Challenges of Integrating Industrial Product Design CAD Packages in Commercial New Product Development in SME Settings

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Abstract. This study helps industrial designers in small and medium-sized enterprises (SMEs) overcome challenges when using commercial computer-aided design (CAD) packages for new product development. While CAD tools are crucial for design finalization, they have limitations in assisting with the conceptualization stage, making it difficult for designers to transition between different stages of the design process. This research, funded by Innovate UK and a medical SME in the UK, focuses on the design and development of a cryo-compression delivering system to manage a chemotherapy side effect called Chemotherapy Induced Peripheral Neuropathy (CIPN). The case study examines the challenges of using 3D CAD tools for the leg wearable design as part of the CIPN system. Overall, this study provides solutions to overcome CAD limitations and supports innovative medical device development in an SME environment.

Keywords: Human Centered Design, SME, Commercial CAD packages, Chemotherapy-Induced Peripheral Neuropathy, New Product Development, Wearable design
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1 INTRODUCTION

This research focuses on one of the many challenges faced by industrial designers in SMEs with commercial CAD packages and offers solutions to overcome these limitations for new product development. Although CAD packages are crucial for design finalisation, CAD tools have limitations to assist the design conceptualization stage and designers struggle to transition between different stages of the design process. This gap in resources means it is necessary for designers to rely on traditional design tools such as sketching, as well as formulate creative solutions while using CAD tools for successful product development.

This commercially funded research in collaboration with Innovate UK and a medical SME in the UK is aimed at pioneering medical device innovations in the field of chemotherapy side effect management. The project is aimed at the design and development of a cryo-compression delivering system including a miniaturized device and wearable limb wraps to prevent the dose-limiting side effect of chemotherapy called Chemotherapy Induced Peripheral Neuropathy (CIPN). The case study investigates the challenges of using 3D CAD tools for the leg wearable design as part of the CIPN system.

2 BACKGROUND: CHALLENGES USING CAD FOR DESIGN AND DEVELOPMENT IN SME'S

Small and medium-sized enterprises (SMEs) are significantly important to the global economy as they lead economic growth and employment. Pursuing innovation enables SMEs to survive in tight competition, economic crises and compete against larger organizations [2]. Industrial or product designers are responsible for driving this innovation, by creating and developing concepts and specifications that enhance the function, value and appearance of products and systems for the mutual benefit of both user and manufacturer [9]. However, in an SME setting, knowledge and capabilities to adopt technological innovation is limited [2]. Hence, it is crucial that the designers work within limited resources, including a minimal number of CAD packages, to produce commercial products. 3D CAD has become an essential tool for designers in recent years, allowing for precise design representations and replacing manual drafting. The benefits are numerous, including increased accuracy in 2D and 3D modelling, greater efficiency by eliminating the need for physical prototypes, improved collaboration, and enhanced visualization of form, function, and performance. CAD can also help reduce costs, making it a valuable tool for many industries. Despite CAD being a valuable asset that can greatly improve the efficiency and accuracy of the design process, it's important to note that CAD has limitations that can impact the design process [1]. One drawback noticed in commercially used CAD packages is the lack of built-in support for conceptual design [14], which in an SME setting can potentially have negative impact. This paper analyses this gap in commercial product development settings using a case study of the design and development of the medical cryo-compression leg wrap in an SME environment, discusses the challenges, and offers solutions for designers to creatively use the commercially available CAD tools to deliver innovative commercially viable products.

