AGILE DEVELOPMENT OF A MICROTITER PLATE IN AN INTERDISCIPLINARY PROJECT TEAM

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ABSTRACT

The industry is currently changing rapidly. Both customers and employees are focusing much more on their own needs. On the one hand, this requires individualized products and, on the other hand, development processes need to be aligned not only more efficiently but also more closely to the needs of employees. Agile development combines these two characteristics and the second point can be further improved through analyses for collaboration. This is not only necessary for consumer products, but also in medical technology, more and more individualized solutions are required to better help patients. This is also the case with the examination of cells using micro titer plates, which is the subject of this project. Due to the interaction of research activities both on the process and on the product side, this paper presents research results regarding agile product development and collaboration analysis of physical products on the one hand and research results regarding additive and biocompatible production of microtitration plates on the other hand.

Keywords: Agile, Colaboration Analysis, Design process, 3D printing, Complexity

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1 INTRODUCTION

In many industries, the demand for user-oriented products is growing. Products must be able to be adapted to individual requirements and implemented within short development cycles (Mourtzis *et al.*, 2014). With these wishes, some companies are pursuing the goal of changing the development from phase-oriented development to agile development. Agile development means responding quickly, flexibly, and adaptably to new conditions in uncertain situations (Hofert, 2016). As a result, requirements can be changed later than usual and new customer requests can be integrated (Beck *et al.*, 2001). Currently, the major challenge is shaping and exemplifying the agile values, principles, and methods of physical product development (Moreira, 2013). On the one hand, elements of the introduction and also the implementation of agile development are helpful, while on the other hand, the collaboration of the team members plays a major role. Investigations in this area can improve development processes in follow-up projects (Schweigert *et al.*, 2017a).
An example of the combination and application of physical agile development and collaboration analysis is the IDAGMED project, which involves the further development of a microtiter plate. With these plates, toxicity testing and drug screening can be performed. For this, chip-occupied sensors are attached to the plate, which makes real-time monitoring possible in order to directly examine statements about cellular vitality and growth, as well as metabolic and morphologic changes (Wolf *et al.*, 2013).
The aim of this research is an improved agile development process for product development that is supported by collaboration analysis and evaluated in a case study for medical device development. The sub-goal for agile product development is to evaluate and improve the findings of Gerber *et al.* (2019). The project is divided into two sub-phases, and the paper from Gerber *et al.* (2019) describes the research results from the first sub-phases, while this paper presents the final results. The sub-goal at the product level is the production of the physical component of the plate, the body and the associated lid. The focus is on a changeover to additive manufacturing to individualize the plates. Particular challenges include biocompatibility, manufacturing accuracy, and the creation of similar frame parameters.

2 LITERATURE BACKGROUND

2.1 Agile product development and collaboration analysis

Values and principles of agile product development are summarized in the agile manifesto. The values focus on the interaction, the product, and the costumer, as well as on the employees. Fixed processes, documentation, and contract negotiations are also part of the agile product development, but these are less prioritized (Beck *et al.*, 2001). The values of the agile manifesto were represented in the processes and methods of software development first, e.g. extreme programming or feature-driven development (Highsmith and Cockburn, 2001). Based on the effort to transform agile development to other development domains, more and more project management and hybrid models have emerged, e.g. scrum, agile stage process, TAFagile framework (Sutherland and Schwaber, 2017; Cooper and Sommer, 2016; Böhmer *et al.*, 2016).
Of all agile processes, scrum is the most applied process (Komus and Kuberg, 2017). Scrum, in addition to several agile processes, focuses on iterative phases, a planning of the phases, a meeting for product feedback, and a continuous process of improvement (Sutherland and Schwaber, 2017; Goevert *et al.*, 2019). In addition, three typical roles exist in the scrum process. The agile coach is responsible for the process, the applied methods, and for teaching the agile values. The product owner represents the needs and requirements of the product and focuses on product advances. The team members develop the prototypes, increments, and the product. (Moreira, 2013; Sutherland and Schwaber, 2017)
Different case studies of agile physical product development exist. For example, Sommer *et al.* (2013) present three case studies of scrum integration in an existing stage gate process. Scrum is applied in the different stages to reach the gates (Sommer *et al.*, 2013). Another case study is described in Böhmer *et al.* (2016). They developed a student seminar for early development phases. In two weeks, the students develop a product from the first idea to a final prototype with customer integration on the basis of the TAFagile framework (Böhmer *et al.*, 2016).
The data generated during the agile development of the case study of the microtiter plate forms the foundation for the collaboration analysis described in section 4.3. The data is gathered through the documentation of tasks, peopl,e and artifacts in the agile development process. The structural analysis

of this data is built upon metrics for the engineering design process by Kreimeyer and Lindemann (2011). Using the Goal-Question-Metric approach as described by Koziolek (2008), which was developed by Basili and Weiss (1984), they define a set of metrics for engineering design processes, which will be used in this work. A similar approach is described in Mathieson and Summers (2017). They describe a protocol that uses e-mail exchange and other data to build networks that can be analyzed via network metrics.

