



Remote Orthotic Fabrication Method Using Small Three-Dimensional Printers and Computed Tomography Data: A Technical Report

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Abstract

Introduction : Computer-aided design and manufacturing (CAD/CAM) methods have gained prominence in early orthotic provision. This study introduces an innovative approach using compact three-dimensional (3D) printers and computed tomography data to generate segmented body models for traditional Damen corset orthoses. The goals included evaluating the comfort and fit of orthoses and assessing the effectiveness of our approach for prosthetic companies with limited financial resources.

Materials and Methods : Lumbar and thoracolumbar orthoses were crafted via CAD/CAM. Four healthy patients wore the orthoses, with whom immediate and 1-week comfort and fit assessments were conducted. A prosthetist assessed fit, and the Japanese edition of OPUS-CSD, the Orthotics Prosthetics Users' Survey-Client Satisfaction with Device, was used for subjective assessment of comfort and fit.

Results : The fit evaluations were satisfactory for all patients with positive predefined criteria. Questionnaire responses confirmed high satisfaction and comfort, confirming a successful orthosis fit.

Conclusion : We established an orthotic fabrication method using CAD/CAM methods with 3D printers. Additionally, we confirmed the comfort and fit of the corsets so produced. The initial cost of 3D printers is lower than that of traditional carving machines, enabling even small-scale orthotic fabrication facilities to utilize CAD/CAM methods. Further research and refinements of this manufacturing approach are expected to expand its applicability.

Keywords/phrases : computer-aided design/computer-aided manufacturing, 3D printer, Damen corset, OPUS-CSD

Introduction

With the advent of computer-aided design and manufacturing (CAD/CAM) technologies, orthotic fabrication has shifted from traditional methods to digital manufacturing processes¹⁻³⁾. CAD/CAM technologies ensure efficiency and accuracy in the fabrication process and can facilitate early orthotic

supply^{3,4)}. Nevertheless, these technologies often require large-scale machinery and substantial capital investments³⁾, posing challenges for prosthetic companies.

To address these challenges, we explored the use of small three-dimensional (3D) printers in the orthotic fabrication process. Recent advancements in 3D printing technology have enabled the cost-ef-

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fective and accurate creation of body models⁵⁾. The most widely adopted CAD/CAM method involves cutting polyurethane using machining equipment to shape a body model designed on a computer⁶⁾. This model is then used as a mold to create the orthoses. However, owing to the evolution of 3D printing technology, we propose using 3D printers as an alternative to carving machines to produce CAD/CAM-based orthoses. We believe that with this approach, the initial cost of CAD/CAM implementation can be reduced without compromising the quality of the orthoses. Computed tomography (CT) is universally used for examining orthopedic diseases. We developed a novel method using small 3D printers and CT data to fabricate a conventional Damen corset, a type of soft brace commonly used to treat spinal conditions (Figure 1)⁷⁾. This method presents new possibilities for cost-effective remote production, particularly for prosthetic companies with limited financial resources.

In this study, we introduce a novel CAD/CAM-based corset manufacturing method. Moreover, we assessed the fit and comfort using the Orthotics Prosthetics Users' Survey-Client Satisfaction with Device (OPUS-CSD)^{8,9)} in healthy individuals to evaluate its clinical applicability and societal implementation.

