# GLOBAL HEALTH 2024

The Thirteenth International Conference on Global Health Challenges

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**GLOBAL HEALTH 2024 Editors**

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# GLOBAL HEALTH 2024

## Forward

The Thirteenth International Conference on Global Health Challenges (GLOBAL HEALTH 2024), held between September 29th, 2024, to October 3rd, 2024, in Venice, Italy, continued a series of international events taking a global perspective on population health, from national to cross-country approaches, multiplatform technologies, from drug design to medicine accessibility, including everything under mobile, ubiquitous, and personalized characteristics of new age population.

Recent advances in technology and computational science influenced a large spectrum of branches in approaching population health. Despite significant progress, many challenges exist, including health informatics, cross-country platforms interoperability, system and laws harmonization, protection of health data, practical solutions, accessibility to health services, and many others. Technological progress, personalized medicine, ambient assistance, and pervasive health, complement patient needs. A combination of classical and information-driven approaches is being developed, where diagnosis systems, data protection mechanisms, remote assistance and hospital processes are converging.

We take here the opportunity to warmly thank all the members of the GLOBAL HEALTH 2024 technical program committee, as well as all the reviewers. The creation of such a high-quality conference program would not have been possible without their involvement. We also kindly thank all the authors who dedicated much of their time and effort to contribute to GLOBAL HEALTH 2024. We truly believe that, thanks to all these efforts, the final conference program consisted of top-quality contributions. We also thank the members of the GLOBAL HEALTH 2024 organizing committee for their help in handling the logistics of this event.

We hope that GLOBAL HEALTH 2024 was a successful international forum for the exchange of ideas and results between academia and industry for the promotion of progress related to global health challenges.

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# Constructing a Criteria Assessment Framework for Early Medtech Innovation Projects at China's Proof of Concept Centers

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***Abstract*—Proof of Concept (POC) plays a key role in reducing the risk of failure and increasing the success rate of translating technology innovation ideas into prototyping and is often applied in technology transfer processes. In recent years, China has introduced public policies to support the construction of proof-of-concept centers to encourage medical technology (medtech) Research and Development (R&D). A comparative case study was done to explore the commonalities and differences between current China and the US practice of government-led proof of concept centers' project assessment criteria. Based on the findings, this research consolidated a criteria assessment framework for early-stage medtech project selection, in hopes to serve as an assessment tool to clarify the selection criteria at proof-of-concept medical technology centers in China.**

***Keywords-Proof of concept; medical technology transfer; medical technology innovation.***

## I. INTRODUCTION

Data from China's Patent Survey Report 2023 revealed that the patent-to-industrialization rate of the pharmaceutical manufacturing industry is 43%, performing significantly lower than that of other types of manufacturing industries, for instance, automobile industry at 63.3%, leaving room for improvement [1].

Driving medtch innovation requires more than market power. At a national level, refining the innovation system can help accelerate early-stage technology projects into industrialization stage. Proof of Concept Centers (POCCs) are a type of infrastructure to help early-stage technology translation, and they have been rapidly growing in China. The idea of proof of concept is recognized as part of the Technology Readiness Level (TRL) pinpointed at the early stage of technology development cycle. The purpose is to test and validate technology components, measure technology progress, and plan for future inputs needed to increase technology maturity. The significance of the proof of concept is to provide technology transfer milestone guidance and financing for high-potential early-stage R&D projects under controlled risk assessment conditions [2].

However, there are operational challenges yet to be addressed and optimized in practice. One of them is to assess the medtech projects applying for POC funding [3]. This research aims at first addressing the evaluation components of POCC samples in China and samples from National Institutes of Health (NIH) Proof of Concept Network, in hope to explain the current commonalities and differences between China and the United States' implementation experiences. Secondly, based on the case study findings, this research aims to consolidate a criteria assessment framework for open discussion on its feasibility in China's POCC setting.

The rest of the paper is structured as follows. In Section II, we present a briefing on POCCs in China and the criteria that two POCCs applied for selecting medtech projects to fund. In Section III, we present two NIH POCCs' project selection criteria and describe the commonalities and differences between China and the US as comparative case studies. Finally, we conclude the work in Section IV.

## II. PROOF OF CONCEPT CENTERS IN CHINA

Since 2018, POCCs have gradually been promoted in various provinces and cities in China. A number of POCCs received public endorsement and funding support from local government. For example, in 2022, Beijing Municipal Commission of Science and Technology announced funding support for 12 local POCCs [4], with the total amount of support for a single POCC not exceeding 15 million RMB within three years [5]. Shenzhen Science and Technology Innovation Bureau announced funding support to 10 local POCCs in 2024 [6], and Hangzhou Science and Technology Bureau announced the establishment of 15 POCCs in 2023 [7].

### *A. Operation Main Body*

In terms of medtech-focused POCCs, they are run by different operation bodies such as local government as a public service, hospital in-house service, university-based service, and corporate-owned commercial service. Some of these can be co-founded by a public-private partnership (See Table I).

TABLE I. POCC FACILITIES IN CHINA-SELECTED SAMPLES

| **Main Body** | **POCC Information** | |
|---|---|---|
| | ***Institution Name*** | ***Year of Establishment*** |
| Government | Xi'an High-Tech Medical Device Proof of Concept Center [8] | 2023 |
| Hospital | Beijing Friendship Hospital Proof of Concept Platform [4] | 2022 |
| University | Medical Proof of Concept Center, Capital Medical University [4] | 2022 |
| Corporation | Hangzhou Denuo High-end Medical Device Proof of Concept Center [9] | 2022 |

### B. Positioning and Function

The role of a POCC is to assess the potential business value and technical feasibility of medtech research projects at early stage of R&D and inform go/no-go decisions to grant funding for proof-of-concept research and product development. Business advisory services such as project management guidance, entrepreneurship training, intellectual property protection, etc., are also provided at the POCC to help improve the translation success rate of an innovation idea into intellectual property, product development, licensing and commercialization.

Some POCCs include services down the translational stream for prototyping, performance testing and manufacturing, which requires facility investment on hardware, equipment, and testing and laboratory space as capital expenditure for the center [10].

### C. Selection for Funding Proof of Concept Projects

A policy text analysis was conducted selecting two government-led POCCs in Beijing (Zhongguancun Administrative Committee) and Hangzhou (West City Science and Innovation Corridor) as examples. Despite the variation in R&D nature of different industries, these two POCCs are positioned to serve projects across multiple industries thus apply a general criterion for project assessment (See Table II).

TABLE II. PROJECT ASSESSMENT OF TWO POCCS IN BEIJING AND HANGZHOU

| Assessment dimension | Beijing [10] | Hangzhou [11] |
|---|---|---|
| Technology | Key tech breakthrough.<br>Technology readiness level.<br>Intellectual property rights.<br>Relevant award. | Key tech breakthrough.<br>Innovation significance.<br>Intellectual property rights.<br>R&D plan. |
| Marketing | Expected market scope, expected economic and social benefits, etc. | Target market, user needs.<br>Market positioning and promotion plan.<br>Relevant performance or revenue that has been generated. |
| R&D capability | R&D experience, research team background. | R&D experience, research team background. |
| POC plan | Task objectives, assessment indicators, deliverables, implementation cycle, and the total amount of funds to be invested. | Specific objectives, implementation plan and deliverables, with a budget plan for two years of implementation. |
| Plan for technology transfer or commercialization | Current conditions for technology transfer. | Financing of the project.<br>Company registration at West City Science and Innovation Corridor. |

## III. COMPARISON WITH NIH POC NETWORK

In 2013, the NIH Centers for Accelerated Innovations (NCAI) program and, in 2015 and 2019, the Research Evaluation and Commercialization Hubs (REACH), formed a nationwide POC network to allocate funding resources to collaborated innovation hubs across 19 states [12].

