Application of Axiomatic Design in Engineering: Designing a Smart Medical Cast

Increasing robustness by decreasing information

Tim Heijne[1], Mitch Kruijer[1], Jakub Kylar[1], Lennard Spauwen[1], Karin Thomassen[1,2], and Erik Puik[3]

[1]HU University of Applied Sciences Utrecht, Padualaan 99, 3584 CH Utrecht, the Netherlands
[2]Delft University of Technology, Mekelweg 5, 2628 CD Delft, The Netherlands
[3]Fontys University of Applied Sciences, De Rondom 1, 5612 AP Eindhoven, the Netherlands
Lennard.spauwen@hu.nl

Abstract. By applying Axiomatic Design, a Smart Medical Cast was developed to provide patients, who are suffering from forearm fractures, with a personalized healing process. The device monitors the overall healing status and three complications, which are: Muscle Atrophy, Compartment Syndrome, and Deep Vein Thrombosis. In the conceptual phase, desk research has been performed to find biomarkers that correlate with the monitored processes. Per biomarker, a measuring principle has been designed and these combined formed the design of the smart medical cast. Following the design phase, two tests were performed on healthy individuals to measure the robustness in a real application. The first test focused on correctly measuring the biomarkers and further specifying the sensor specifications. For the second test, a new prototype was used to determine correlations between the measured data and the monitored process and the impact of application during the casting process. The test results show that the measuring system can measure the biomarkers within the expected range, except for bone density. No significant impact on the casting process was measured. The Smart Medical Cast has only been evaluated in situations without a fracture, the next step will be to test the measurables in an environment with a fracture.

Keywords: Axiomatic Design, Information Axiom, Smart Medical Cast

1 Introduction

This paper describes the application of axiomatic design in the design process of the Smart Medical Cast (SMC). The SMC is a device that will be implemented into an orthopaedic cast to measure the healing process of fractured bones. This information can be used to help a physician make an informed decision on removing the orthopaedic cast. Besides the healing status, the SMC also measures biomarkers that are correlated to the most occurring complications. When these biomarkers approach worrisome values, the physician and patient will be informed and advised to make an appointment or go to the hospital immediately, depending on the severity of the case.

The SMC is designed according to the guidelines of Axiomatic Design. Tools such as functional decompositions and design matrices are used to minimize coupling within the system. To minimize information, the device is thoroughly tested, evaluated and revised based on test results.

1.1 Axiomatic Design

Axiomatic design is a system engineering methodology that exists of two axioms, explained below, that help guide a project to create the best possible solutions for the desired functions [1].

Independence axiom
In axiom one, the independence of the problem is considered. Every sub-problem or requirement should have a dedicated solution to prevent coupling. Coupling is when one solution satisfies two functional requirements. This is not desired because this creates limited capability to adapt to changes.

Information axiom
In axiom two, the information content of the design is reduced to a minimum. The objective is to apply the intended solution in one way only. This is also referred to as increasing robustness.

1.2 Current situation

The current medical process for healing a fractured bone is built on the knowledge of a medical team. Through the experience of different bone fractures and patient groups, a treatment plan is personalized as much as possible. Depending on this healing plan, several x-rays are made to monitor the process [2]. Between these measurements and visits to the hospital, there is no further insight into the healing process and the possibility of complications occurring [3].

The above-mentioned situation can be divided into two sections. Firstly, the necessary hospital capacity to properly take care of patients and extra check-ups. With the expected medical personnel shortage in the health sector [4], reducing the number of hospital visits will have a positive impact on this issue.

Secondly, is the lack of insight into the process which results in uncertainties for patients and physicians whether the process is going well, or complications are starting to arise. Complications due to immobilization are often noticed too late. This results in unnecessary large consequences for the rehabilitation time [5] [6].

2 Objectives of this research

This chapter describes the desired outcome of the project and what is currently to be developed (research gap).

2.1 Ideal situation

With growing knowledge in the field of biomedical engineering, more possibilities emerge every day on combining technology with biological processes inside the human body. By having insight into these processes, physicians can monitor the healing process and complications very closely. These insights can be obtained by adding specific sensors inside the cast, that measure biomarkers, correlated to bone healing and the common complications. These sensors should be non-invasive and non-interruptive for the current healing process.