2.2 Microtiter plate

Microtiter plates are plates with 6 to 1536 wells to parallelize cell analysis (Lob, 2009). Basic microtiter plates are produced in high numbers and are manufactured using an injection molding process (Lücking *et al.*, 2015). Lücking *et al.* (2015) manufactured specific microtiter plates additively in a selective laser sintering process and highlighted the cost reduction by low quantity. In this project, the focus is on a specific injection molded microtiter plate. The plate was designed by Pfister (2015), who used the developed plate from Lob (2009) as a basis. The plate has 24 wells, and each well has three cavities. One is for the inflow of the substrate, one is a reaction chamber, and the third one is used for the substrate outflow. This approach is based on the physioControl microsystem approach (Lob, 2009). From below, the electronics, which are integrated in a glass plate, are glued. From above, the reaction cavity is limited by a piston (Pfister, 2015).

3 RESEARCH METHODS AND BOUNDARY CONDITIONS OF THE PROJECT

3.1 Research gap and research questions

The literature background in the previous section showed the state of the art for agile product development at the method level and described two example case studies. Both are very interesting and represent added value for agile mechatronic product development. However, Böhmer *et al*. (2016) focused on the early phases and a starting point in which no product, no company, and no organizational requirements without capacity requirements exist. On the other hand, Sommer *et al*. (2013) focused on industry requirements, but they integrated agile development in defined processes and did not integrate the tasks and goals of physical product development in an agile framework. Integrating the tasks and goals of physical, medical device development into an agile environment is the research focus at the process and method level of this project. The initial results are described in Gerber *et al*. (2019), but this paper shows the evaluation and improvement of the agile process of Gerber *et al*. (2019) and the following research question derived from it: How does the agile process have to be built so that the tasks, goals, and requirements of medical device product development can be integrated?

Research is required not only at the method level. The first challenge at the product level is the change from the injection molding process to an additive manufacturing process because high accuracies, biocompatibility, and small structures are required. Another challenge is a new plate geometry, which our project partner has patented. The following research question is derived from it: How can a biocompatible microtiter plate with different geometries be built with an additive manufacturing approach?

3.2 Research design

The design of the research methodology of Blessing and Chakrabarti (2009) helps to structure the research process. The initial research clarification phase defines the goal and the initial situation (Blessing and Chakrabarti, 2009). In this project, a project vision with detailed information about the focus group, their needs, developed products, and the research goal were formulated (vision see section 4.1.1). The descriptive study 1 is the second phase. In this phase, the focus is on a deeper understanding of the research fields (Blessing and Chakrabarti, 2009). Research fields are the agile product development, collaboration analyses, and additive manufactured biocompatible microtiter plates (see section 2). Third, the prescriptive study is applied. In this phase, solution approaches of the identified challenge are solved (Blessing and Chakrabarti, 2009). This research focuses on two solution approaches at different levels. One operates at the product level and on a biocompatible additively manufactured microtiter plate. The other work is at the process and method level, with an approach for agile medical product development (see section 4). The prescriptive study 2 focuses on the discussion

and evaluation of the approaches (Blessing and Chakrabarti, 2009). In this research, retrospectives were used, as well as a team survey. The phases were applied in iterations and worked well with an agile mindset.
The described research process is based on predefined boundary conditions. The boundary conditions are listed in the following: student project with four to five students (agile coach, design, simulation, requirements & testing), no agile knowledge at the beginning (students), 6-month project duration, project partner who develops non-agile, further development of the microtiter plate of Pfister (2015) and the version described in Gerber *et al*. (2019), requirement changes during the project, possibility to get continuous stakeholder feedback.
During the whole project, data on the collaboration of the team members and other stakeholders was gathered to analyse it afterwards and propose improvement measures to increase the efficiency of the collaboration. The data consisted mainly of exchanged emails, documents that were generated, and the documentation of the agile development process, i.e. user stories, sub-user stories, tasks, and requirements.

4 RESULTS AND REALIZATION

First, this section focuses on the research results from the method and process level. The agile process supported the development of the microtiter plate. The research results of the plate are described in 4.2.