The NIH Proof of Concept Network focuses on providing funding support and entrepreneurial training to medtech projetcts at the stage of TRL 3 to 5 [13]. The entire TRL spectrum classifies the life cycle from technology R&D to commercial deployment into nine levels [14]. While TRL 1 represent the theoretical principle for an innovative idea, and TRL 9, the last readiness level, represent operational status, TRL 3 to 5 are early-stage levels from hypothesis testing to pre-clinical studies or prototype testing, when applied in medtech setting.

### A. Assessment for Funding Proof of Concept Projects

While NIH has specific evaluation metrics for the hubs within its POC network, every hub conducts individual assessment for local medtech projects applying for either NCAI or REACH grants. Table III provides a brief overview of the assessment dimensions from two selected hubs (SPARK, WE-REACH) of REACH 2019 to review their funding applicants.

TABLE III. PROJECT ASSESSMENT OF TWO REACH 2019 HUBS

| Assessment dimension | SPARK [15] | WE-REACH [16] |
|---|---|---|
| Unmet need | Clinical need<br>Stakeholder perspective<br>Relevant evidence | Unmet human health need significance.<br>User investigation. |
| Technology | Solution setting.<br>Expected benefit and preliminary data.<br>Intellectual property rights.<br>Tech advancement. | Intellectual property rights.<br>Available information on U.S. Food and Drug Administration predicate devices and systems. |
| Marketing | Patient target.<br>Market size, and target price of the technology.<br>Market population trends.<br>The competition mix. | The usefulness and novelty of the product.<br>Market identification and scope estimation.<br>Competitive landscape. |
| R&D capability | Team member credentials.<br>Expertise needed ongoing. | Team member credentials. |
| POC plan | Total funding required to bring the product to a commercial exit.<br>Project plan and go/no-go decision points. | Primary milestone goal.<br>Evidence to support the proposed POC.<br>Staffing, equipment, and funds needed. |
| Plan for technology transfer or commercialization | Tech transfer outcome.<br>Financial overlap explained.<br>Estimated long-term return on investment. | Other funding awarded.<br>Pathways to commercialization, including regulatory, reimbursement, etc. |
| Risk declaration | Define the potential risks (scientific, technical, personnel, market, and commercialization) and the mitigation processes. | Define the potential risks (scientific, technical, personnel, market, and commercialization) and the mitigation processes. |
| Ethical review | Human subject use and Institutional Review Board approval<br>Institutional Animal Care and Use Committee approval<br>Human Embryonic Stem Cells | N/A |

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### B. *Commonalities and Differences between China and US Case Studies*

By comparing the case studies from China and the US, several commonalities are identified. To start, the assessment frameworks from case studies all include business and economic components, POC implementation and technology transfer plan, to review the projects feasibility and return on investment potential. R&D capability also plays a crucial element for project selection, as it explains the technical skill sets of the entire project development.

The differences are shown as follows. The US case studies put heavy emphasis on clarifying stakeholder perspectives and demands, applying a user-centered approach to clarify project significance, while the China case studies look deeper into honorary credentials of the technical performance, novelty and business forecast. This may be because NIH's network specifically focuses on funding projects at the stage of TRL 3-5, which are relatively early to accumulate credentials, conduct market validation or create sales record, while China's POCCs receive applications from a wider range of TRL status, some of which may result in commercial, real-world feedback.

In addition, the US assessment requires risk declaration from the principal investigator team. Rather than focusing on the potential market performance, the assessment process takes a more risk-averse view to grant funding.

## IV. Conclusion and Future Work

Literature review on current assessment frameworks found a lack of consensus on methods and key variables needed to conduct early stage medtech assessment. The appropriate timing for conducting assessment in the development cycle is not clearly articulated in many assessment as well [17]. The findings from the comparative case studies between China and the US resonate with the literature review. From the case study findings, it is clear that TRL assessment is practiced in some POC settings, but not universally applied. Some raise open-ended questions for principal investigator to describe the maturity of the medtech project, which could lack a systematic method to pinpoint the status quo and track the progress of medtech development after receiving POC funding.

Based on the above-mentioned discoveries, this research proposes a criteria assessment framework (Table IV) as initial draft for POCC project selection practice, applying TRL as a standardized, qualitative analysis for early medtech project's maturity measurement to better identify its status quo and resource demand, and outcome objective setting.

The experience of patients as medtech recipients and healthcare professionals as medtech users will determine the success or failure of the product's clinical performance [18]. Thus, aside from TRL, stakeholder identification and analysis should be thoroughly considered as an influential variable at POC stage to better ensure product design and market positioning.

TABLE IV. Criteria Assessment Framework Proposed for POC

| | |
|---|---|
| **Project criteria** | |
| Unmet need | Clinical need and significance.<br>Stakeholder and end-user investigation and relevant evidence. |
| Technology feasibility | Setting in which the solution will be utilized.<br>Expected benefit and preliminary research data.<br>Intellectual property rights status.<br>Technology advancement or breakthrough.<br>Current TRL identification. |
| Business prospect | The primary patient population for use.<br>Market size, and target price of the technology.<br>Market population trends.<br>The competition landscape. |
| R&D capability | Team member list with credentials and role in the project.<br>Expertise needed for future development. |
| **Implementation criteria** | |
| POC research | Task objectives, assessment indicators, deliverables, implementation cycle, and the total amount of funds to be invested. |
| Technology transfer or commercialization | Tech transfer outcome to be achieved.<br>Financial overlap with other projects.<br>Estimated long-term return on investment (optional). |
| Risk declaration | Define the potential risks (scientific, technical, personnel, market, and commercialization) that exist and the mitigation processes available. |
| Ethical review (If appropriate) | Human subject use and IRB approval.<br>Animal use and IACUC approval.<br>Human Embryonic Stem Cells. |

This is working research to construct a POC criteria assessment framework for early-stage medtech projects. Current work is completed based on literature and open online resources available. Since the NIH proof of concept network is a medtech-focused program, and the case studies from China receives projects applications from multi-industries, thus the latter's assessment framework could appear to be relatively general. Further interviews and onsite investigation with Chinese POCC stakeholders should be conducted to obtain constructive feedback. Hospital-based or medtech-specific POCCs should be further explored in order to understand how assessment is conducted.

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# Evaluation of Segmentation Schemes for Noisy and Denoised Dental Cone Beam Computed Tomography (CBCT) Images

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***Abstract*—Segmenting Cone Beam Computed Tomography (CBCT) images is challenging due to high noise levels, artifacts, and limited resolution. This paper evaluates the effectiveness of various segmentation methods on both noisy and denoised CBCT images. We examine the performance of state-of-the-art segmentation techniques on CBCT scans processed with three efficient denoising methods tailored for low-dose CBCT images. Our findings indicate that introducing a denoising step before segmentation significantly enhances the segmentation quality of CBCT images. Additionally, the 3D Slicer approach demonstrates the most robust segmentation performance for both noisy and denoised CBCT images. Among the denoising techniques, Chang et al.'s method proves to be the most effective, yielding promising results across all evaluated segmentation methods.**

***Keywords—Cone Beam Computed Tomography (CBCT) images; segmentation; denoising.***

## I. Introduction

Cone-Beam Computed Tomography (CBCT) is being widely used in dental imaging since it has low cost, high-quality images, and low radiation exposure which can guarantee patient safety [1]. It has enabled more precise treatment planning by connecting 2D representations with 3D reality [1] [2]. In implant dentistry, CBCT imaging enables accurate assessment of bone quality and quantity for appropriate implant size and placement [3]. It also enhances root canal therapy success by offering comprehensive visualization of complex root canal anatomy [4]. In orthodontics, CBCT images support the evaluation of craniofacial growth and development for more accurate treatment plans and tooth movement predictions [5]. Additionally, CBCT is crucial in diagnosing Temporomandibular Joint (TMJ) disorders, providing detailed images of the joint structure and surrounding tissues, thus improving patient management and treatment outcomes in dentistry [6]. The most difficult task in creating 3D models for orthodontics is currently the segmentation of CBCT images [7]. This process involves dividing CBCT images into different anatomical regions of interest. For instance, segmenting teeth is challenging because the tooth roots have a similar intensity to the surrounding alveolar bone [7]. Moreover, accurately segmenting bony structures is challenging due to high noise levels, limited image resolution, and metal artifacts [8]. To address these issues, denoising methods are essential for enhancing the image quality, thereby facilitating improved segmentation [9].