Then through the integration of Artificial Intelligence (AI), this process could even be automated. Physicians only need to take a closer look when biomarkers are not within expected ranges. This results in a very optimized and controlled process with fewer unknowns for both patients and physicians.

Besides getting data out of the biomarkers, the cast can be even more personalized, e.g., 3D printed with the added benefit of lower weight and higher breathability of the cast. Research has shown a positive effect of having a lighter and more breathable cast on the healing and complications [7].

Fig. 1. Patient reading healing data from his smartphone. Data is collected by the SMC and transmitted wirelessly for analysis.

Fig. 1 shows a visionary outcome for a new type of medical cast. The patient uses the mobile app to connect to the cast and sees that his healing process is according to plan.

The SMC is focusing on gathering data during the healing process. Therefore, a redesign of the cast itself, and the addition of AI to process the data are not part of the scope of this project.

Focusing on obtaining data, previous research has been conducted that mostly focuses on one specific biomarker and often invasively. Therefore, the goal of this

research is to combine multiple measurables, through non-invasive measuring, which gives insight into both the healing process and complications that can occur. By providing this information to both patient and physician, a more personalized process can be realized.

Table 1. Performed research on the topic of measuring biomarkers correlated to bone healing and bone healing complications.

Issues Considered	Addressed By	Related Work
Methods for improving a cast to improve the healing process of a fracture.	Different cast iterations and improvements for reducing complication risk and improving healing time.	[7] [8] [9] [10] [11]
Methods for measuring bone healing to improve the healing process of a fracture.	Changing properties, measurables and methods for measuring bone healing.	[12] [13] [14] [15] [16] [17] [18] [19] [20] [21] [22] [23] [24] [25] [26] [27]
Methods for monitoring complications to improve the healing process of a fracture.	Changing biomarkers on the occurrence of Muscle Atrophy.	[5] [6] [28] [29] [30] [31] [32]
	Changing biomarkers on the occurrence of Compartment Syndrome.	[12] [13] [14] [15] [16] [17] [18] [19] [20] [21] [22] [23] [24] [25] [26] [27]
	Changing biomarkers on the occurrence of Deep Vein Thrombosis.	[33] [34] [35] [36]

2.2 The key limitations

The higher goal (get more insight into the healing process of a fractured bone) is split into three key limitations:

- limited monitoring of the healing process of a fractured bone;
- no monitoring of complications during the immobilization phase;
- providing healing data for the patient and physician.

2.3 The scope of the project

With these key limitations specified, the project scope is created, starting with the main question:

How should the SMC be designed to improve the healing process of a fractured bone, through non-invasive data collection and analysis, to reduce the rehabilitation time after immobilization?

For the healing status, the aim is to include as many fractures as possible with similar bone structures. Therefore, the *forearm* and *lower leg* are chosen, these bones make up for 24 per cent of all fractures in the Netherlands [37]. This paper focuses on the application of the SMC on the forearm, but the lower leg is considered when choices are made. The SMC monitors three complications. The first monitored complication is compartment syndrome. When treatment of a lower extremity compartment syndrome case is delayed for more than twelve hours, the chance of amputation increases to almost 50% [38]. There is even a chance of mortality if the case is not treated early enough [39]. The second monitored complication is deep vein thrombosis due to its unpredictable nature [40]. The third complication that will be monitored is muscle atrophy. This was chosen because it occurs in all patients after one week [41], is a source of other complications, and contributes greatly to the rehabilitation time [42].