4.1 Research results at the method and process level

Section 4.1 describes agile development in the project, the collaboration analysis and the resulting agile model. Section 4.1.1 shows the initial implementation of agile development at the beginning of the project, while section 4.2.2 presents impressions of the sprints and resulting changes in the agile framework. Section 4.1.3 describes the collaboration analysis. Finally, the agile model based on the experience of the project is presented in section 4.1.4.

4.1.1 Initial implementation of agile development in the project

Based upon the boundary conditions presented in section 3, agile development was implemented in the second phase of the project. At the beginning of the project, the agile process of Gerber *et al*. (2019), which is based on Scrum, was used. The process of Gerber *et al*. (2019) resulted from the first phase of this project. The basic process integrates the process of Gerber *et al*. (2019) as well as other agile and product development methods.
Before the development starts, the team members were familiarized with agile development, as mentioned in the approach of Gerber *et al*. (2019). Theoretical input and the simulation game lego4scrum were used (Krivitsky, 2018). The simulation game worked well in the first project phase, even though it is not exactly the applied approach. In a second step, the vision of the second phase was formulated from the team. The vision description helps to support entrepreneurial thinking and sensitizes the different areas to one another. The vision also describes the target group, the needs of the target group, products, scientific goals, and economic goals (see Figure 1). The vision is continuously considered and possibly updated.

Vision	The vision of the second phase is a 3D printed, biocompatible, electronically compatible and agile developed microtiter plate.		
Target Group	**Needs**	**Product**	**Economic Goals / Scientific Objectives**
• Cell scientists	• Biocompatible • Adaptable • Full medium replacement • Cell mechanics • Electronically compatible	• Microtiter plate • Documents	• Injection molding competition • Possible material and process • Evaluation of an agile approach • Metrics of collaboration analysis • Evaluation of flow parameters

Figure 1. Vision of the second phase

The product backlog with user stories and the linked requirements of the first phase, similar to a specification book, were used at the beginning. User stories are applied to focus on customer needs and project partner needs. The backlog can be extended by more user stories or sub-stories at any time to

help gradually sharpen the understanding of the product. User stories and the product backlog are typical agile artefacts and replace the requirements list. Nevertheless, in this project, requirements could not be replaced because they are used to fulfil the documentation obligation and to focus on legal requirements, which are not part of the user stories.
The sprint length was set to 3 weeks, which was discovered to be a good length in the first phase. At the beginning of a sprint, the user story planning event was hosted by the agile coach and attended by the product owner and the requirement manager of the development team. In this event, the set of user stories was refined, extended, and prioritized according to the upcoming sprint. It was essential for the requirements engineer to be a part of this meeting and to support the agile planning process as closely as possible.
Given the nature of the product and the high standards and number of guidelines in the development of medical devices, the updated product backlog was used in the sprint planning event to decide on what to do. The team gathered and decided which items from the product backlog should be part of the sprint backlog for the upcoming sprint and then defined an initial set of work packages.
During the sprint planning, it is first checked which user stories with the highest priority may possibly be realized. Planning poker with fibonacci numbers is used for this (Tamrakar and Jørgensen, 2012). Planning poker helps to identify the workload and complexity of each user story. As a second criterion, the competences of the team members are applied. Not every team member can work on every user story. It must be ensured that every team member has something to do and that the fulfilment of the selected user stories is possible within the capacity.
Within a timeframe of three weeks, the development team worked in a self-organized manner to reach the agreed sprint backlog. The team member responsible for requirements management supported the design engineering and simulation experts during the development process and ensured that the work completed met all relevant requirements, standards, and guidelines. During the 3-week development phase of a sprint, the development team worked transparently and had regular internal update meetings, which were held every three days due to the lack of full-time members on the team. In addition, a weekly meeting was set up in which the development team, the product owner and the agile coach had the opportunity to discuss technical matters and to identify any process-related ambiguities. The agile coach worked closely with the development team to identify any impediments as early as possible. The self-organization of the team helps to motivate the team members. The transparency during the working process and the regular meetings help to speed up the decision process.
At the end of each sprint, a review event was held to evaluate the completed elements of the sprint backlog. Besides the team, the project partner also attended the meeting, as he represented the customer by being the initiator for the development of the product. Thus, the review could be used to gather feedback on the work of the previous sprint, to identify new product backlog items and to further sharpen the team understanding of the product. The retrospective meeting was also held at the end of each sprint to identify key improvements in the process, team work, and the adaption of the agile process. The retrospective meeting also worked as a continual evaluation and process improvement.