In recent decades, extensive research has been conducted to denoise and enhance the visual quality of CBCT images. For example, Chang et al. proposed enhancing CBCT images by applying a simple Wiener filter, followed by a sharpening filter to recover details, and finally, a Gaussian filter to further reduce noise [10]. Zhong et al. introduced an effective CBCT enhancement method which classifies wavelet coefficients into irregular and regular categories based on their magnitude sum within a Cone of Influence (COI), then processes them differently with a new noise estimation algorithm [11]. Also, Li et al. suggested a hybrid denoising technique for low-dose CBCT images [12]. Their technique involves separating data into frequency components using wavelet transformation. High frequencies are cleaned with wavelet thresholding, while low frequencies are filtered with Wiener filter. An inverse wavelet transformation recombines these components, and an anisotropic diffusion function further reduces image artifacts. In another study, researchers compared four denoising algorithms for enhancing low-dose CBCT images: total variation minimization, Bayes Least Squares-Gaussian Scale Mixtures (BLS-GSM), Non-Local Means (NLM), and Block Matching and 3D Filtering (BM3D). This study found that NLM and BM3D can offer superior visual quality [13].

Numerous methods have also been proposed to segment CBCT images for diagnosis purposes. For example, Zheng et al. proposed a Mixed-Scale Dense (MS-D) convolutional neural network for multiclass segmentation of the jaw, the teeth, and the background in CBCT scans [14]. In another study, a semiautomatic method was proposed to segment individual teeth in dental CT images [15]. This method outperformed the standard Dense U-Net in lesion detection accuracy and dice coefficient indices for multilabel segmentation. Another study assessed the segmentation accuracy and reliability of approaches such as 3D Slicer and Blue Sky Plan compared to commercial alternatives, namely Mimics and OnDemand3D. The former approaches could serve as a viable alternative to commercial packages in terms of accuracy and efficiency for threshold-based segmentation [15]. The Insight Toolkit - Segmentation and Non-rigid registration, and Automatic Partitioning (ITK-SNAP) is another approach for medical image segmentation while Priyadharshini et al. utilized its thresholding-function to segment the dental CBCT images for age estimation [16]. The results showed that the maxillary right canine Pulp Volumes (PV) can be used to predict the dental age and ITK-SNAP segmentation serves as a good estimator in determining the PV [16]. While these segmentation techniques have shown promising results on noisy CBCT images, their performance has not yet been investigated on enhanced and denoised CBCT images.

In this paper, we evaluate the performance of three state-of-the-art segmentation methods on CBCT images enhanced by three well-known denoising techniques. Both the denoising and segmentation methods selected are considered cutting-edge approaches for CBCT imaging. Our primary objective is to compare the robustness of these segmentation methods on both noisy and denoised CBCT images.

The rest of this paper is organized as follows. Section II describes the CBCT denoising and segmentation methods selected for this study. In Section III, we compare the performance of different segmentation methods on noisy and denoised CBCT scans and discuss the robustness of each technique. Finally, Section IV presents the conclusion.

## II. Our Proposed Method

This paper aims to perform a comparative analysis of three leading segmentation techniques applied to noisy and denoised dental CBCT images. More specifically, we assessed the segmentation accuracy of the 3D Slicer [14], Blue Sky Plan [15], and ITK-SNAP [16] segmentation techniques on CBCT images enhanced by three prominent denoising methods, namely Chang's et al. [10], Li's et al. [11], and Hao's et al. (BM3D) [13], all considered cutting-edge approaches for CBCT denoising.

We utilized 10 3D CBCT images of patients consisting of 440 2D slices from a top view perspective. Initially, the 2D CBCT images are enhanced using the proposed denoising methods, and subsequently, we segment both the noisy and denoised CBCT images using the proposed segmentation techniques.

### A. Denoising Techniques

To mitigate the risk of cancer from high radiation exposure in CBCT scanning, dentists and clinicians use lower levels of radiation. However, this reduction in radiation results in increased noise levels and additional artifacts [8]. Therefore, enhancing the quality of CBCT images before using them for segmentation or other treatment purposes is essential. In this study, we employ three well-known CBCT denoising methods, which we describe below.

*1) Denoising technique in [10]*: This method aims to enhance the visual quality of CBCT images by initially applying a simple Wiener filter to reduce noise. However, this can cause blurring of some details and microstructures. To preserve edges, a Laplacian filter is subsequently used, but it can accentuate both desired edges and unwanted noise. Finally, a Gaussian filter is applied to suppress some of the newly emerged noise.

*2) Denoising technique in [12]:* This method is a hybrid denoising technique designed to enhance the visual quality of noisy CBCT images. First, a single-level wavelet transform is applied to obtain one set of low-frequency and three sets of high-frequency components. Low frequencies are denoised using a Wiener filter, and high frequencies are corrected using a wavelet thresholding method based on soft thresholding (thresholds are chosen using the Birge-Massart strategy). Then, an inverse wavelet transformation recombines the filtered low- and high-frequency components. Finally, an anisotropic diffusion function further reduces image artifacts while preserving details.

*3) Block Matching and 3D Filtering (BM3D) in [13]:* BM3D is a denoising algorithm that divides an image into overlapping blocks, finds similar blocks in the image to form 3D groups, and then applies a 3D decorrelating unitary transform to each group. This process transforms the group into a different domain to exploit sparsity, then uses a shrinkage operator to reduce noise while preserving the signal. Finally, the filtered blocks are aggregated to reconstruct the denoised image, resulting in effective noise reduction.

### B. Segmentation Techniques

As previously mentioned, our primary objective is to evaluate the performance of various segmentation techniques on both noisy and denoised CBCT images. Below, we describe the three state-of-the-art CBCT segmentation techniques utilized in our study.

*1) ITK-SNAP:* The ITK-SNAP segmentation approach, developed by the Penn Image Computing and Science Laboratory, is an open-source medical image processing application. It offers a blend of manual and semi-automatic tools for extracting structures from 2D and 3D image data of various modalities and anatomical regions. This solution is based on the Insight ToolKit library of image analysis algorithms and the Visualization ToolKit library of visualization algorithms and advanced modeling techniques. One of its segmentation tools is based on the Thresholding function, which we used for CBCT segmentation in this paper.

*2) Blue Sky Plan:* The Blue Sky Plan is a comprehensive segmentation solution tailored for virtual surgical planning and guided surgery, particularly in implant dentistry, oral surgery, and maxillofacial surgery. This approach enables the manipulation of 3D medical imaging data, such as CBCT scans, to plan surgical procedures with high precision. A key feature of the Blue Sky Plan is its advanced segmentation tools, which use sophisticated algorithms and image processing techniques to separate different anatomical structures, such as bone, teeth, and soft tissue, from scan data. This segmentation is essential for creating accurate surgical plans and designing custom surgical guides. In this paper, we employ the Advanced Jaw Segmentation tool in the Blue Sky Plan, which semi-automatically segments the CBCT images based on a predefined minimum density threshold.