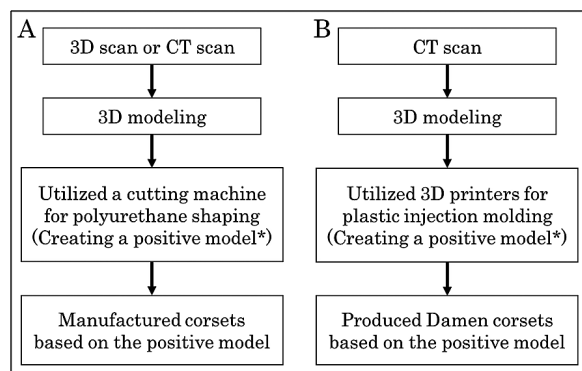


Fig. 1. The various methods for CAD/CAM-based corset fabrication can be broadly categorized into several steps: capturing human body data in 3D format, creating a 3D model (3D modeling), generating a positive model based on the 3D model, and producing the corset using the positive model. (A) The process of CAD/CAM-based corset creation using a carving machine, which is currently the mainstream approach. (B) The process of CAD/CAM-based Damen corset creation using 3D printers, as we propose. *Note: The term “positive model” refers to the model used as a reference or template for further corset production. 3D, three-dimensional; CAD/CAM, computer-aided design and manufacturing

Materials and Methods

Study Population

We included patients who underwent trunk CT at Fujita General Hospital in Fukushima Prefecture between 2021 and January 2023. According to the World Health Organization classification of body mass index (BMI), patients were classified as “Underweight” ($\text{BMI} < 18.5$) or “Normal Range” ($18.5 \leq \text{BMI} < 25$), and one man and one woman were selected from each category to enroll a total of four patients. The intended population for orthoses using this method was primarily older patients with lumbar and thoracic vertebral fractures. Considering that such patients tend to be underweight or have a normal BMI, overweight and obese patients were excluded.

Patients were recruited via telephone and registered as research patients to obtain their consent. Before enrollment, we confirmed that the patient had already undergone a plain CT scan for diagnosis and that the CT data contained sufficient information (data from the body surface with no defects) for the manufacturing process of our orthosis. Recruitment was concluded upon reaching a total of four patients.

The exclusion criteria for this study were as follows: patients with a history of heart diseases (including hypertension), patients with significant weight changes (greater than ± 2 kg) within a year, patients with severe skin fragility, and patients with dementia or mental health disorders.

Fabrication of Orthosis

First, we used InVesalius software (Center for Information Technology Renato Archer, Campinas, Brazil) to reconstruct patient thoracoabdominal CT data (Digital Imaging and Communications in Medicine data) and produce 3D models (STL files). Subsequently, we used Blender software (Blender Institute, Amsterdam, Netherlands)¹⁰⁾ to extract the body surface, shape the parts of the 3D model, and process the single-body model into multiple parts, each of which was printed on a 3D printer. We divided the trunk model created on the software from above the anterior superior iliac spine to above the clavicle into multiple sections for separate outputs (Figure 2). Each model was produced using a 3D printer, SermoonD1 (Creality 3D Technology Co., Ltd., Shenzhen, China), and the produced parts were assembled to create a single trunk model. Using this model, a prosthetist created a

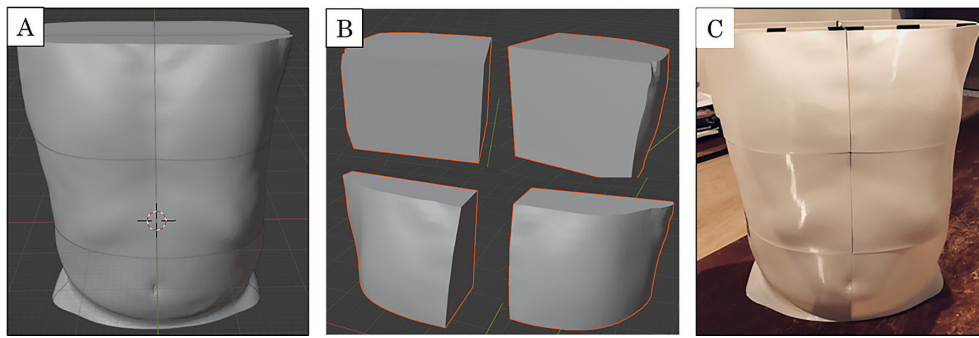


Fig. 2. The process from 3D modeling to model segmentation, output, and assembly. (A) The formation of the model before segmentation is performed using Blender software, (B) the model is divided into sizes suitable for 3D printing, and (C) the segmented models are 3D printed and assembled. 3D, three-dimensional

Damen corset using an established method. The time required for 3D printing during the process of creating the orthosis was recorded.

