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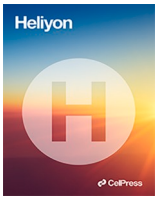

Research article

3D printing traceability in healthcare using 3Diamond software

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ABSTRACT

Background: 3D printing is one of the fastest-growing technologies in medicine, but it is essential to have a system for 3D printing documentation that is accessible for not only clinical engineers and surgeons, but also quality managers and data-privacy officers in hospitals. Dedicated software such as product lifecycle management (PLM) software could enable comprehensive management and traceability of all data relevant to 3D printing tasks in a hospital and would highly beneficial. Therefore, customizable software called 3Diamond was developed for 3D printing in medicine.
Methods: The software development process involved several stages, including setting specifications based on end-user requirements, design, implementation, and testing. In order to ensure the software's long-term success and smooth operation, critical phases were also considered, such as deployment and maintenance.
Results: The developed software provides immediate and complete traceability of all preparations and controls, as well as management of reports, orders, stock, and post-operative follow-up of tasks related to 3D printing in a hospital. Based on user requirements, software testing is provided automatically with each release. The software was implemented in a natural clinical environment with a developed 3D printing center.
Conclusion: Although 3D printing has potential for innovation in the medical profession, it is nevertheless subject to regulations. Even though there are exemptions for patient-specific products, the effects of their local legal implementations related to 3D printing cannot be fully overseen. To this end, 3Diamond provides a robust system for 3D printing documentation that is accessible to different personnel in hospitals.

1. Introduction

3D-printed models can be fabricated from patients' radiological data, such as computer tomography (CT) or magnetic resonance imaging (MRI) data, and provides advantages of haptic feedback and enhanced understanding of the patient's anatomy. Patient-specific models can be rapidly fabricated, which opens new horizons in personalized patient care in many clinical fields [1,2]. This is one of the primary reasons healthcare providers are incorporating 3D printing technologies in clinical practice, and in-house 3D printing labs are being established worldwide.

Hospital-based environments are starting to host 3D printing labs outside of the engineering and manufacturing sector. However, there is currently no central oversight or organization of these facilities. While there is considerable knowledge about the applications

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Printing in healthcare, there is limited data and tools available for the infrastructure of the facilities and their resources (e.g., management structure/personnel, budget and equipment resources and outputs) [3]. Despite the benefits and potential innovations, 3D printing technologies used in medicine are subject to international regulations. In European Union countries, the Medical Device Regulation (MDR, Regulation (EU) 2017/745) was fully implemented in May 2021. Although there are exemptions for patient-specific products, the impact of their local legal implementation on in-house legal implementation in in-house 3D printing cannot be fully overseen. It is essential to have a system for 3D printing documentation that is accessible to not only clinical engineers and surgeons, but also to quality managers and data privacy-officers in hospitals.

Such a system should include the whole history of any 3D printing task for every patient. Such information must be easily traced from the 3D model to the clinical data relevant to patient follow-up [4–7]. Good documentation is essential for a quality assurance system [8]. However, a downside of quality assurance in healthcare is the significant increase in paperwork before, during, and after production.

It has been shown that this problem could be solved by dedicated computer software such as product lifecycle management (PLM) software. Therefore, this study introduces PLM software for comprehensive management and traceability of all data relevant to 3D printing tasks in a hospital. This customizable software is called 3Diamond and provides immediate and complete traceability of all preparations and controls. The software could provide great help in managing reports, orders, stock, and post-operative follow-up.

2. Methods

2.1. Agile user stories for software specifications

The software development process involved several stages, including setting specifications based on end-user requirements, design, implementation, and testing. It is also essential to pay attention to critical phases like deployment and maintenance to ensure the software's long-term success and smooth operation. We used an agile approach to define the specifications of 3Diamond, and requirements were expressed as user stories [9,10] with the following format: "As a ⟨type of user⟩, I want ⟨goal⟩ [so that some reason]". One example is, "As a biomedical engineer, I want to receive an email when a 3D print is needed so that I can initiate the procedure." User stories were classified as "must-haves," "nice-to-haves," or "very-nice-to-haves" for the roles of (A) biomedical engineers, (B) clinicians, and (C) quality managers. The classification was based on the needs and requirements of the system. All user stories describe different use cases of the PLM system.

2.2. Design and data structures

The 3Diamond software was built on Clade-IS (CLinicAl Data warEhousing – Information System), an established and modular web-based electronic data capture (EDC) platform for clinical trial management. In addition to clinical trials, Clade-IS has been successfully used as a universal data-management platform for real-world evidence projects across many clinical specialties, such as oncology, neurology, rheumatology, hematology, and hemato-oncology. As a result, Clade-IS has recently gained attention for post-market follow-up studies, which are essential for medical device manufacturers to comply with the new MDR in the European Union.