*3) 3D Slicer:* The 3D Slicer is a widely used open-source software package for dental CBCT scans analysis and visualization. It provides a comprehensive set of tools for processing and analyzing 3D CBCT images, making it valuable for researchers and clinicians. One of its key features is its segmentation tools, which offer a variety of manual, semi-automatic, and fully automatic methods for segmenting dental structures or regions of interest. In this paper, we utilize a semi-automatic segmentation method from the Segment Editor

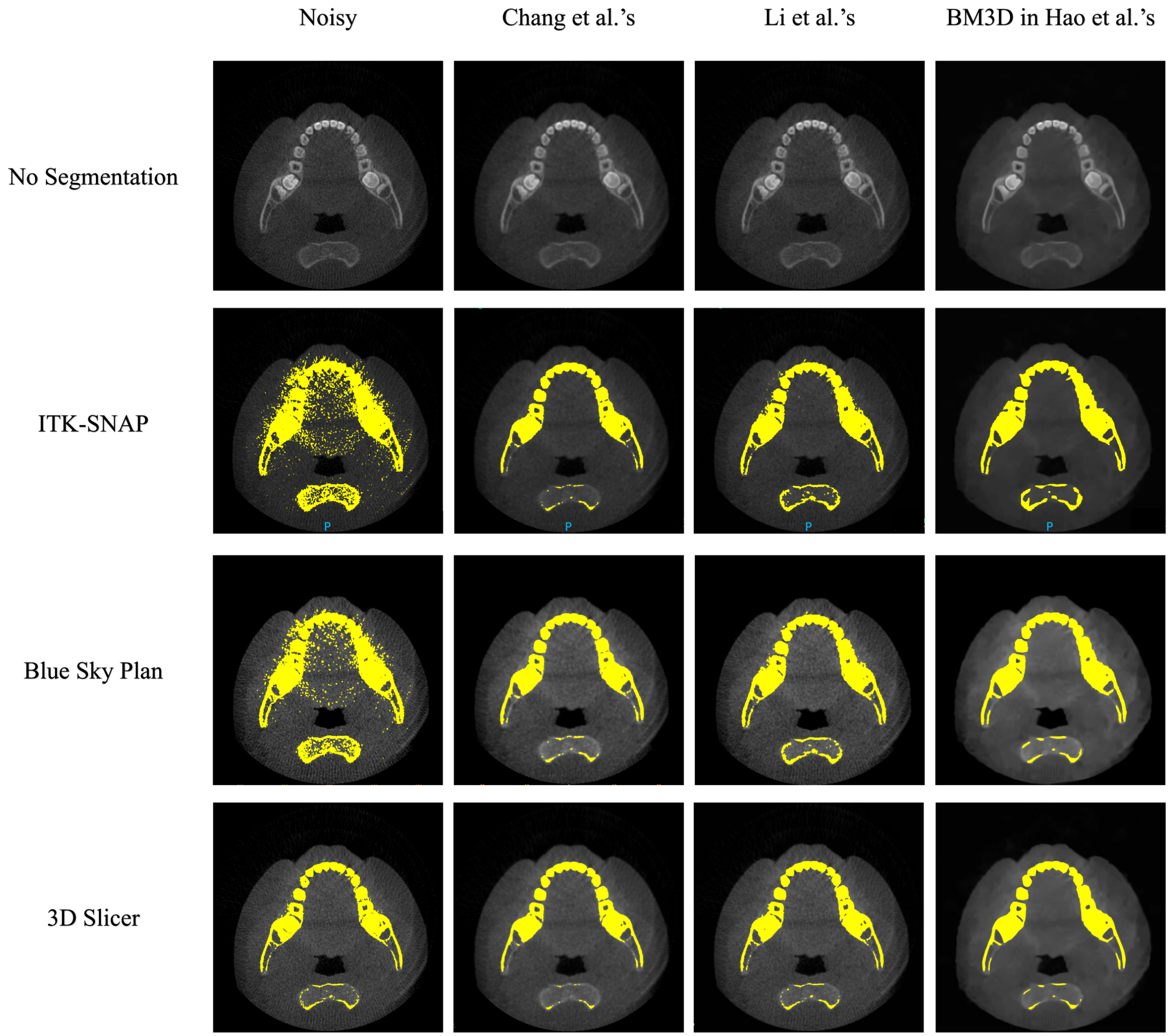


Figure 1. Results of the different segmentation methods on noisy and denoised CBCT images.

module in 3D Slicer, which segments the CBCT scans based on a thresholding technique.

## III. Experimental Results And Evaluation

We conducted a subjective test to compare the performance of three state-of-the-art segmentation methods on CBCT images, assessing their effectiveness on both noisy and denoised datasets. Twenty participants, aging from 22 to 35 years, participated in the subjective tests. All of them were screened for visual acuity and color blindness. Since subjective tests are highly dependent on the proper training of the subjects, each subject was trained by means of a short practice (training) session demonstrating the range of qualities to be expected in the test in order to become familiar with the presentation scoring process. The latter follows the ITU-R BT.500-14 recommendation, with scores from 0 (low quality) to 10 (high quality) [17]. All subjects were shown 440 2D slices from a top view perspective of 10 3D CBCT images of real patients. Table I shows the average results of the subjective tests, comparing and ranking the different denoising and segmentation methods.

We observe that the 3D Slicer demonstrates superior accuracy in CBCT segmentation, exhibiting robustness across both noisy and denoised images. In summary, the 3D Slicer's segmentation technique outperforms both Blue Sky Plan and ITK-SNAP, while Blue Sky Plan demonstrates superior performance compared to ITK-SNAP. Moreover, Chang et al.'s method emerges as the best denoising strategy, as all three segmentation methods achieve better performance after using this denoising method. This is due to the fact that Chang et al.'s method effectively removes a significant amount of noise while maintaining edges, resulting in improved image quality.

TABLE I. COMPARISON AND RANKING FOR DIFFERENT DENOISING AND SEGMENTATION METHODS.

| | | Excellent | Good | Fair |
|---|---|---|---|---|
| **Denoising Techniques** | Chang et al.'s | ✓ | | |
| | Li et al.'s | | | ✓ |
| | BM3D | | ✓ | |
| **Segmentation Techniques** | ITK-SNAP | | | ✓ |
| | Blue Sky Plan | | ✓ | |
| | 3D Slicer | ✓ | | |

The BM3D denoising approach ranks second in terms of enhancing image quality for better segmentation. As shown in Figure 1, only two segmentation methods (Blue Sky Plan and 3D Slicer) show acceptable performance on the CBCT image denoised by BM3D technique. However, some segmentation errors are still visible since the BM3D method oversmoothed the CBCT image.

Finally, Li et al.'s method ranks the lowest in denoising CBCT images. As shown in Figure 1, Li et al.'s method fails to effectively remove all noise, resulting in inaccurate and noisy segmentation, particularly by ITK-SNAP and Blue Sky Plan. Only 3D Slicer manages to achieve acceptable segmentation results on the images enhanced by Li et al.'s method.

For visualization purposes, we show in Figure 1 the 315$^{th}$ slice to of a 3D CBCT image after denoising and segmentation. The first row, from left to right, displays the noisy low-dose CBCT image followed by the denoised images produced by the methods of Chang et al., Li et al., and Hao et al. (BM3D). Rows 2 to 4 present the segmented images produced by the state-of-the-art methods ITK-SNAP, Blue Sky Plan, and 3D Slicer, respectively, for both the noisy CBCT image and the denoised images from Chang et al., Li et al., and Hao et al.

In the first column of Figure 1, the segmentation outcomes on noisy CBCT images are displayed using the three approaches. Notably, 3D Slicer excels at accurately highlighting teeth and bony structures despite the presence of noise and artifacts. In contrast, ITK-SNAP and Blue Sky Plan perform sub-optimally on noisy CBCT images, mistakenly detecting noise as teeth and bones around these structures.

The second column of Figure 1 shows the segmentation outcomes on a CBCT image denoised using Chang et al.'s method. In this scenario, all three segmentation techniques demonstrated improved accuracy, as the visual quality of the CBCT image was enhanced by this noise removal and edge preservation method. The second column clearly illustrates that all three segmentation approaches yield promising results on the denoised image, effectively detecting and highlighting teeth structures. In a more detailed comparison, 3D Slicer and Blue Sky Plan exhibit superior performance compared to ITK-SNAP, which incorrectly identifies the space between the third and fourth teeth as bone.

The third column deals with CBCT images denoised by the Li et al.'s method [12]. This column demonstrates that the proposed denoising method can enhance CBCT images, leading to improved segmentation compared to the noisy images in the first column. We observe that while both Blue Sky Plan and ITK-SNAP achieved higher accuracy in segmenting the denoised CBCT images compared to the noisy ones, they still fall short of the superior segmentation results produced by 3D Slicer.