Two types of orthoses were fabricated : a short Damen corset with the head end positioned at the level of the suprasternal notch and a long Damen corset with the head end positioned at the level of the axilla. Each patient was provided with two orthoses, one of each type.

Assessment of Orthosis Fitting, Safety, and Comfort

All four patients were fitted with short and long Damen corsets created using our method after explaining the study and obtaining informed consent to participate. A prosthetist assessed the fitness and safety of each orthosis. Furthermore, the patients evaluated the fit and comfort of the corset immediately after donning it (at the time of the initial fitting). Assessments by the prosthetists and patients were performed onsite.

Subsequently, the patients were provided with a long Damen corset and instructed to wear it for 1 week. However, they were allowed to remove the corset during activities that were not typically performed during vertebral fracture treatment, such as driving or work. The patients were also permitted to remove the corset during sleep. After wearing the corset for 1 week, the patients reevaluated their fit and comfort. Evaluation results were collected via mail.

Prosthetist's Evaluation

The prosthetist, a research collaborator (M.A.), attached the orthosis to the patient and evaluated its fit. The evaluation items included whether it hindered hip flexion movements while standing or sitting, whether the edge of the orthosis hit the body, whether any looseness was present in the belt of the orthosis, whether any maladjustment existed that

could cause pressure sores, and whether any maladjustment that could cause lateral femoral cutaneous nerve paralysis was present. The response options were "Strongly Agree," "Agree," "Neither Agree nor Disagree," "Disagree," and "Strongly Disagree" for each item.

Furthermore, the prosthetist assessed the safety of each orthosis immediately after it was fitted by checking for potential sites of decubitus ulcers. If any were identified, they checked how the orthosis made contact with anatomical landmarks such as the suprasternal notch, manubrium of the sternum, xiphoid process, costal margin, anterior superior iliac spine, pubic symphysis, scapular spine, spinous process, 12th rib, posterior superior iliac spine, coccyx, and greater trochanter.

Patient's Evaluation

For the patients' evaluation, the OPUS-CSD Japanese edition¹¹⁾ (OPUS-CSD-J) was used to evaluate the fit and comfort of the orthoses. As patients received no actual treatment, they were asked to respond to questions 1-9 of the OPUS-CSD-J questionnaire, which were applicable to this study.

Assessment of Compliance and Skin Condition, 1 Week After Wearing a Corset

In studies assessing the suitability and comfort of orthotics, recording the actual wearing time of the orthoses is crucial. In the second evaluation, in addition to the OPUS-CSD-J, patients were asked about the average corset-wearing time per day and the presence of skin erythema after 1 week. These data were obtained through self-report.

Ethical Considerations

Ethical approval was obtained from the hospital's ethics committee (Approval Number : 223). The principal investigator explained the study to

each patient and obtained their consent. This study received ethical approval in November 2022, and the trial was concluded in July 2023. The orthoses were provided to patients free of charge.

Results

Patients

The study included four patients : a 35-year-old woman, a 67-year-old woman, and two 64-year-old men.

Fabrication Process

The 3D printing settings are presented in Table 1. For each patient, the 3D model was divided into 16 parts and printed using a 3D printer. The mean

Table 1. Three-dimensional printing parameters in our method

Parameters	
Nozzle diameter (mm)	1.0
Printing material	Poly-lactic acid
Layer height (mm)	0.4
Initial layer height (mm)	0.4
Wall thickness (mm)	1.0
Printing temperature (°C)	220.0
Build plate temperature (°C)	80.0
Printing speed (mm/s)	50.0

printing time per segmented body part was 89 min (standard deviation, 21.3 min). Figure 3 illustrates a patient wearing a Damen corset.