A machine learning-based algorithm was implemented and evaluated to detect anomalous patterns in quantitative data using the Clade-IS platform [11]. The algorithm showed high sensitivity in detecting anomalies, demonstrating the platform's ability to handle large and diverse datasets while ensuring data quality and integrity. This capability is beneficial for managing large and varied

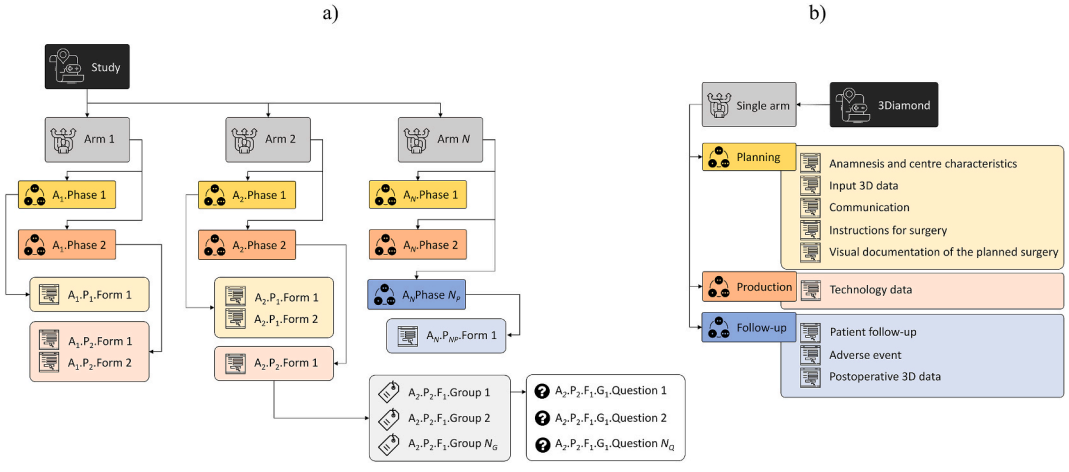

Fig. 1. (a) Structural overview of eCRF entities in the generic Clade-IS EDC system (adapted from Churová et al. [11]) and (b) application of these entities in the three phases of the 3D printing process, which are subdivided into nine specific forms.

datasets, making it a valuable tool for data management in various processes, including medical 3D printing.

The Clade-IS EDC system's database model is an entity-attribute-value (EAV) model (also known as a vertical database model) and serves as the foundation for the 3Diamond PLM system. It is known for its efficiency in capturing entities with sparse features, making it particularly beneficial for clinical or patient registries, which typically include numerous parameters but often lack specific values. The generic Clade-IS EDC system is eCRF, which is constructed using the following data structures: arms, phases, forms, question groups, questions, and answers. A question-answer pair represents an attribute-value pair. Fig. 1a illustrates the basic setup of the eCRF entities in the 3Diamond PLM system. The hospital 3D printing procedure is divided into three main phases: (1) planning, (2) production, and (3) follow-up, as depicted in Fig. 1b, which also illustrates the nine data-gathering forms associated with these phases.

2.3. Software description

The 3Diamond software was designed as a web-based application with a client-server architecture that adheres to modern design principles and best practices in software development. The application's user interface (UI) was designed to ensure an optimal user experience focusing on usability, accessibility, and responsiveness. Primary navigation is achieved through an organized main menu (see Fig. 2) with relevant submenu items presented contextually based on the user's role and current task.

The software consists of three interrelated modules designed to serve specific functions in the 3D printing process, such as data input, data retrieval, and process management. The user roles, including clinicians and engineers, are visually distinguished by distinct color coding to facilitate quick identification and minimize the risk of confusion or errors. Key features of the 3Diamond software are elaborated below with emphasis on technical aspects and functionalities that contribute to its effectiveness in facilitating 3D printing tasks within the healthcare domain.

2.4. Planning

The planning module is dedicated to the preparation of the 3D print before printing. Physicians provide the anamneses, photo documentation needed for understanding the task, specifications of the 3D print use, and the deadline for obtaining the physical model. Afterwards, a biomedical engineer inputs a virtual 3D model into the software in a stereolithographic or 3D pdf format. At this point, an approval procedure is needed. Once the physician approves the virtual model in the software, the production module can be started. Two other optional modules are available and can be used for planning a surgery. A physician can also store documentation needed for surgery, such as a design draft or a list of used instrumentation.