4.1.2 Impressions of the sprints and resulting adaption of the agile development framework

The gathered feedback and identified improvements in the retrospective as well as further boundary conditions of the medical development environment led to certain changes in the agile process of Gerber *et al*. (2019), which will be presented in this section. The main source of adaptions were the internal feedback from the development team gathered by the agile coach as well as jointly agreed changes identified in six retrospectives.
In the given physical and medical development environment, a team of specialists from different fields had been formed to meet the project vision. As a result, certain effort had to be put into creating a transparent work environment to enable a collaboration of the experts in their daily work. For example, the task board was digitalized, and a chat for the team members was implemented. The team members agreed on an immediate update of the digitized task board as soon as a task had received a new status. As a result of all retrospective meetings, the team developed more into a self-organized team, accepting the agile framework and adapting it to the physical and medical development environment.
The team members also used different product development methods in the development phases, for example, benchmarking, risk matrix, kano-model, or weak-point-analysis. On the one hand, these methods help to improve the product quality and on the other hand, the methods were only so complex that they could be used in one sprint.

Another change was the integration of documentation in the *definition of done* for increments. A user story is finished once the function or the added value has been presented and the results are documented. Nevertheless, the working product/increment is to be set through documentation according to the agile manifesto (Beck *et al.*, 2001), but a transparent and comprehensible process is essential in the development of medical products to meet the numerous guidelines and requirements for these products. As described in 4.1.1, the integration of requirement management at all levels of planning and development in the agile process is necessary. The combination between the user stories and requirements was improved and a tool was developed. In a matrix, the dependencies between user stories and requirements are shown. Furthermore, the matrix visualizes the status of fulfilment of the different user stories and requirements. This was done to strengthen user centricity while meeting the stringent requirements of the medical device industry. Another result of the number of requirements were the interdependent user stories. This means that although a certain user story was not subordinate to another user story, it could only be worked on after the development of the other user story was completed. This interdependency was unavoidable and resulted in higher managing effort. The last major influence on the adaption of the agile framework to the medical and physical development environment was the management of external factors such as suppliers. As the team came closer to the end of the project, it became obvious that the final phase had an undeniable influence on the success of the project. As certain user stories were highly dependent on suppliers, risk management had to be integrated into the agile framework. This means that the product owners, the agile coach, and the team strongly focused and reassessed risk due to external factors on a regular basis, taking actions to prevent damage.

4.1.3 Collaboration analysis

The goal of the collaboration analysis in this project was to identify improvement potential, especially in the communication, and to provide a foundation for a comparison of the performance of the teams in this project with other teams based on the methodology described in Schweigert *et al.* (2017b).
Figure 2 shows an example of the collaboration network from the first six months of the project. Despite the relatively short period of time and small size of the core team, the resulting graph consists of 330 nodes (122 persons, 97 tasks, 111 artifacts), connected by 2610 relations.

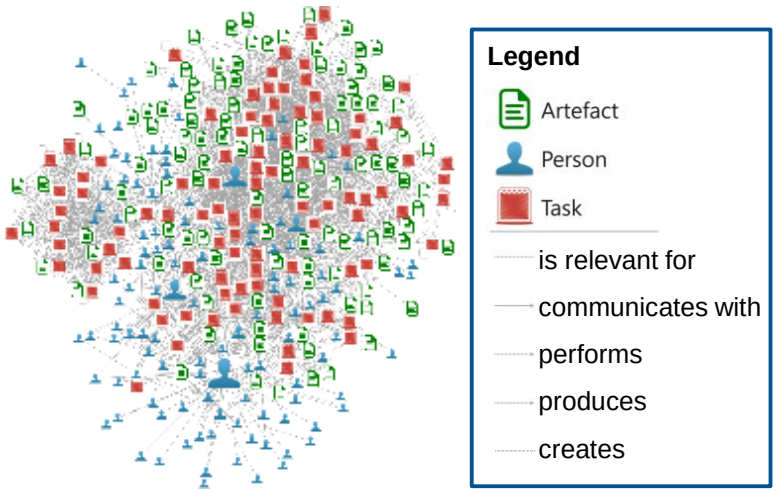


Figure 2. System graph of the involved persons, performed tasks, and produced artifacts of the first phase of the project

The graph-based and matrix-based analysis of the collaboration behavior lead to insights on the barriers between team members and involved parties. For instance, a number of unfinished tasks and, subsequently, user stories was the focused metric, as it lead to iterations in later stages of the project. Based on these findings, measures were implemented to overcome the barriers. In this specific example, the amount of workload per user story was reduced and smaller tasks were formulated (97 tasks in the first six months of the project in comparison to 256 in months seven to twelve). The workload of these tasks was easier to estimate during the sprint planning, resulting in more accurate planning and fewer unfinished user stories and sub-user stories per sprint (24 % in phase 2 in comparison to 31 % in phase 1). As a result, the progress of the project could be planned more accurately and a timely delivery of the final results was ensured.