Prosthetist Questionnaire Results

The results of the prosthetists' evaluations revealed an overall high level of satisfaction with the fit and safety of the orthoses (Table 2). In both standing and sitting positions, the orthosis did not interfere with hip flexion. In addition, neither the edges nor components of the orthosis disrupted the patient's body. No loosening of the orthotic belt, maladjustments that could cause pressure ulcers, or compression due to the orthotic that could cause lateral femoral cutaneous nerve palsy were observed. Simultaneously, the prosthetist confirmed that in almost all orthoses, no compressive areas could cause future decubitus ulcers.

Patient's Questionnaire Results, Immediately After Orthosis Application

All responses from the first questionnaire were collected, with four responses related to the short Damen corset and four related to the long Damen corset ; all were completed immediately after wearing the corset. Patient assessments following the immediate application of the orthosis exhibited a high degree of positive feedback, although some scattered negative responses were present (Table 3).

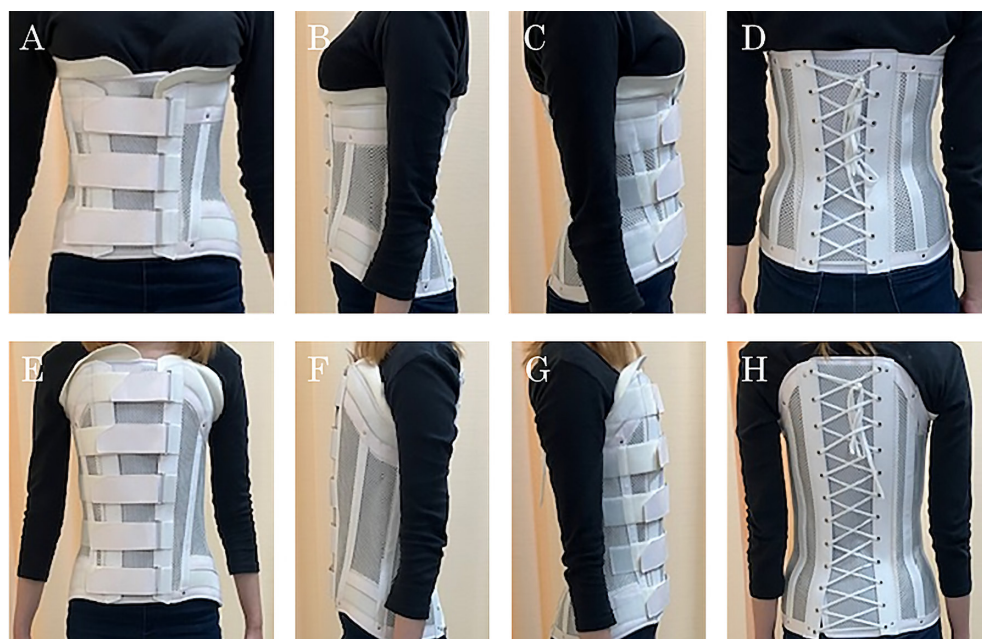


Fig. 3. Damen corsets created using our method. Photographs (A) to (D) were captured from various angles, including front, left, right, and back, with patients wearing short Damen corsets. Photographs (E) to (H) were captured similarly, with patients wearing long Damen corsets.

Table 2. Results of the Prosthetist Evaluation Questionnaire Assessing Fit and Safety

Question items	Short Damen corset (N=4)					Long Damen corset (N=4)				
	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
Fit Checkpoints										
Q1. Is the hip flexion of the patient impaired in the standing position?	0	0	0	1	3	0	0	0	1	3
Q2. Is the hip flexion of the patient impaired in the sitting position?	0	0	0	2	2	0	0	0	2	2
Q3. Does the edge or any part of the orthosis cause disturbance to the patient's body?	0	0	0	1	3	0	0	0	1	3
Q4. Is there loosening of the orthotic belt?	0	0	0	0	4	0	0	0	0	4
Safety Checkpoints										
Q5. Does the orthosis have any non-conformities that could pose a risk of pressure ulcers?	0	0	0	0	4	0	0	1	0	3
Q6. Does the orthosis have any non-conformities that could cause lateral femoral cutaneous nerve palsy?	0	0	0	0	4	0	0	0	0	4