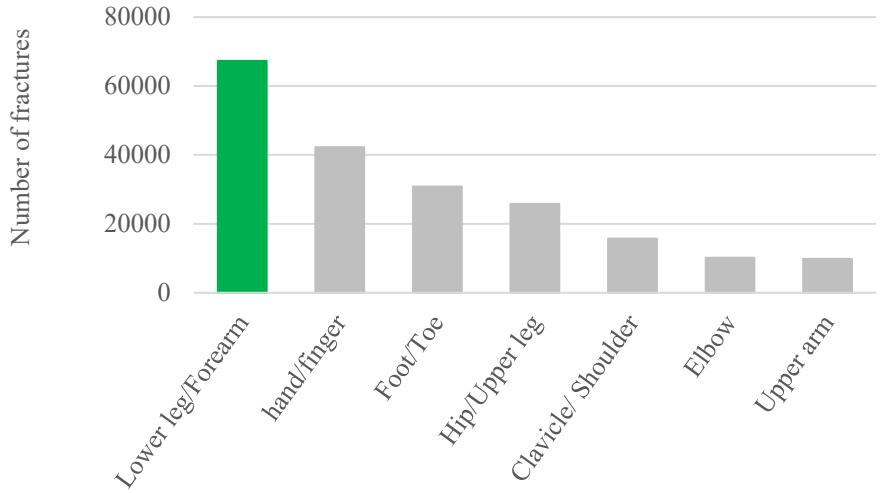


Fig. 2. Most fractured bones in the Netherlands in 2012. Source: [43]

3 Methodology

In this paper, Axiomatic design is applied to address the key limitations as stated in section 2.2.

3.1 Projects key limitations

To get a better sense of the most important areas within the scope of this project, three key limitations are described.

Limited monitoring of the healing process of a fractured bone.
The conventional method of assessing the status of a bone fracture is by making an X-ray or MRI. For this, patients need to come to the hospital where these procedure costs can be €50, - for an X-ray, or €350 for an MRI scan [44]. Between appointments, the patient does not know how the healing is progressing, and if immobilization could be shortened.

Through testing, where an SMC prototype is worn, decisions can be made on the necessity for each sensor, how often to measure (influences battery capacity), and which sensor version is the best option.

No monitoring of the complications during the immobilization phase.
When complications are detected, it is often too late to avert them. Therefore, preventing complications is acting on biomarkers in an early stage which would be beneficial for the patient.

Through testing, where an SMC prototype is worn, decisions can be made on the necessity for each sensor, how often to measure (influences battery capacity), and which version of the sensor is the best option.

Providing healing data for the patient and physician.
It is essential to process the data and provide that correct data to the physician and patient. The most important are the trends of the individual complications, as with that, it should be easier to predict whether a complication is about to occur and what stage the healing process is in. The values are expected to be different for everyone though, it fairly depends on the health status of the patient. This way the correct treatment decision can be made by the physician.

3.2 How Axiomatic Design is used to address the key-limitations.

Once specifications are analysed, customer attributes (CAs) are then translated into Functional Requirements (FRs) and lay the foundation of the design for the project and product. Every FR is addressed with Design parameters (DPs), which are based on both scientific research and creative design [45]. The lowest level, process variables (PVs), are only partially considered, depending on the measurable.

During the conceptual design, the independence of the DPs is assessed using a design matrix. With this tool, the design is checked for coupling, which can be resolved afterwards and therefore increase robustness. The robustness of the design can be increased further by performing the correct tests with the prototype. With output data from the prototype, the amount of information from the SMC can be assessed and possibly reduced.

4 Application of Axiomatic Design

Because of the application of Axiomatic Design, a quick overview of the independence axiom is shown to review the foundation for the information axiom.

4.1 Independence axiom.

With a clear direction for the project, customer attributes are shown in Table 2. The CAs are divided into 10 sections which are of added value for the SMC.

Table 2. Customer Attributes (CAs)

Customer attribute		**Description**
1	Health	The SMC should benefit the health of the patient.
2	Compatibility	The SMC should be compatible with the current medical process.
3	Usability	The physicians should get the information to judge the healing process.
4	Reliability	The SMC should give sophisticated information from multiple variables.
5	Economics	The business case should be feasible.
6	Implementation	The SMC should be easy to implement within the medical cast.
7	Safety	The SMC should not harm the patient.
8	Performance	The SMC should be better performing than the current process.
9	Efficiency	The SMC should work throughout the whole immobilization process.
10	Ergonomics	The SMC should not interfere with the ergonomics of the cast.