4.1.4 Resulting agile model

Figure 3 shows the resulting agile model for physical, medical device development based on the impressions and lessons learned from the sprints. It is especially derived from internal feedback, experience with process changes, and retrospectives. The agile model shown in figure 4 is split into four phases, which form a macro process around the framework. Thus, in the sense of agile development, the four phases are not to be worked through in a linear but rather in an iterative way.

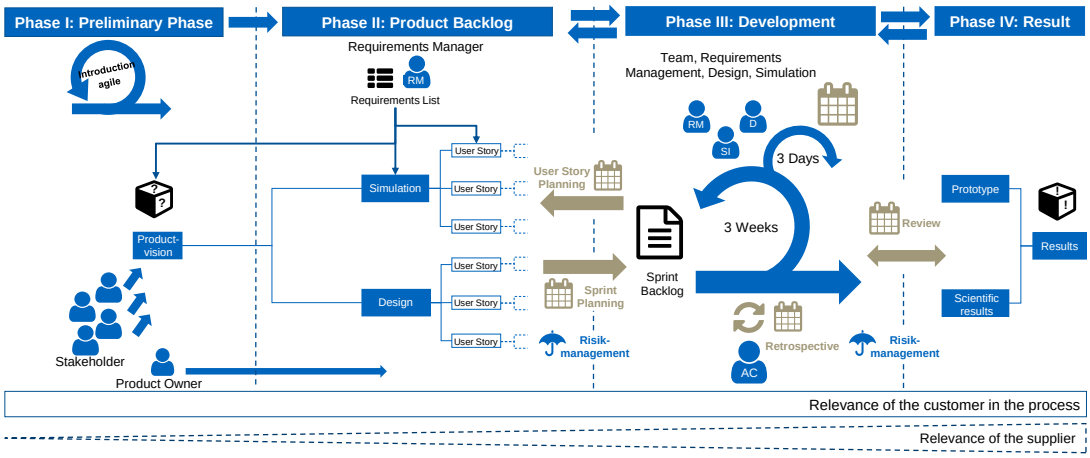


Figure 3. Resulting agile model for physical and medical product development (black symbols), events (gray arrows), processes (blue arrows) and roles

Phase I: Preliminary phase

The first phase is a preliminary phase. The vision of the product/project is defined with the stakeholders of the project. Furthermore, all relevant persons are introduced to agile development (theoretically and simulation game). Based on the information from the stakeholders, the product owner transfers the information from phase I to phase II.

Phase II: Product backlog

The second phase is the product backlog phase. As Figure 3 shows, the product owner (PO) is responsible for the product backlog and its refinement. This includes a pre-definition of user stories. From the team, relevant user stories can be added. It is worth noting that in the given project, a division of user stories by fields of expertise was unavoidable. Experience showed that the experts and their work were unified in the working product, so their collaboration as a team was essential. Nevertheless, development inside the fields of expertise was often separated from one another. Therefore, the product backlog included separate user stories for the field's simulation (SI), design, (D), and testing, and it was up to the development team to organize their work.

Another thing that can be seen in phase II of the agile model is the integration of requirements management (RM) throughout all levels of planning. Due to the numerous requirements and guidelines, the influence on the product vision, the fields of expertise and each user story is fundamental to strategically meeting all technical requirements. The combination of user stories and requirements is organized by a matrix (see 4.1.2). In addition, guidelines regarding a transparent and comprehensible development process for medical devices can be fulfilled.

Phase III: Development

The sprint planning event marks the transition from phase II to III, as the user stories that should be developed within a 3-week sprint are taken into account in the sprint backlog. The elements of the sprint backlog are developed within the sprint, and the team organizes all relevant work itself. The team member responsible for requirements management (RM) is part of the development team to ensure that the high standards of this development environment are considered in the daily work of the team. An event similar to the Daily Scrum is held every three days or more often, if possible, to maximize the collaboration in the team and detect impediments early on. At the end of a sprint, the completed elements and the progress are reviewed by the whole team and relevant stakeholders. All new information is taken back to the product backlog through the user story planning event, which is held by the agile coach and attended by the product owner and the expert for requirements management.