The new product development process can be quite intricate, and often, depending on the nature of the product and the designer's capabilities, different pathways and methods are used to reach the final design [1]. During the ideation stage, designers aim to create the maximum number of evolving concepts possible. These are then modified or combined to form design solutions that are developed and finalized. During ideation, focusing on details is unnecessary, and more importantly, keeping ideas vague and incomplete is important to prevent limiting the designers' creativity. Traditionally, sketching and hand modelling were the main tools used by designers in the ideation stages to generate and validate design concepts. In light of the advancements made in CAD and CAS (Computer Aided Sketching) software, there has been a noticeable pressure placed on designers to create design concepts within increasingly shorter timeframes, particularly within commercial settings. While this has led some to question the necessity of sketching activities, arguing that CAD applications are better equipped to handle the task, it is important to approach this shift with caution [4]. Currently available CAD packages require precise and quantitative design information to compute a 3D model, which is typically not available in the design ideation stage and evolving these designs can be time-consuming. Also using CAD packages in the ideation stage can lead to creativity-hindering effects like circumscribed thinking, premature fixation, and bounder ideation [14]. Due to this limitation in CAD systems, designers are still using traditional design tools like freehand and digital sketching, as well as model making for concept generation. The downside of using traditional design tools is that the conceptual outputs delivered through sketching and modeling need to be reproduced in CAD, which can be a time-consuming and error-prone process, and the lack of 3D geometric information in sketches can cause difficulty in interpreting the designs algorithmically limiting the automated process [14]. Some argue that CAD offers sketching facilities, however, commercially available CAD tools with some "pseudo-sketching" capabilities are far from being a satisfactory alternative to sketching as they are oriented towards detailed instead of conceptual design [4]. There are some new developments in the field of computer- aided sketching (CAS) which provides a sketching environment for the designers that 'enhances their talents for conceptual design and innovation, and at the same time provide full integration with the subsequent phases of the product creation process' [4]. This development is promising; however, a usable product is not yet delivered.

Depending on the new product development setting, the design output expectations are different- for instance, in an academic environment, expected research outputs are often conceptual designs, whilst in a commercial setting, technically viable manufacturable products are also expected. Available human and financial capital and associated risks are also considerations for new product development. In the case of an SME with limited financial and human resources, investing in multiple CAD packages for new product development is not feasible [15]. Most commercially available software also has steep learning curves, with some software knowledge being less intuitive and not necessarily being closely linked to the design process [14]. Hence, often, the smaller design teams in SMEs will not have the time or expertise to learn and use these systems, forcing the designers to find alternative and mostly not conventional solutions to transfer design solutions into CAD to then push to manufacture. Whilst developing the cryocompression leg wearable in the medical SME, the authors have experienced the challenges described above during the design process. This is explained in the case study below, along with the design team's solutions to overcome these challenges.

3 CASE STUDY: DEVELOPMENT OF CRYO-COMPRESSION LEG WEARABLE FOR CIPN MANAGEMENT

Cancer diagnosis and treatment can have a significant impact on patients and their families, both psychologically and physically. Many patients experience severe side effects related to the cancer or the treatments used, with Chemotherapy-Induced Peripheral Neuropathy (CIPN) being the most common neurological complication. This disorder can lead to dose reductions in chemotherapy, which may be life-threatening, and long-term functional impairments that affect the patient's quality of life. CIPN can cause sensory and functional deterioration, as well as severe pain in the extremities (hands and legs), and although it may improve after chemotherapy, around 30-40% of patients continue to experience chronic symptoms. As cancer diagnosis and treatment continue to improve, survival rates are increasing, and the prevalence of CIPN may also rise [11].

The development of prevention and treatment options for CIPN is inadequate and requires immediate attention [3]. Although clinical trials of various neuroprotective agents are ongoing, none have displayed significant efficacy [7]. Lately, there has been an increasing amount of evidence backing up the effectiveness of non-pharmacological treatments for managing CIPN, particularly cryotherapy or hypothermia [10].

Limb cryocompression during chemotherapy has demonstrated promising early data for preventing/reducing CIPN severity. Recent studies suggest that regional limb cryotherapy can help reduce chemotherapy-induced damage by inducing vasoconstriction and limiting the delivery of toxic chemicals to the cooled region, while simultaneous cyclical compression improves the tolerability of cryotherapy for patients. Frozen gloves were found to be effective in preventing and reducing the occurrence of CIPN [6]; however, they have been recalled due to safety concerns. Other limb-cryotherapy products utilizing ice/gel packs and frozen gloves have limited effectiveness due to non-uniform cooling and lack of thermoregulation, causing patient discomfort. Additionally, frequent replacement of the gloves or packs can cause interruptions in cryotherapy delivery [3]. Currently, there are no medical devices available that are dedicated to the specific requirements of CIPN prevention, affecting 1.4 million patients worldwide and over 30,000 in the UK annually [13], highlighting the need for a novel innovation for the treatment of this debilitating chemotherapy side effect.