The last column in Figure 1 illustrates the segmentation results of three proposed software options on the CBCT image denoised using the BM3D method described in Hao et al.'s paper [13]. Here, we can observe that both 3D Slicer and Blue Sky Plan software achieve higher segmentation accuracy compared to ITK-SNAP. The BM3D denoising method oversmoothed the CBCT images, leading to some segmentation errors, such as highlighting areas between two completely separate teeth, particularly noticeable in the ITK-SNAP tool.

## IV. CONCLUSION

This paper provides a comprehensive comparative analysis of three leading segmentation techniques applied to noisy and denoised dental CBCT images. We assessed the accuracy of 3D Slicer, Blue Sky Plan, and ITK-SNAP on CBCT images enhanced by three prominent denoising methods, all considered cutting-edge approaches for CBCT imaging. Our study highlights the challenge posed by high noise levels and limited resolution in CBCT scans, which diminish segmentation accuracy. However, we demonstrated that incorporating denoising techniques significantly enhances the performance of segmentation tools for CBCT images.

Our findings underscore 3D Slicer's superiority as the most robust segmentation tool for CBCT images, consistently outperforming its counterparts on both noisy and denoised images. Additionally, Chang et al.'s denoising method emerged as the most efficient technique, consistently delivering superior results across all segmentation tools compared to other denoising methods. These results emphasize the critical role of denoising in improving segmentation accuracy and highlight the potential of 3D Slicer and Chang et al.'s method in enhancing CBCT image quality for clinical applications in dentistry and maxillofacial surgery.

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# Detecting Gait Changes with Front-Facing Video and MediaPipe: A Hemiplegic Patient Case Study

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***Abstract*—Obtaining numerical skeletal data is a crucial method for objectively evaluating a patient's walking condition. Using MediaPipe, we evaluated data from the early stage of rehabilitation of a hemiplegic patient and five weeks later, using images taken from the front, where the area of the imaging facility is less restricted. We attempted to reduce spatial uncertainty owing to the influence of distance by measuring and evaluating changes in the height of the left and right ankles normalized by waist width, inclination of the shoulders, width between the toes and heels, and width between the left and right elbows. We proposed a method for detecting changes in the gait of patients undergoing rehabilitation. By applying this proposal, changes in gait could be determined.**

***Keywords—MediaPipe; rehabilitation evaluation; skelton analysi; digital health; walking analysis; front-facing recorded video.***

## I. INTRODUCTION

Assessing changes in a patient's condition is crucial in rehabilitation [1]-[3]. In particular, gait assessment in the clinical setting reveals considerable potential health status and predictive information. Quantitative instrumented gait analysis is recommended for clinical gait assessment; however, it is currently insufficient. With the rapid advances in machine learning research recently, reports on rehabilitation recovery are rapidly increasing. According to previous studies, various sensors are used to measure the time taken to perform a defined exercise, and the data are used to perform k-nearest neighbor approximation, support vector machine, random forest logistic regression, and other machine learning methods [4].

Spatio-temporal parameters during gait are considered an effective means of quantifying gait performance and determining the state of physical function. Inertial measurement units have the advantage of not having measurement space limitations, as they do not take measurements in a pre-installed 3-dimensional motion capture systems, which is released by Vicon Motion Systems Ltd UK and used as the de facto standard; however, validation against the de facto standard is needed [5][6].

Kinect for Windows v1 released by Microsoft has a Green-Red-Blue (RGB) camera for color video and an InfRared (IR) emitter. The camera allows depth measurement when the baseline between the camera and projector is known, and v2 has improved skeleton tracking. Azure Kinect DK, released in 2019, integrates with Artificial Intelligence (AI) applications. The potential for clinical applications of the ever-improving Azure Kinect camera is also being investigated [7]-[11].

Recent advances in machine learning and other technologies have enabled skeletal recognition in software, such as OpenPose [12]-[16], without using an IR camera like the Kinect. Because it can estimate the whole-body skeleton and human posture, it is currently used for the knee and ankle motion analysis. MediaPipe [17]-[23] supports various frameworks and can use video cameras and images captured by smartphone cameras for analysis. It has advantages such as the use of high-performance graphics processing unit (GPU) through Google Colaboratory. However, currently, no-code programming is possible and understanding of the

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source code is required. Therefore, applications such as reporting gait analysis are rare. In addition, owing to the problem of the rehabilitation area required for video recording, which is necessary for analysis, analysis from the sagittal plane direction is difficult, and only a few cases of implementation have been reported.

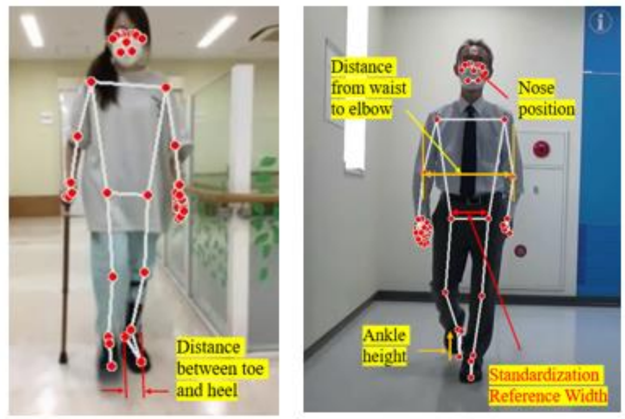
We reported on the possibility of using MediaPipe to analyze images taken from the frontal plane in terms of stride length and ankle angle at last year's conference. In addition, we measured the gait of subjects who had undergone physical and occupational therapy training and verified the effectiveness of walking aids for subjects who required hospitalization. The effectiveness of the walking aids was verified as follows: the dispersion of the nose position in the left and right directions was used as an index of body shake during walking; the tilt of the shoulders, hips, and neck during walking was calculated from MediaPipe data to determine balance; the time variation of these data was used as the basis for discrete Fourier spectrum decomposition and heel spectrograms. The effect of the walking aids on the subject's gait was demonstrated from multiple perspectives.

In this paper, we report the results of an investigation into whether MediaPipe can be used to detect gait changes during rehabilitation. The remainder of the paper is organized as follows. Section II presents the experimental conditions. Section III presents the experimental results, highlighting points that were characteristically observed in the subjects during rehabilitation as previously reported. Section IV discusses the obtained results, and by applying the proposal, the effect of distance from the camera was reduced by standardizing on hip width, and changes in gait were confirmed by determining height at the feet, tilt of the right and left shoulders, toe and heel width, and elbow width during gait. Section V concludes the paper.

This study was approved by the Ethics Committee on Research with Humans as Subjects of Teikyo University of Science.

## II. Experiments

Video recordings of the walking condition on the ORPHE ANALYTICS screen were recorded using the Snipping tool and analyzed using MediaPipe. During the measurement, walking for a distance of 3 m was filmed using a smartphone camera from the frontal plane. The subject, a patient, is a female in her 40s, right-handed. Her diagnosis was right capsular hemorrhage, her disability was left hemiplegia, severe sensory impairment, and she was independent in activities of daily living before the stroke onset; she was employed full time 5 days/week and commuted to work using public transportation. She was transferred to the hospital for convalescent rehabilitation approximately 2 weeks after the onset of stroke. Physical (120 min) and occupational (60 min) therapy were provided to her, and gait training was conducted during physical therapy. The first image was taken 72 days after onset, and the second image was taken on the 109th day. The patient was discharged from the hospital 4 days after the video recording, and rehabilitation was performed on an outpatient basis (subject A in the paper). When she was discharged from the hospital, she was walking with a T-cane and Short Leg Brace (SLB) outdoors. For reference, a subject without walking disabilities (subject B in the paper) videotaped a male subject in his 60s at a university. The video for subject B's analysis was captured using a video camera.




(a) Subject A (b) Subject B

Figure 1. Definition of evaluation parameters.