Throughout the sprint, the agile coach coaches the team in matters of agile development and self-organizing work. In addition, the product owner and agile coach protect the team from undesirable

external influences. As each sprint nears the final result, the early detection of these influences becomes increasingly important. Therefore, risk management was established at every transition from one phase to another. Techniques like the newly developed user story risk map can be used to assess the risk of a user story that is not being developed due to external influences. It helps to analyze the uncertainties of the next sprint. The probability of each challenge of a user story (x-axis) is mapped with the extent of damage (y-axis) to identify the most uncertain user stories with a focus on external influences. With this technique, actions aiming to reduce the external influences can be defined and prioritized.

Phase IV: Result

In the last phase, prototypes are created at the end of each development phase or added value is created for the customer so that he or she can provide simple feedback in early development phases. In this project, a prototype could be created at the end of each development phase that increasingly fulfilled further user stories and requirements. With the generated prototypes, initial tests could be carried out, e.g. for tightness, and feedback could be obtained from our project partner.

4.2 The product: Design and simulation of the microtiter plate

The main goal of the project on the technical side was the development and realization of a 3D-printed microtiter plate. It was especially the transformation of the design for injection molding into a design for 3D printing that resulted in major changes in the geometry. Additionally, in the course of the project, a new geometry was patented that uses an angular micro reaction chamber instead of a round one like the predecessor product. Figure 4 depicts the changes from an injection-molded product with a round micro reaction chamber to a 3D-printed prototype with a rectangular chamber, as well as the new geometry with a hexagonal reaction chamber as a 3D-printed prototype.

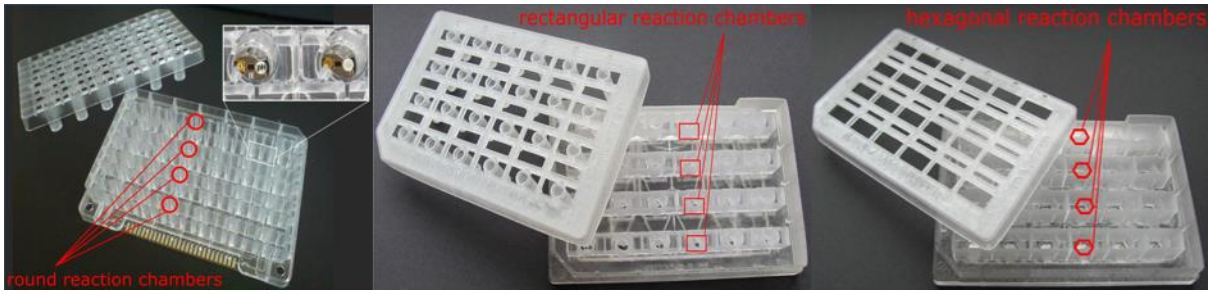
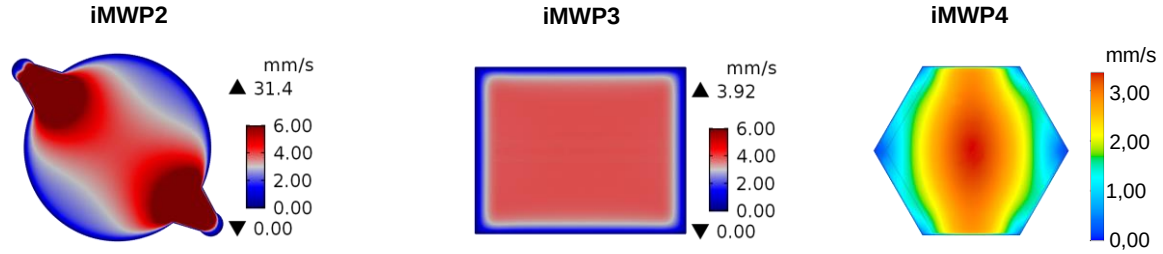


Figure 4. Evolution from an injection-molded product (left) to 3D-printed prototypes (rectangular, middle, and hexagonal reaction chamber, right)

One of the main advantages of the predecessor product is the micro fluidic that was adjusted to the proper living conditions of the cells. Changes in the geometry due to the altered production procedure brought about the need for further examinations of the fluidics to verify the fulfilment of multiple requirements. Therefore, CFD simulation models were set up to investigate the prevailing conditions.

For instance, the shear stresses on the cells at the floor must not exceed a critical threshold of $\tau = 1$ Pa (DePaola *et al.*, 2001). Figure 5 compares the maximum shear stress that results from the fluid exchange in the reaction chambers of the three prototypes (iMWP2, iMWP3 and iMWP4). As the nutrient medium can be modelled as a Newtonian fluid, the stress can be calculated directly from the velocity gradients perpendicular to the flow direction. The simulations prove that the shear stress could be reduced with each prototype. The maximum shear stress after all geometric changes are below the tolerable value.