A collaborative and multidisciplinary approach is adopted by the medical SME to develop this dedicated CIPN treating system. This study only focuses on one aspect of the system – the design and development of the cryocompression treatment delivering medical grade leg wearable/ wrap. The aim was to design a one size fits all leg wrap design that covers and has close skin contact with the patient's leg up until the knee providing optimum cooling and cyclic compression, while also ensuring safety and comfort for the user.

3.1 Methodology

This project utilizes a human-centered design thinking approach to assist with the development of wearable medical devices and the double diamond design approach is followed. This includes focus on human factors such as usability, safety, ergonomic and anthropometric research collected through primarily stakeholder activities and combined with secondary data available. This collated data is used to inform the double diamond design process.

For SMEs, the risks to firstly identify suitable CAD packages and to purchase and adopt these packages are significant, owing to the lack of financial and skill resources. Encouraging collaborations with academic institutes can help the SMEs gain access to resources such as funding, knowledge, and support for feasibility studies. This solution of a collaborative approach is employed for the project in this case study using the UK government's Knowledge Transfer Partnership (KTP). This allowed the designers at the SME to assess different CAD packages with relative ease.

3.2 Computer-Aided Design

'When considering wearable design development alone, CAD is not the most appropriate design tool to be used in the design process' [5]. This is because designing wearables poses challenges of its own as designing for a complex organic shape, such as the human body, is not generally well supported in heavily engineering-based NURBS packages like Solidworks. The development of the cryo-compression leg wearable was particularly challenging, as the aim was to create a semi-boot-shaped, coolant, and air circulating multi-chambered RF welded flexible bladder enclosed in a medical grade fabric cover that has enough adjustability for 5th to 95th percentile leg sizes in the world, whilst ensuring patient comfort, safety, and treatment efficacy. Ideally, the design development of this project would benefit from software that can be used to animate the wrapping of the wraps on different leg sizes and simulate the coolant flow pathways and potential restrictions for the same. Hence at the start of this project, a plethora of CAD packages were considered.

Since wearable design has an element of flexible organic modelling requirements, textile design and pattern-cutting oriented CAD packages like Optitex (as seen in Figure 1) [12], and Clo 3D were analyzed initially. However, they were not found suitable for data mapping of polygon-based data to NURBS software for taking to manufacture. Also, the cost and learning curves for these textile packages for industrial designers are significant and, therefore, require further time and resources, both of which are limited in the SME setting.

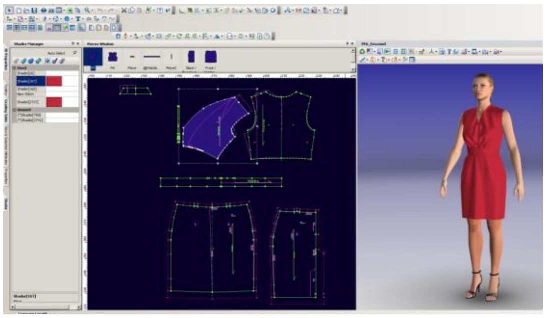

Figure 1: Evaluated textile software Optitex [12].

Other software like Alias from Autodesk and Rhino were also considered, however, this being a commercial project in an SME setting, the cost that is associated with such software packages for use in a single project was not supported by the commercial partner.

As a suitable CAD system could not be identified for the design conceptualization, traditional design tools like freehand and digital sketching, and model making were employed for concept generation, and in the design testing and finalization stages 3d engineering tool Solidworks was used to create 2D patterns for prototyping and tool making. A multidisciplinary team approach was also highly beneficial, promoted by the KTP partnership with the university. Drawing from the knowledge of different department like Arts, Humanities, Medical and Engineering including international partners allowed early investigation for the design team at the SME to enable safe analysis and accurate adoption of commercial software for developing leg wearable.

3.3 Design and Development

Industrial design process has many phases including research, ideation, concept evaluation, development, and finalisation, and at each of these stages of this project, designers had to find creative techniques to use engineering-based CAD packages to assess concepts, make prototypes, test, and deliver final design. The design process of the leg wrap went through multiple design iterations before reaching the final design (as seen in Figure 2). Being designed in accordance with a Human Centered Design approach, user's feedback is integrated in the entire product development process. The steps of this iterative design process are explained below.