As shown in Figure 1, the width of the waist was used as the standard, and the coordinates of each part were assigned and normalized by this value. This was done because we thought it would solve the problem of measurement error in parameters during walking such as stride length, as the subject's image at the start of walking is small. This makes it easier to determine stride length and walking speed from the measurement results. The values shown in the results are defined as the distance between the toes and heel, the nose position, distance from the waist to the elbow, and ankle height, as shown in Figure 1(a) and Figure 1 (b).

## III. Experimental results

### A. *Height of left and right ankles*

When the images were taken from the frontal plane direction owing to the features of MediaPipe, the z-axis values increased as the subject approached the camera, and the z-axis values of the ankles and other parts of the body at the start of walking were normalized by the width of the hips to avoid the lack of clarity in gait conditions, such as stride length. Figure 2 shows the left and right ankle heights normalized by the width of the hips for subject at 72 days after onset. Figure 3 shows the same subject's ankle heights at 109 days after onset, normalized by the width of the hips.

### B. *Normalized shoulder angle*

The results at the beginning of rehabilitation and after 5 weeks are presented in Figures 4 and 5, which were obtained from the inner product of vectors using the coordinates of the left shoulder as the origin and the right shoulder angle with respect to the horizontal direction, normalized by the width



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of the hip. A difference in blurring was observed at the beginning of walking when measured at 72 days after onset compared to that at 109days after onset.

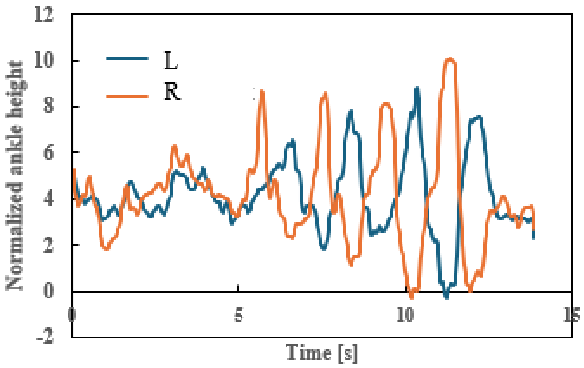


Figure 2. Normalized ankle height during gait at 72 days after onset.

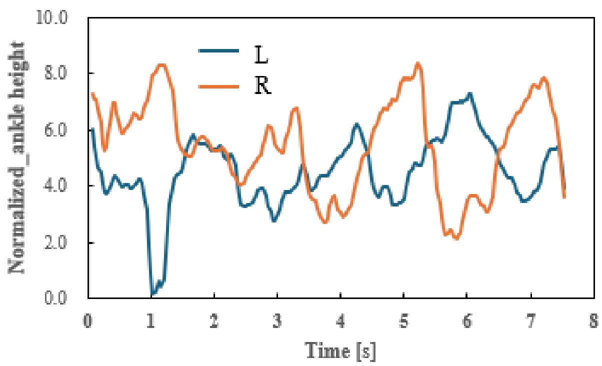


Figure 3. Normalized ankle height during gait at 109 days after onset.

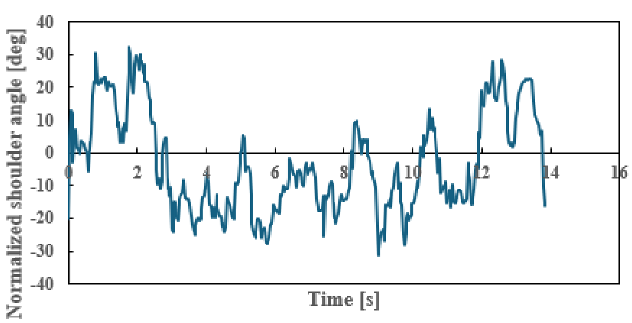


Figure 4. Angle of the right shoulder with respect to the left shoulder at 72 days after onset.

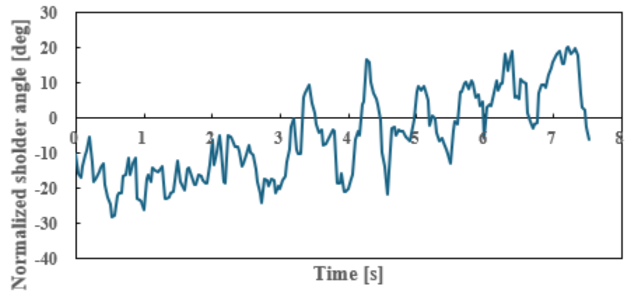


Figure 5. Angle of the right shoulder with respect to the left shoulder at 109 days after onset.

## C. *Blurring of the nose position*

Figures 6 and 7 show the lateral swing of the nose during walking as observed from the frontal plane at 72 days after onset and 109 days after onset, respectively. The initial measurement at 72 days after onset showed a minor blurring at the beginning of walking because it took longer to start walking than the measurement at 109 days after onset; however, the overall variation in amplitude was approximately similar when viewed over the entire time period.

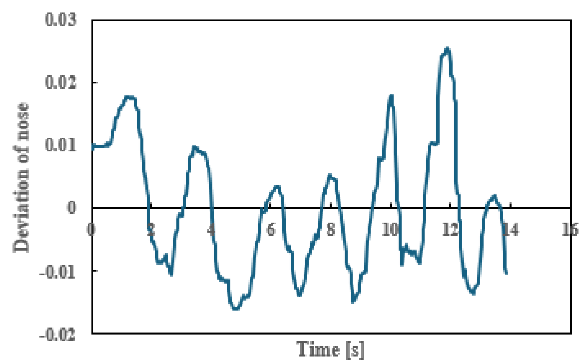


Figure 6. Nasal blurring in the left and right directions at 72 days after onset.

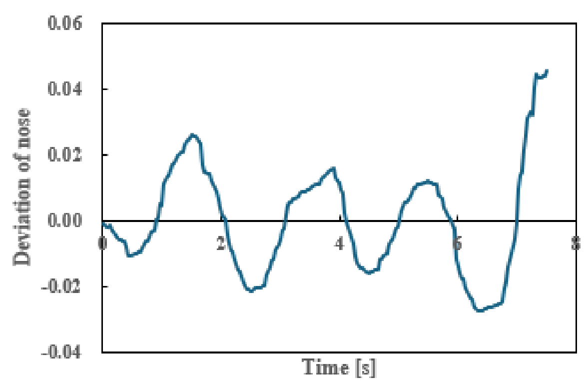


Figure 7. Nasal blur in left and right direction at 109 days after onset.



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### D. Change in the width between the toe and heel

Figures 8 and 9 show the changes in the width between the toes and heel of the left and right foot at 72 days after onset and 109 days after onset. It can be observed that the width is smaller at 109 days after onset.

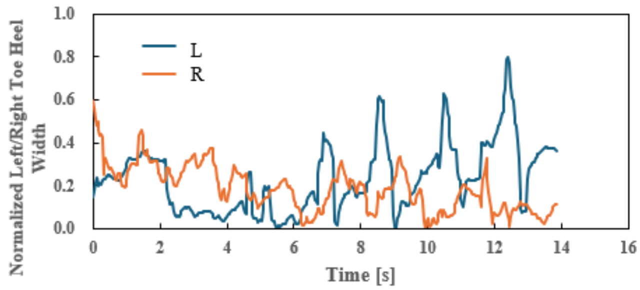


Figure 8. Normalized Width between the toe and heel of the right and left foot at 72 days after onset.

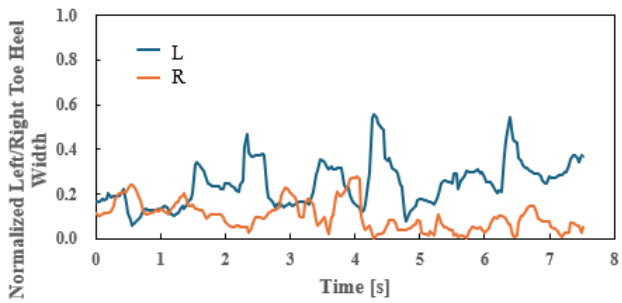


Figure 9. Normalized width between the toe and heel of the right and left foot at 109 days after onset.