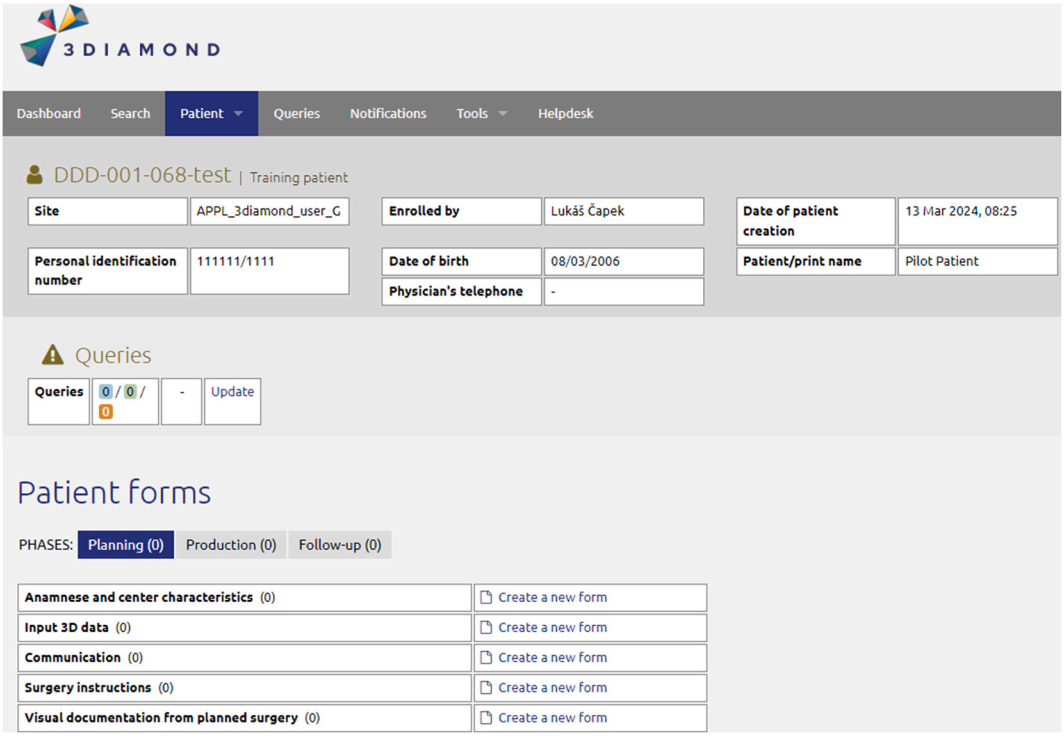

Fig. 2. Preview of main menu of 3Diamond. It is organized into three main 3D printing steps: planning, production, and follow-up.

2.5. Production

The production module is dedicated to biomedical engineers. They can fill in all information concerning the procedure of 3D printing, such as the type of 3D printer, technology, type of material used, the quality of the print, temperatures, printing type, infill type, and others. When the 3D model is printed, a quality dimensional check of the model is done, and a G-code report is stored in 3Diamond.

2.6. Follow-up

The follow-up module acts as a dynamic repository for post-intervention information. It allows the entry and storage of post-procedural 3D models and relevant patient outcomes. Additionally, it can capture textual or graphical surgeon feedback and document any adverse events, which enhances the scope and accuracy of patient records after 3D print-assisted interventions.

2.7. Other features

The 3Diamond software leverages the robust foundation of a generic EDC system while inheriting numerous advantageous features that enhance its functionality and ease of use for medical professionals and biomedical engineers. Building upon the existing capabilities of the EDC system, 3Diamond can be customized and optimized by experienced data managers to meet the unique needs of 3D printing tasks in medicine and healthcare.

2.7.1. Audit trail and traceability

The 3Diamond system benefits from the traceability and audit-trail functionality inherent in clinical-trial EDC systems. This feature maintains a comprehensive log of all user activities and data changes within the system, providing a secure and reliable means of tracking the progress of each 3D printing task. The audit trail ensures data integrity, accountability, and transparency in the 3D printing process while also serving as a valuable resource for troubleshooting, quality assurance, and regulatory compliance.

2.7.2. Automated email notifications

Adapted from the adverse-event reporting mechanism in clinical trials, the 3Diamond software features an automatic email notification system. This functionality streamlines communication between physicians, biomedical engineers, and other stakeholders throughout the 3D printing process. For example, when a virtual 3D model is ready for approval, the system automatically notifies the relevant physician via email, ensuring timely review and approval for subsequent steps in the workflow.

2.7.3. Scalability and customizability

The modular nature of the EDC system provides the 3Diamond software with a high degree of scalability and customizability. As the field of 3D printing in medicine and healthcare continues to evolve, the 3Diamond system can be easily adapted and expanded by skilled data managers to incorporate new features, technologies, and workflows. This flexibility ensures that the software remains a cutting-edge and effective tool for managing 3D printing tasks in the rapidly changing medical environment.