$\tau < 0.32\ [Pa]$ $\tau < 0.014\ [Pa]$ $\tau < 0.008\ [Pa]$

Figure 5. Comparison of the velocities in the reaction chambers of the different prototypes and the resulting shear stresses

5 EVALUATION

The evaluation is divided into five steps: retrospectives, burndown charts, survey, requirement fulfilment, and the fulfilment of the research questions.
The retrospectives are a continuous process improvement. From this, the described changes and impressions of the sprint are deduced (see section 4). During the first four phases, the burndown charts from the development phases show that the tasks resulting from the user stories are largely completed. In the last two development phases, the degree of fulfilment is less. Reasons for this are that the detail work is greater effort and not as good as appreciated. Another reason is that all work should be completed and too many user stories are part of the development phases. One lesson learned is that we should plan the project with an agile time plan. The plan is only a rough estimation and is to be compared with the value "a product is more important than following a plan" (based on the agile manifesto).
The process was also evaluated in a survey. The team members were the participants. Therefore, the survey only shows trends because the number of participants is too small for statistical evaluation. It shows that the integration of product development methods supports the team, as well as in structuring the agile process. The perceptions of the extent to which agility is exemplified in the project differ, especially with regard to the value of functioning products via documentation from the agile manifesto. This value is in strong contrast to the requirements of medical device development.
To evaluate results at the product level, requirements are used, and 24 of 27 requirements are (partly) fulfilled. One of the non-fulfilled requirements is, for example, "the plates have to be covered with a foil". This requirement was given such a low priority every time that the requirement is not realized. Some others are only partially fulfilled because they have to be checked in a real application. In addition, further research currently exists into the connection of the plate and electronics. The produced prototypes in combination with the simulation present a value for the product owners and project partner.
Lastly, the answering of the research question is discussed (see section 3.1). The question at the method level is answered with section 4.1. Based on the impressions, the case study and the collaboration analysis, an agile process model for medical, physical product development is presented. The model works in a research environment. To apply the model in an industrial environment, further requirements have to be integrated. The research question at the product level "How can a biocompatible microtiter plate with different geometries be built with an additive manufacturing approach?" is answered in section 4.2. In combination with a laser sintering approach and a biocompatible material, two different geometries of a microtiter plate could be built.

6 CONCLUSION

The aim of the research is an improved agile development process for physical product development, supported by collaboration analysis and evaluated in a case study for medical device development. The sub-goal at the product level is the production of the physical component of the plate, the body and the associated lid. For the agile process, the approach of Gerber *et al*. (2019) is evaluated and adapted in this research project.
Based on the findings, the next step at the process level is to apply the developed agile framework to larger projects and in an industry environment. Then, additional boundary conditions have to be integrated, e.g. internal processes and legal requirements. To support this step, additional collaboration analyses of the second phase of this project have to be implemented and recommendations derived.
At the product level, the connection of the plate and electronics is the next step. Initial prototypes of an electronic microtiter plate exist, but the gluing process has to be improved. Furthermore, the project partner is still improving the electronics, and further cell tests have to be conducted.

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REFERENCES

Basili, V.R., and Weiss, D.M. (1984), "A Methodology for Collecting Valid Software Engineering Data", *IEEE Transactions on Software Engineering*, Vol. 1, pp. 728–738.

Beck, K., Beedle, M., van Bennekum, A., Cockburn, A., Cunningham, W., Fowler, M., Mellor, S., Thomas, D., Grenning, J., Highsmith, J., Hunt, A., Jeffries, R., Kern, J., Marick, B., Schwaber, K. and Sutherland, J. (2001), *Manifesto for Agile Software Development*.

Blessing, L.T. and Chakrabarti, A. (2009), *DRM, a Design Research Methodology*, Springer, London.

Böhmer, A.I., Richter, C., Hostettler, R., Schneider, P., Plum, I., Böhler, D., Lindemann, U., Conradt, J. and Knoll, A. (2016), "Think.make.start. - An Agile Framework", in *Proceedings of the DESIGN 2016 14th International Design Conference*, Dubrovnik, 16.-19.05.2016, Design Society, Glasgow, pp. 917–926.

Cooper, R.G. and Sommer, A.F. (2016), "The Agile-Stage-Gate Hybrid Model. A Promising New Approach and a New Research Opportunity", *Journal of Product Innovation Management*, Vol. 33 No. 5, pp. 513–526.