### E. Blurring between the left and right elbow widths

Figures 10 and 11 show the blurring between the left and right elbow widths at 72 days after onset and 109 days after onset, respectively. It can be observed that the width decreased at 109 days after onset.

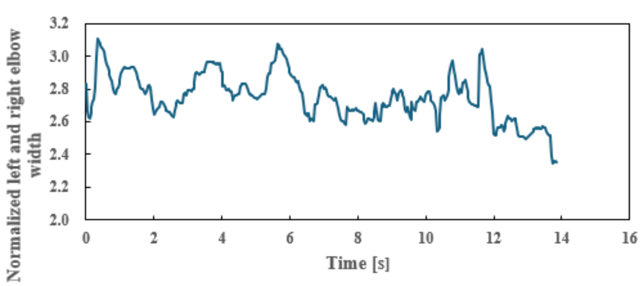


Figure 10. Normalized left and right elbow widths at 72 days after onset.

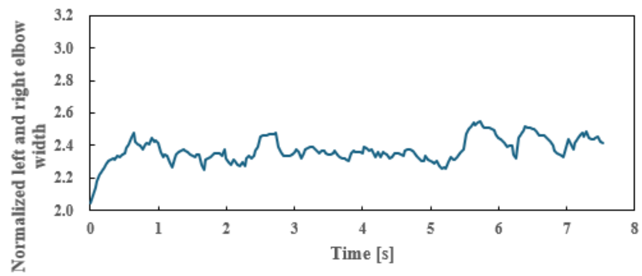


Figure 11. Normalized left and right elbow width at 109 days after onset.

### F. Temporal changes in knee and ankle during gait

Figures 12 and 13 show the left and right knee and ankle heights at 72 days after onset and 109 days after onset normalized by the width of the waist.

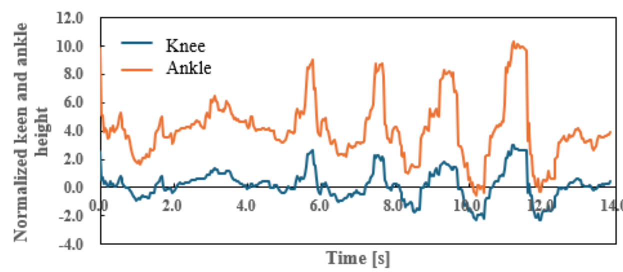


Figure 12. Normalized left knee and left ankle height at 72 days after onset.

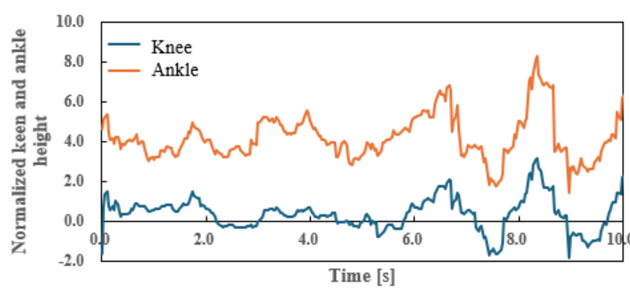


Figure 13. Normalized right knee and right ankle at 109 days after onset.

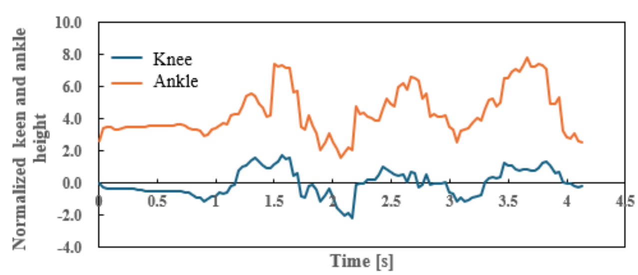


Figure 14. Left knee and left ankle height of subject B.

Figure 14 shows the left knee and left ankle heights normalized by the width of subject B's waist.



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## IV. Discussion

We will separately examine the extent to which differences can be detected between subject A's initial rehabilitation and five weeks later using MediaPipe's skeletal recognition data with videos taken from the anterior forehead direction.

### A. *Difference in normalized left and right ankle height due to width of the hips*

Because the normalization by the width of the hips allows us to obtain the amplitude of the foot height even in the early phase away from the camera and a flat area can be observed, it can be used to determine the stance and swing phases, although a detailed study has not been currently conducted.

### B. *Normalized shoulder angle*

The first-order component was not in the exact forehead direction at the time of video recording; which was thought to be because the gait started slightly to the left of the center of the screen and eventually shifted to the right. The linear component could be because the gait started slightly to the left of the center of the screen and eventually shifted to the right side.

### C. *Blurring of the nose position*

When the variance of the horizontal value in the direction of travel was used to blur the nose position, the blurring width was almost the same and the variance values were $1.6 \times 10^{-4}$ and $2.7 \times 10^{-4}$. This may be owing to an increase in walking speed at 109 days after onset. When normalized by the width of the waist, the component horizontal to the direction of travel became smaller as one approached the camera and could not be evaluated.

### D. *Change in the width between the toe and heel*

In the early phase of rehabilitation, the toe and heel width of the left foot, which is paralyzed, is wide, and it can be observed that the width of the right toe and heel is also affected by this effect. At 109 days after onset, the left toes and heels became narrower and improved, and the right toes and heels also became smaller owing to this effect.

### E. *Blurring between the left and right elbow widths*

The elbow width during walking was reduced by approximately 20% between the pre-rehabilitation period and at 109 days after onset, confirming the improvement effect of rehabilitation.

### F. *Temporal changes in the knee and ankle during gait*

The temporal difference between the knee and ankle was not evident in this experiment with MediaPipe, although the knee was slightly ahead of the ankle when evaluated on a time axis in some cases. As a comparison, the analysis of the experiment conducted with subject B did not reveal a time difference between the knee and ankle onset of movement.

## V. Conclusions

The effect of rehabilitation was verified using images taken from the forehead direction using MediaPipe. Standardization by the width of the hips reduced the influence of the distance from the camera, and the change in gait could be confirmed by determining the ankle height during walking, tilt of the left and right shoulders, width between the toes and heels, and width between the left and right elbows. The evaluation method for cases where it is difficult to take images from the sagittal plane and only from the forehead plane owing to limitations on the direction of imaging that occur in actual rehabilitation settings was demonstrated.

In clinical gait assessment, both the ability to walk and the method of walking pattern are crucial. Quantitative instrumental gait analysis is recommended for clinical gait performance and gait quality; however, it is currently insufficient. Although this study was conducted over a short time and distance and it cannot be said that this method of assessment is highly relevant to the evaluation of walking ability in real life, the walking ability of one of the patients studied also improved in real-life.

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# A Grounded Theory Study on Developing Competency Models for Technical Managers in Transformation of Medical R&D Findings

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***Abstract*—Despite its critical importance, the transformation (aim to industrialization) rate of medical Research and experimental Development (R&D) findings is significantly lower than in other fields, mainly due to the scarcity of skilled professionals. This study employs grounded theory and semi-structured interviews with key stakeholders from both the supply and demand sides to develop a competency model tailored for medical technical managers. By aligning the model with specific challenges and requirements of transformation of medical R&D findings, this research aims to significantly enhance these professionals' capacity. In addition, the competency model will provide a foundational tool for enhancing the quality and quantity of such professionals and facilitate the public's ability to benefit from scientific research findings more quickly and effectively.**

***Keywords—Transformation of medical R&D findings; technology transfer; technical managers; competency models; grounded theory.***

## I. INTRODUCTION

The experiences trying to combat the COVID-19 pandemic have highlighted the importance of transforming biological and clinical discoveries. In China, the concept of "transforming R&D (research and development) findings" aligns with the international notion of "technology transfer." Unlike the general definition of technology transfer, which involves the process from its owners or holders to another entity, the "transformation of R&D findings" emphasizes the complete process from experimentation, development, application, and promotion of valuable scientific results to the creation of new products, processes, materials, and industries. Thus, the transformation of R&D findings in the medical field not only improves health but also enhances the dynamism of the health industry, boosts employment, and yields substantial social value.