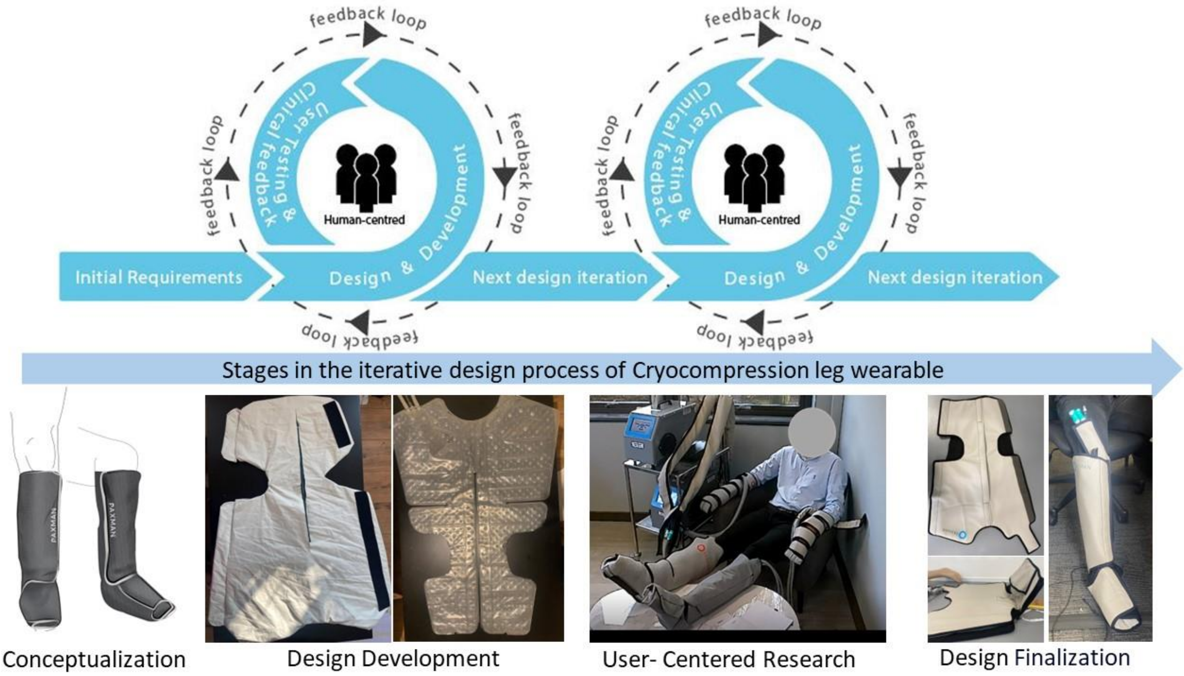

Figure 2: Stages in the iterative design cycles of the cryocompression leg wearable.

3.3.1 Design Conceptualization

In this wearable design there are two parts - a soft plastic RF welded heat exchanger and a fabric outer cover. For the design conceptualization stage, these components were taken into consideration separately for concept generation as they had different forms, differing materials, and different modes of manufacture, but still had to be integrated into one product and perform as one to function. As available CAD tools were not supportive of concept generation, the design team used a wide taxonomy of design representation like sketches, diagram and in-house handmade prototypes were made to test and evaluate the design concepts (refer Figure 3). Lack of automation in this process made this stage the longest in the design development process. Also, the designer had to self-teach new skills like pattern making, sewing, and stitching at an accelerated pace to meet the timelines of the project. As part of this development phase, it was evident that an ideation generating software tool that could be augmented with simulation capabilities would have greatly accelerated the process as well as checked whether each concept would be viable before committing time, energy, and effort to prototyping it in-house.

Figure 3: Some of the in-house prototype iterations generated during the design conceptualization stage.

3.3.2 User Centered Research and Design Development

Collecting user feedback for each cycle of this iterative development was a key part of the design process. This product being a medical device to be used in chemotherapy facilities, the primary stakeholders are nurses and patients. Evaluation of each iterative product prototype was done with multiple stakeholders, including patients, nurses, oncologists, technicians, etc., using several stakeholder activities such as design workshops, focus groups, and interviews to gain usability feedback to redefine the design requirements before the next design iteration and to continually improve the medical device. In each of these iterative cycles, the designers had to return to the traditional design tools mentioned previously to generate or tweak concepts. During this phase, it was recognized that the process of physical evaluation would have been more efficient if 3D tools were capable of initial evaluation of the design concepts.