Table 3. Patient Self-Administered Questionnaire Immediately After Corset Application

Question items	Short Damen corset (N=4)					Long Damen corset (N=4)				
	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Q1. My orthosis fits well.	0	0	1	2	1	0	0	0	4	0
Q2. The weight of my orthosis is manageable.	0	0	0	1	3	0	0	0	1	3
Q3. My orthosis is comfortable throughout the day.	0	0	1	2	1	0	1	1	2	0
Q4. It is easy to put on my orthosis.	0	0	0	2	2	0	0	0	2	2
Q5. My orthosis looks good.	0	1	0	3	0	0	1	0	3	0
Q6. My orthosis is durable.	0	0	0	2	2	0	0	0	2	2
Q7. My clothes are free of wear and tear from my orthosis.	0	1	0	2	1	0	1	0	2	1
Q8. My skin is free of abrasions and irritations.	0	0	0	0	4	0	0	0	0	4
Q9. My orthosis is pain-free to wear.	0	0	0	0	4	0	0	0	0	4

Patients mostly felt that their orthotic fit appropriately (six agreed, one strongly agreed) and that the orthotic was lightweight and easy to handle (six strongly agreed, two agreed). Many also felt comfortable wearing orthotics throughout the day (four agreed, and one strongly agreed). Many also found the orthotics easy to wear (four strongly agreed, four agreed), and many found them durable (four

strongly agreed, four agreed). All agreed that the orthotic caused no skin abrasions or irritation (eight strongly agreed) and that it caused no pain when worn (eight strongly agreed).

A few negative responses were identified regarding the comfort of the orthotic throughout the day (one disagreed), the cosmetic appeal of the orthotic (two disagreed), and clothing wear (two dis-

agreed).

Patient's Questionnaire Results, 1 Week After Orthosis Application

Four responses were collected in the second questionnaire related to the long Damen corset (1 week after wearing). One week after the orthotic was fitted, the patients reported positive experiences with the orthotic and no negative responses were observed (Table 4).

Patients agreed or strongly agreed that the orthotic fit appropriately (two strongly agreed and two agreed) and that it was lightweight and easy to handle (three agreed and one strongly agreed). However, the orthotics were also slightly more uncomfortable to wear throughout the day compared with the initial assessment (three agreed, one disagreed), and their durability was slightly more controversial (three agreed, one disagreed). Ratings of the esthetic appeal of the orthotic were neutral (three disagreed), and issues related to garment wear remained unchanged (two agreed, one strongly agreed, and one disagreed). The skin remained free from chafing and irritation 1 week after orthotic use (two strongly agreed, one agreed), and the orthotic remained pain-free when worn (four agreed).

Compliance and Skin Condition, 1 Week After Wearing a Corset

The patients reported wearing the orthotic for an average of 6 h and 15 min (range, 4.5–8 h) per day. No patient reported skin redness 1 week after using the orthosis.

Discussion

We explored the use of CAD/CAM technology with small-scale 3D printers for its potential impact on the production of prosthetic orthoses. We conducted fit evaluations and examined the suitability of this approach for small- and medium-sized prosthetic orthosis companies.

Fit evaluation by the prosthetist confirmed the validity of the proposed method, demonstrating that the CAD/CAM approach using a small 3D printer and CT data can produce orthoses anatomically aligned with the patient's body. Subjective feedback was favorable, supporting the comfort and functionality of CAD/CAM-based orthoses, and no significant deterioration in the wearing experience was observed after 1 week of continuous wear. One participant was dissatisfied with the comfort of the orthosis during the day immediately after wearing it, although it was well received by all at the 1-week evaluation. Problems related to esthetic preferences and clothing wear probably stem from the quality of the orthosis itself rather than the method. In summary, both prosthetists and patients reacted positively to the corsets made using our method, highlighting the potential of 3D printing in prosthetic manufacturing.