The pathway for transforming research and development findings in the medical field is particularly challenging. Its human-centric focus, prolonged processes, and substantial investment requirements characterize it. Additionally, medical professionals, such as doctors and nurses, often lack crucial business and legal knowledge. Coupled with the immense pressures of their work, these factors contribute to a significantly lower transformation rate in this field in China, as depicted in Figure 1 [1].

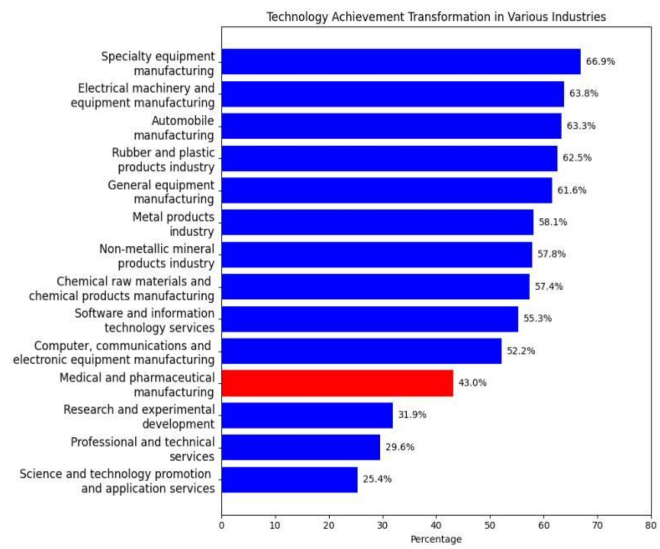


Figure 1. Industrialization rate of invention patents of Chinese enterprises in different industries, 2023 [1].

In July 2022, the revised "Occupational Classification Code of the People's Republic of China" was published, introducing the position of "technical managers" [2]. These professionals are engaged in the excavation, cultivation, incubation, maturation, evaluation, promotion, and trading of R&D findings and provide related financial, legal, and intellectual property services. Despite its recent development, research on technology managers remains in its infancy due to a lack of historical data and experience.

Since the 1970s, the cooperation between enterprises, universities and research institutes has become increasingly close [3]. As a result, some famous universities and research institutes, like Stanford University, began to set up technology transfer offices and hired technical managers. In 1974, the Association of University Technology Managers (AUTM) [4] in the USA was founded, aiming to promote the exchange and cooperation opportunities for technical managers. In 2010, AUTM, together with other national and regional associations, established the Alliance of Technology Transfer Professionals (ATTP) [5], which provide international standards and professional qualifications for practitioners in the field of technology transfer.

As medical technical managers are a kind of special and complex profession that relies heavily on experience, the training content of medical technical managers is difficult to quantify. Also, there are large differences in the regulatory policies of medicine and health in countries, so there are currently no standardized courses for medical technical managers that take into account the specificities of medicine. Above all, previous studies have addressed the positioning, skills, and expectations of technical managers [6]-[10], but some limitations and deficiencies remain yet:

- **Singular Perspective:** Previous studies primarily focused on the supply side of technology transfer personnel [8][10], ignoring demand transformation of medical R&D findings.
- **Not Specific Enough:** Existing competency models for technical managers have been developed across a wide range of scientific and technological fields, but no comprehensive competency model has been developed explicitly for medical technical managers.
- **Incomplete Analysis:** Transformation of medical R&D findings is a sequential and prolonged process. However, current research rarely delves into the specific skill requirements at different stages of the transformation process.

This study utilizes the Grounded Theory methodology [11], high-quality project samples, and interviews with stakeholders from both supply and demand sides to assess competency needs in medical R&D transformation. It aims to create a comprehensive competency model for medical and technical managers that could greatly enhance their effectiveness and increase the success rate of medical R&D transformation once implemented.

## II. METHODOLOGY

### A. *Semi-structured Interview Methodology*

Semi-structured interview methodology is a common way to acquire perceptions and experiences of a broad range of stakeholders [11]. This study uses semi-structured interviews to engage critical stakeholders in transforming medical R&D findings, focusing on both supply and demand. The supply side includes at least 12 employed technical managers and the demand side includes at least 36 researchers, clinicians and government officials. All participants are affiliated with Peking Union Medical College and its hospitals, which are actively engaged in transformation projects, ensuring a comprehensive insight into the challenges and needs of transformation of R&D findings.

- **Supply side (to technical managers):** Interview content was mainly included the match between their previous majors and current job, learning gains from the technical manager training courses, professional competencies that have been developed and need to be developed, and channels for acquiring new competencies.
- **Demand side (to researchers, clinicians and government officials):** Interview content mainly based on their work experience, which include questions about their level of need for technical managers, the specific transfer tasks/steps they expect to be assisted with, the major and minor competencies that the technical managers should have, and ideal cooperation model they expected with.

### B. *Grounded Theory*

Grounded Theory, introduced by Anselm Strauss and Barney G. Glaser in 1967 [12], is a methodology primarily used for qualitative research [13]. In this study, extensive interviews with stakeholders involved in the transformation of medical R&D findings are conducted, employing a three-level coding process of Grounded Theory (open coding, axial coding, and selective coding) to develop a comprehensive competency model for medical technical managers.

### C. *Data Analysis Tools*

The study uses NVivo and Microsoft Excel for source analysis. NVivo facilitates the deep reading, coding, and analysis of textual data, while Excel supports additional statistical analysis. Python scripts will also be utilized to create visualizations, enhancing the ability to analyze and interpret data trends effectively.

## III. EXPECTED RESULTS

### A. *Developing Competency Models for Medical technical managers*

The competency model for medical technical managers developed in this study is structured around two interdependent aspects, with plans for future expansion and refinement:

- **Individual Competency Perspective:**

*1)* ***Ethical Foundation:*** At the core, technical managers must possess strong moral and ethical standards, including integrity and a commitment to ethical practices.

*2)* ***Basic Competence:*** Essential professional knowledge spanning medical, legal, financial, and technological domains is required.

*3)* ***Soft Skills:*** Effective communication and collaboration skills are crucial.

*4)* ***Advanced Competencies:*** Experience-based skills such as leadership and strategic foresight.

- **Transformational Stage Perspective:** First, technical managers should be able to evaluate the market potential of findings and determine the finding's current stage of development and future development path. In the middle stage, technical managers need intellectual property protection and business negotiation skills. Finally, their ability to navigate the challenges of clinical trials and ultimately bring a product to market is critical, particularly during the rigorous phases of trial and commercialization.

### B. *Training Model for Medical Technical Managers*

Based on the developed competency model, this research proposes a comprehensive training model for medical and technical managers, which incorporates several key components:



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- **Course Content:** The curriculum spans from foundational medical knowledge to advanced topics in technology transfer strategies and regulatory compliance.
- **Educational Methods:** The educational framework includes degree programs for newcomers and continuing education for existing professionals.
- **Project Participation:** Engaging actively in projects from the initial research phase to market promotion provides technical managers with practical skills and capabilities.
- **Assessment Requirements:** This system will measure their technical knowledge, operational competencies, and strategic thinking and problem-solving skills.

Through this integrated training approach, medical technical managers will be comprehensively equipped to meet the diverse challenges and demands of the technology transfer process. This model aims to cultivate high-quality professionals capable of leading and driving the transition of medical and scientific achievements from the laboratory to the market.

## IV. CONCLUSION

This study addresses the challenge of medical technical managers' insufficient quantity and capabilities in transforming medical R&D findings due to unclear competency requirements. Utilizing Grounded Theory methodology, it aims to construct a competency model from both supply and demand perspectives, detailing the essential qualities, knowledge, and skills required for this role. This model will enhance the capabilities of existing medical technical managers and facilitate the training of new professionals, thereby improving the success rate of medical technology translation. Ultimately, this will enable research findings to benefit public health more swiftly, safely, and effectively.

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