

Some risk of measurement bias is present, as the data collection was performed by the treating therapists. The fact that the time was measured during the manufacturing of an orthosis might have influenced the working speed of the therapist. However, as this was the case in both groups, the validity and transferability of the results is likely not affected.

Conclusion and prospects

The 3D-printing of palmar wrist orthoses is significantly more expensive than the traditional fitting of low-temperature thermoplastic orthoses. Main cost factors are the labour cost and purchase cost of the equipment, which might have impeded the use of this technology in daily practice so far, as the financial investment needed to implement 3D-printing is considerable.

Nevertheless, the material cost of 3DPOs is substantially lower than LTTOs in the present evaluation. If the purchase cost of the equipment was diminished or shared with other departments, the hurdle of initial investment could be overcome and the implementation of 3DPOs in routine hand therapy services seems realistic.

However, further research is needed to evaluate the advantages of 3DPOs and LTTOs in hand therapy practice, with both an economic and clinical focus. As the 3D-printing technologies are diverse, cost-effectiveness analyses of different printing methods, involving the patient's satisfaction with both the end-product and the manufacturing process might lead to new insights.

Furthermore, the HCP's perspective on the manufacturing process of orthoses needs to be investigated before a large-scale implementation of 3D-printing. It seems important that hand therapist's views and experiences are used and applied in the further development of these new techniques, in order to ensure the maintenance of high quality and patient-centred upper extremity orthosis provision.

Abbreviations

3D	Three-Dimensional
3DPO	Three-Dimensionally Printed Orthosis
CMA	Cost Minimisation Analysis
DLP	Digital Light Processing
FDM	Fused Deposition Modelling
HCP	Health Care Provider
LTT	Low-Temperature Thermoplastics
LTTO	Low-Temperature Thermoplastic Orthosis
MDR	Medical Device Regulations
SD	Standard Deviation
STL	Stereolithography or Standard Tessellation/Triangle Language

Supplementary Information

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Supplementary Material 1

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Author contributions

MvH researched literature and conceived and conducted the study, incl. data analysis, and wrote the first draft of the manuscript. LC was involved in protocol development. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval for this study was waived by the Ethics Committee of Northwest and Central Switzerland (EKNZ, Req-2023-00175) because the research project does not fall under the scope of the Human Research Act. This study was completed in accordance with the Helsinki Declaration as revised in 2013.

Consent for publication

not applicable.

Competing interests

The authors declare no competing interests.

Consent to participate

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