Being a one-size-fits-all product, the wrap needs to be adjustable enough to fit the 5th to 95th percentile of all leg sizes in the world. The ideal option for the designer during the ideation and concept evaluation phases was to have access to CAD software with integrated human sizing and ergonomic data to inform the scale of the product and also to have an option to simulate the product on the human body to check for fit and sizing. Since this was not a feasible option with the available CAD packages, the sizing of the wearable was informed by thorough anthropometric research conducted in-house and analyzing existing literature available. This was again a research that required several design iterations and physical prototype generation to test for fit in users with different leg sizes (refer to Figure 4).

3.3.3 Design Finalisation

Considering this fabric like design is difficult to model in Solidworks, flat 2d patterns were modelled instead, which was then laser cut and sewn together to test the concept inhouse before investing in professional prototypes. This method proved helpful, as multiple iterations were created based on the anthropometric data, by just modifying the data input into Solidworks (refer Figure 5). A flat pattern of the wrap created in Solidworks was also provided to manufacturers for both professional prototypes and final close to commercial product. Although these 2D patterns can be generated in textile packages like Clo 3D as well, besides the reasons mentioned above, industrial manufacturers preferred engineering 3D CAD files for ease of translation.

Figure 4: User-centered research – Fit testing the anthropometric research backed wrap prototype on volunteers from different ethnic backgrounds and UK foot size ranging from 4 to 12 (representative of the 5th to 95th percentile population in the world).

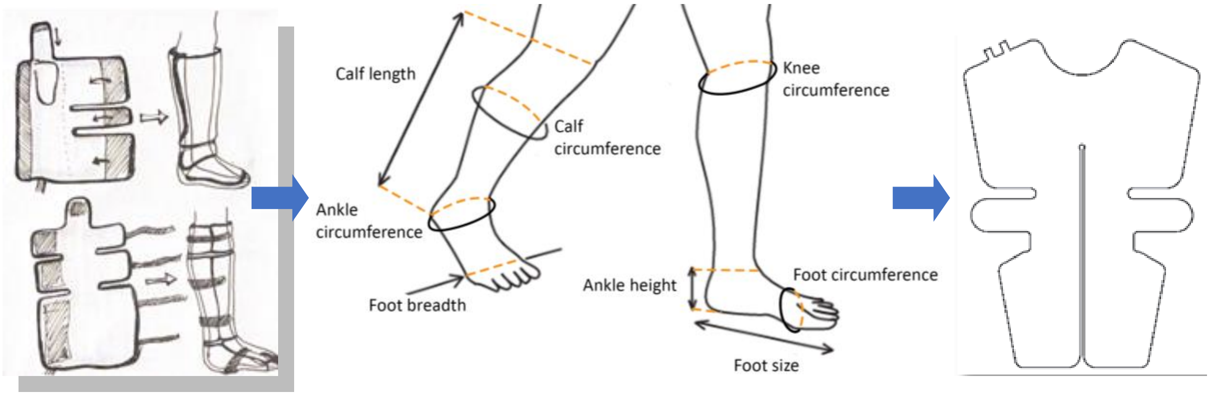

Figure 5: 2D patterns of concepts scaled to size based on the anthropometric research data is created in Solidworks, to provide to manufacturers for professional prototype generation.

4 DISCUSSION

The research conducted has brought to light a number of inadequacies in the current commercially available CAD packages. Specifically, during the concept generation and development stages of the cryocompression medical limb wearable, these drawbacks were highlighted in a practical setting. As a result, it is valuable to consider several opportunities or recommendations for the creation of a new and improved CAD package. Doing so will undoubtedly pave the way for more efficient product development, particularly within the context of small and medium-sized enterprises.

When embarking on the process of developing a new product, it is imperative to begin with thorough research. This initial stage sets the foundation for the entire project and can greatly impact its success. When it comes to the design of commercial and wearable products, anthropometrics and ergonomic factors are of utmost importance. However, it has been noted that existing sources of anthropometric data can be vague and inadequate, making it difficult for designers to accurately collate this information. As a result, designers may need to conduct additional studies, which can be both time-consuming and costly. To streamline this process, it would be highly beneficial for industrial designers to have access to CAD software with integrated human sizing and ergonomic data. Such software would not only save time but also ensure that the product is designed with the user's needs in mind and optimize the new product development process in SMEs.