Pain Reduction

A primary advantage of our proposed method is pain reduction during casting, which is particularly crucial in patients with vertebral fractures. Traditional plaster casting causes discomfort, hindering ideal posture and extended molding periods. Traditional casting processes often cause discomfort and pain in patients. However, CAD/CAM allows digi-

Table 4. Patient Self-Administered Questionnaire 1 Week After Corset Application

Question items	Long Damen corset (N=4)				
	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Q1. My orthosis fits well.	0	0	0	2	2
Q2. The weight of my orthosis is manageable.	0	0	0	3	1
Q3. My orthosis is comfortable throughout the day.	0	0	1	3	0
Q4. It is easy to put on my orthosis.	0	0	0	1	3
Q5. My orthosis looks good.	0	0	3	1	0
Q6. My orthosis is durable.	0	0	1	3	0
Q7. My clothes are free of wear and tear from my orthosis.	0	0	1	2	1
Q8. My skin is free of abrasions and irritations.	0	0	1	1	2
Q9. My orthosis is pain-free to wear.	0	0	0	4	0

tal data collection, particularly CT data, effectively avoiding casting-related pain. This approach enables patients to receive orthoses, facilitating early rehabilitation^{1,12}.

Fit and Comfort Provided by the Orthosis

We chose soft orthotics as the end product of the CAD/CAM process. Spinal orthoses can be divided into two categories: rigid (including semi-rigid) or soft orthoses¹³. Properly fitted orthosis improves patient comfort and compliance and increases the likelihood of successful treatment¹³. Orthotic fit cannot be ignored, and differences in body shape caused by differences between the supine and upright positions¹⁴ are hypothesized to have a negative impact on orthotic fit. A soft orthosis is more flexible and adaptable to changes in body shape. Rigid orthoses provide higher spinal stability than soft orthoses¹⁵. However, in our main target group (patients with vertebral fractures), the clinical difference in treatment outcomes between rigid and soft orthoses was minimal¹⁶, which is why we produced a soft orthosis using our method.

Manufacturing Process Improvement

CAD/CAM has streamlined the process from orthotic design to production. Design data can be directly transmitted to computer-controlled manufacturing equipment, enabling rapid production. In many countries, orthosis manufacturing using CAD/CAM is widely practiced, resulting in high operational efficiency^{3,4,17}. Further, substantial cost reductions and increased efficiency have been reported compared with traditional methods. In some regions, traditional casting methods remain mainstream, and CAD/CAM-based molding methods have not gained widespread adoption in orthosis manufacturing. In regions and facilities where it is feasible, the adoption of CAD/CAM-based techniques should be considered.

Reduction of Initial Implementation Costs for CAD/CAM Integration

Our approach reduces the initial costs, especially for facilities introducing CAD/CAM technology. Traditional CAD/CAM manufacturing methods require the purchase of an expensive carving machine, which incurs a substantial initial investment. In a price comparison with the manufacturing equipment used in a previous report¹⁸, the initial cost required for a carving machine was \$200,000, versus \$10,000 for 3D printers. The small 3D printers that we

used cost approximately \$1,000 each. Employing our method with approximately 10 of these small 3D printers would result in a total cost of approximately \$10,000, which is similar to that described in previous reports.

CT Radiation Exposure, Cost, and Benefits of Our System

The use of CT imaging in our corset manufacturing system is essential, although some concerns exist, especially regarding potential radiation exposure from CT; this is a significant consideration for both patients and physicians.

However, societal acceptance exists related to enhancing the quality of orthopedic treatments by leveraging CT data. Procedures such as joint replacements and spinal surgeries already utilize CT data for navigation and robotic-assisted surgeries. In our system, the use of CT imaging allows us to supply corsets more rapidly compared with conventional methods, which is beneficial in regions where the time to provide an orthotic is delayed. This advantage may outweigh the associated costs and shortcomings of CT.