DePaola, N., Phelps, J. E., Florez, L., Keese, C. R., Minnear, F. L., Giaever, I. and Vincent, P. (2001), "Electrical Impedance of Cultured Endothelium Under Fluid Flow", *Annals of Biomedical Engineering*, Vol. 29 No. 8, pp. 648–656.

Gerber, C., Goevert, K., Schweigert-Recksiek, S. and Lindemann, U. (2019), "Agile development of physical products - A case study of medical device product development", in Chakrabarti, A. and Chakrabarti, D. (Eds.), *7th International Conference on Research into Design (ICoRD'19),* Springer Nature Singapore.

Goevert, K., Brombeiss, M. and Lindemann, U. (2019), "Integration of mechatronic product development methods in an agile development area", in Chakrabarti, A. and Chakrabarti, D. (Eds.), *7th International Conference on Research into Design (ICoRD'19)*, Springer Nature Singapore, Singapore.

Highsmith, J. and Cockburn, A. (2001), "Agile software development. The business of innovation", *Computer*, Vol. 34 No. 9, pp. 120–127.

Hofert, S. (2016), Agiler führen, Springer, Wiesbaden.

Komus, A. and Kuberg, M. (2017), "Status Quo Agile. Studie zu Verbreitung und Nutzen agiler Methoden. Eine empirische Untersuchung".

Koziolek, H. (2008), "Goal, Question, Metric", in: Eusgeld, I., Freiling, F.C., Reussner, R. (Eds.), Dependability Metrics. Springer, Heidelberg, pp. 39–42.

Kreimeyer, M. and Lindemann, U. (2011), *Complexity metrics in engineering design: managing the structure of design processes*, Springer Science & Business Media.

Krivitsky, A. (2018), *lego4scrum: One of the most interactive ways of introducing Agile thinking and Scrum framework*, Leanpub.

Lob, V. (2009), "Design und Realisierung eines High-Content-Screeningsystems für lebende Zellen", PhD Thesis, Technical University of Munich, München.

Lücking, T.H., Sambale, F., Schnaars, B., Bulnes-Abundis, D., Beutel, S. and Scheper, T. (2015), "3D-printed individual labware in biosciences by rapid prototyping. In vitro biocompatibility and applications for eukaryotic cell cultures", *Engineering in Life Sciences*, Vol. 15 No. 1, pp. 57–64.

Mathieson, J. and Summers, J. D. (2017), "A protocol for modeling and tracking engineering design process through structural complexity metrics applied against communication networks", *Concurrent Engineering*, Vol. 25 No. 2, pp. 108–122.

Moreira, M.E. (2013), *Being Agile: Your roadmap to successful adoption of Agile*, Apress, New York, NY.

Mourtzis, D., Maropoulos, P. and Chryssolouris, G. (2014), "Digital Enterprise Technology. Systems and methods for the digital modelling and analysis of the global product development and realisation process", *International Journal of Computer Integrated Manufacturing*, Vol. 28 No. 1, pp. 1–2.

Pfister, C. (2015), "*Mikrofluidisch gestützte zellbasierte Assays mit gedruckter Sensorik für High-Content Analytik*", PhD Thesis, Technical University of Munich, Munich.

Schweigert, S., Çavuşoğlu, M. and Lindemann, U. (2017a), "Enhancing Collaboration between Design and Simulation Departments by Methods of Complexity Management", *The Journal Of Modern Project Management*, pp. 62–67.

Schweigert, S., Luft, T., Wartzack, S. and Lindemann, U. (2017b). Combination of Matrix-based and Graph-based Modeling for Product and Organizational Structures. *Proceedings of the 19th International DSM Conference Espoo (Finland)*, 11–13 September 2017, 2017.

Sommer, A.F., Slavensky, A., Thuy Nguyen, V., Steger-Jensen, K. and Dukovska-Popovska, I. (2013), "Scrum integration in stage-gate models for collaborative product development — A case study of three industrial manufacturers", in *IEEE International Conference on Industrial Engineering and Engineering Management (IEEM), 2013*, Bangkok, IEEE, Piscataway, pp. 1278–1282.

Sutherland, J. and Schwaber, K. (2017), *The Scrum Guide - The Definitive Guide to Scrum: The Rules of the Game*.

Tamrakar, R. and Jørgensen, M. (2012), "Does the use of Fibonacci numbers in Planning Poker affect effort estimates?", 14-15 May 2012, Ciudad Real, Spain.

Wolf, P., Brischwein, M., Kleinhans, R., Demmel, F., Schwarzenberger, T., Pfister, C. and Wolf, B. (2013), "Automated platform for sensor-based monitoring and controlled assays of living cells and tissues", *Biosensors & bioelectronics*, Vol. 50, pp. 111–117.