"Current CAD tools push designers in precisely the wrong direction, encouraging users to bypass the refinement process of creative and critical thought and go straight to the finished work" [4]. Considering this, a crucial aspect that can truly aid the SME based industrial designers is the availability of a CAD package that not only supports design conceptualization but also facilitates a smooth transition into design development and finalisation. While the traditional design development tools such as sketching, modelling, and prototyping have their own benefits, they may not be the most efficient in certain situations, especially when time is a critical factor. Take, for instance, the case of time bound leg wrap development where multiple iterations were required based on stakeholder feedback. Under such circumstances, relying solely on traditional design methods could prove to be time-consuming, expensive, and even inaccurate. Moreover, these methods may require learning new skills and often pose challenges when it comes to translating the designs into CAD packages. Therefore, having a CAD package that enables designers to quickly create conceptual designs and simulate necessary actions can provide them with a unique opportunity to make the best use of traditional design development tools. By using such a package, designers can work more efficiently and effectively, ultimately leading to better outcomes and increased success for their businesses.

In the realm of wearable design development, it is crucial to have access to a CAD package that is capable of efficiently mapping polygon-based data to NURBS software. This is particularly important because most manufacturing facilities require NURBS based data. It is undeniable that innovative wearables are becoming increasingly common in today's society. In fact, health monitoring technologies that were once only found in hospitals for medical diagnosis and monitoring of critical diseases are now readily available to the general public through consumer wearables. This has allowed a vast majority of people to purchase these devices for monitoring their personal health [5]. Whether it is a wearable product or any product that features a more organic or complex shape, software that is capable of achieving this level of data mapping will prove to be an incredibly valuable toolkit for industrial designers. With such a software, designers will be empowered to create innovative and cutting-edge designs that can be seamlessly manufactured with NURBS based data. The ability to produce such designs will not only benefit the designer but also the manufacturer and the end-users.

In today's competitive business environment, innovation has become a key factor for the survival of SMEs. The ability to continuously develop new and improved products and services is essential for SMEs to stay ahead of the game, especially during challenging economic times. This is where innovation comes in, providing SMEs with the necessary tools and strategies to compete against larger organizations and overcome obstacles [2]. While conventional computer-aided design (CAD) tools have been beneficial for SMEs in terms of detailed engineering design, they have also presented limitations that hinder novice designers' creativity. These limitations stem from the intuitive ideation restriction that designers face when using such tools. In addition, the need to use different design media during various stages of the design process has made the integration of CAD tools a challenging task. As a result, this constricted approach can hamper the capability of the design process and the collaboration that goes along with it. It can also lead to miscommunication amongst designers, further complicating the design process [8]. Therefore, it is crucial to develop an accessible and more inclusive design software that can create long-term benefits for SMEs.

5 CONCLUSION

Although there are many advanced CAD tools developed and packages available for research and academia, implementing these packages into a commercial environment like an SME is still difficult. Hence, there is an opportunity here for CAD developers and relevant industrial design stakeholders to collaborate for creating a new SME or commercial environment focused CAD package that is suitable to cater for all stages of the design process while also having the benefits of advance tools like CAM, AI, VR and tools for testing, production, and simulation. This would enable design teams in SMEs to speed up the design process whilst still delivering creative and technically viable end products.

Up until then, as evidenced in the case study of the commercial leg wearable design, designers should employ creative methods to use currently available CAD packages to aid the design process. Where the product form is complex and organic, as evidenced in the case study, making 2d flat patterns, and using techniques like laser cutting and sewing can accelerate the design process phases such as ideation and concept evaluation. Also, to reduce the risk element in research and development, SMEs can consider collaborating with international teams and academic institutions to draw from their knowledge on CAD packages before investing in one.

In conclusion, pursuing innovation is vital for SMEs to survive in today's competitive market. With the development of more user-friendly and inclusive design software, SMEs can overcome the limitations of conventional CAD tools and enhance their design process. This, in turn, will enable SMEs to create innovative products and services that meet the changing needs of their customers and stay ahead of the competition.

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