Clinical Indications for Our Product

Our system produces the Damen corset as the final product, which we believe can be applied to conditions previously treated with Damen corsets. In particular, our product is suitable for patients with lumbar or thoracolumbar vertebral fractures, especially patients who have difficulty maintaining an upright position or desire early corset supply. It is important to note that our product may not be suitable in all cases. Specifically, it is not appropriate for situations with unstable vertebral fractures, such as burst fractures. Clinicians must properly assess the patient's condition to determine whether our product is an appropriate.

Influence of Our Method on Corset Provision in Japan

Our product is anticipated to alleviate regional variations in orthotic supply across Japan, thereby enhancing the overall quality of healthcare. The provision of a corset in Japan typically involves three hospital visits for patients. The first visit entails receiving a diagnosis of vertebral fractures after an injury and obtaining a prescription for a corset from a physician. The second visit involves a prosthetist creating a mold (casting) based on the patient's body shape, resulting in a significant initial waiting period. The third visit occurs after the corset is manufactured and the patient returns to receive and wear

the corset. In medically underserved areas in Japan, where prosthetists are only available once a week or less, patients often have to wait for approximately 2 weeks or more.

We aim to streamline this process by introducing CAD-based orthopedic device manufacturing methods, which greatly reduce waiting times. Patients will no longer need to wait for mold creation after receiving a prescription because orthopedic devices created using CT data will be provided during the first follow-up visit. By implementing this method, the corset supply period can be reduced to approximately 1 week in medically underserved areas, facilitating early treatment and rehabilitation for patients.

However, despite the evident benefits of CAD/CAM corsets, the lack of insurance coverage in Japan has hindered their widespread adoption. Japan's National Health Insurance program has a mandate to enroll all residents. This system helps to alleviate the financial burden of healthcare costs in Japan and ensures widespread access to medical services. Within this framework, the Japanese healthcare insurance system manages coverage of specific medical devices and treatments. To achieve insurance coverage for CAD/CAM orthopedic devices in Japan, continued research and dissemination of information on their utility, safety, and cost-effectiveness is crucial.

Limitations

This study has some limitations. Evaluations were conducted in patients without spinal disorders, necessitating further research to assess the long-term durability and effectiveness in patients with specific conditions.

We applied the OPUS-CSD-J to assess the fit and comfort of the patient's orthosis. According to a previous study¹¹⁾, the OPUS-CSD-J is considered unreliable when used to assess orthotics, as the Cronbach's alpha coefficient was 0.63, which is less than 0.7. However, we consider its value to be moderate and, given that the questions comprising the OPUS-CSD-J scale consist of items that represent the participants' subjective conformity and comfort, the actual use of this scale is acceptable with the understanding of this limitation.

Additionally, comparative studies of traditional versus CAD-CAM corsets for various outcomes (pain, physical function, and medical-economic indicators) are needed. While this study focused on Damen corset orthosis manufacturing, expanding this approach to other types of prosthetic orthoses is

subject to future research.

Finally, it should be noted that applying our system directly in some regions may pose challenges, which may be a limitation of our system. We have developed a system to reduce regional disparities in the supply of corsets. However, it is anticipated that in areas with limited medical resources, there may be clinics or hospitals where CT scans cannot always be conducted in a timely manner. Going forward, efforts will be needed to explore solutions to address this issue.

Conclusion

The CAD/CAM-based prosthetic orthosis manufacturing approach using small-scale 3D printers is a promising solution for remote orthosis production. This method enhances patient care and accessibility while maintaining cost-effectiveness, making it an attractive option for prosthetic orthosis companies. Further research and refinement of this innovative approach are expected to expand its applicability.

Acknowledgments

The authors thank all clinicians and health professionals who contributed to this study.

Conflict of Interest Disclosure

In this research, we provided a total of eight corsets to four healthy individuals at no cost.

The First Author (T.Y.) collaborated with two orthotists (M.A., Y.K.) from Touhoku Prosthetic and Orthotic Co., LTD to develop corsets using 3D printers. T.Y. supplied the 3D printer and the filament materials used for 3D printing. Touhoku Prosthetic and Orthotic Co., LTD was responsible for manufacturing the corsets and covering the costs associated with their production.

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