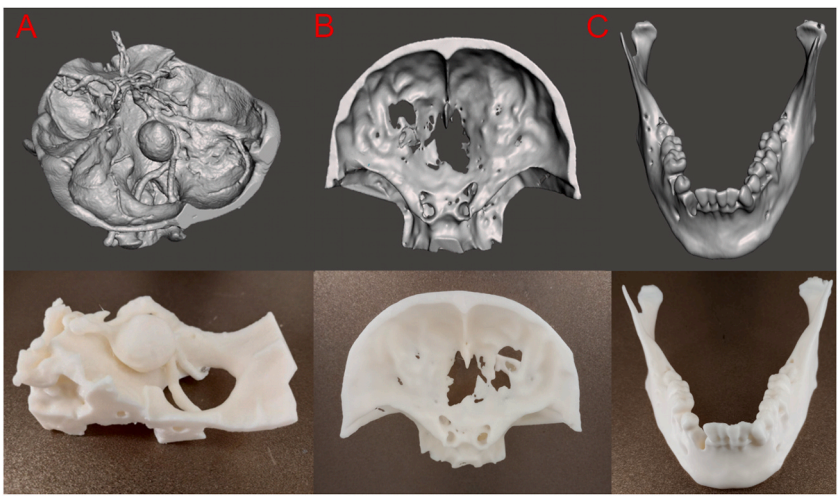

Fig. 3. Typical examples of 3D printed models for pre-operative planning: A) intracranial aneurysm, B) skull base defects, C) mandible bone.

3. Results

The 3Diamond PLM system was designed with all the functionalities that are considered to be "must-haves." There are two deployment modes for the software: through SaaS (Software as a Service) using the information-technology infrastructure provided by the developing Institute of Biostatistics and Analyses and through conditional licensing using a hospital's own infrastructure. The software was implemented in Liberec Regional Hospital (Czech Republic), a midsize hospital with 1143 beds. The uses were primarily for neurosurgery, orthopedic surgery, and maxillofacial surgery.

The software was tested on 25 real cases in the hospital. There were six cases from the maxillo-facial department, five from the department of traumatology, six from the orthopedics department, and eight from neurosurgery. A typical example of these models is shown in Fig. 3(A-C). The time needed for filling in most of the columns with 3Diamond (excluding follow-up) was 3–7 min, depending on the skills of the service.

4. Discussion

"Health 4.0" is based on developing new technologies such as 3D printing in healthcare facilities [12,13]. The results of implementing this new technology point out benefits of improved quality, flexibility, productivity, cost-effectiveness, and reliability of healthcare services. Furthermore, it increases patients' satisfaction. 3D printing is one of the newest technologies being introduced into the healthcare system and is bringing increased demands on the quality of required procedures. It has been shown that rapid prototyping technology has an irreplaceable position in personal medicine and tissue engineering [14–17].

Quality system regulations generally state that design-input requirements must be documented and that specified conditions must be verified. 3Diamond software is focused on managing the lifecycle of 3D printing in hospitals but does not help to print the models themselves. A standard quality management procedure can generate vast amounts of printed documents per year (quality controls, reports, etc.). In this respect, the software decreases the number of staff needed because it helps to save and store documents. Printing every report is unnecessary since it is stored on a computer and can always be easily located. The traceability and responsibility of every individual in the 3D printing cycle are visible and can be easily found at any time. The authors' concerns about the inappropriate handling of patient records required for 3D printing were confirmed in discussions with stakeholders.

There are two particular issues that pose a risk to the hospital, and an opportunity for the wider adoption of the 3Diamond PLM system: (i) interdisciplinary communication between biomedical engineers and clinicians via WhatsApp or other unsuitable messaging applications and (ii) file transfer via physical USB flash drives. At the very least, these are sensible departures from recommendations, especially in a time when strict data protection regulations have been established, fines are imposed, and there are notable breakthroughs in hospital networks. In addition, in order to support further business development processes, the unmet needs of various stakeholders have been formulated.

Further development of the features of the 3Diamond PLM system is expected mainly in the handling of image data, with a focus on the rendering of STL files that are carried over 3D printing models. There are several ways to display STL data on the web. Besides the PDF format, the most suitable way seems to be to use the HTML <canvas> element rendered on a client device using WebGL and the three.js library.

5. Conclusion

Robust software for 3D printing documentation was developed. Concerning the regulation of medical devices such as 3D printed parts for clinical use, such software offers many benefits. It is easy to use, the data are traceable, and implementation in a quality management system is feasible. Our experience has confirmed these assumptions. The implementation in a natural clinical environment proved that 3D printing is easy to implement in an in-house quality management system of the hospital and saves time.

Data availability statement

No underlying data are available for this article, since no datasets were generated or analysed during this study.

CRediT authorship contribution statement

Lukas Capek: Writing – original draft, Validation, Supervision, Software, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Daniel Schwarz:** Writing – review & editing, Validation, Supervision, Software, Resources, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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