A total of 10 CAs are translated into FRs. The decomposition of high-level FRs is shown in Fig. 3 (A). For every FR, a specific DP is selected. The selection procedure has been done through a creative session. In the end, three concepts were defined. These three concepts were assessed individually to meet the CAs as closely as possible. This resulted in the concept that is shown in Fig. 4.

Next, every FR\DP combination is referenced to the required CAs. This way it is ensured that all the CAs are properly addressed. This is shown in Table 3.

Every monitored process is divided into biomarkers that change over time during the specified process. These measurables are shown in Table 4. The changes over time, which represent a trend, are more useful than the absolute values. These trends can be monitored and reviewed, and absolute values can differ per patient which would result in false- positives and negatives.

Table 3. Mapping FRs to CAs

FR	**CAs Addressed**
FR1.1 Determine healing status	CA1 CA2 CA3 CA4 CA6 CA7 CA9 CA10
FR1.2 Check complications	CA1 CA2 CA3 CA4 CA6 CA7 CA9 CA10
FR1.3 Process data	CA4 CA7 CA9 CA2 CA3 CA9 CA1 CA8
FR2 Inform on process	CA1 CA5 CA8

Table 4. The development of the biomarkers over time, which are correlated to the processes. Arrows indicate the change of value. For example, ↓ shows a decrease in value for that measurable. The processes occur in chronological order from left to right. White boxes are not included in the conceptual design.

FR11 Determine healing status				
Time →				
Bone healing				
Blood flow	Blood flow	Bone density	Oxygen levels	
↓	↑	↑	↑	
FR12 Check complications				
Muscle atrophy				
Muscle activity	Muscle strength	Blood flow		
↓	↓	↓		
Deep vein thrombosis				
Muscle activity	Blood flow	Blood clots	Blood pressure	
↓	↓	↑	↑	
Compartment syndrome				
Blood flow	Cast pressure	Blood flow	Blood pressure	Skin temperature
↑	↑	↓	↓	↓

The independence of the high-level FR is addressed in the design matrix in Table 5. FR11, FR12, and FR13 directly represent key limitations 1, 2, and 3. Within the current phase of the project, these are the focus areas of the design. Although informing on the process is included in the conceptual design, this is not in scope for decreasing information.

The design matrix shows a decoupled design. Processing of the data is influenced by both the measurements of the healing status and the complications.

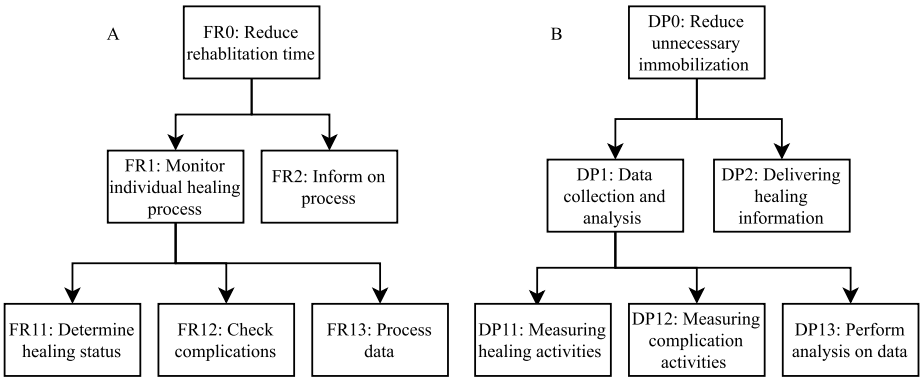


Fig. 3. High-level FRs (A) and DPs (B). Full decompensation given in Appendix A

Table 5. Design matrix of the concept as proposed in Fig. 4. The FRs that directly represent one of the key limitations are marked. The overall design shows a decoupled character.

		DP0: Reduce unnecessary immobilization	DP1: Data collection and analysis	DP11: Measure healing activities	DP12: Measure complications level	DP13: Perform analysis of data	DP2: Delivering healing information
	FR0: Reduce rehabilitation time	X					
	FR1: Monitor individual healing process		X				
Key limitation	FR11: Determine healing status			X			
Key limitation	FR12: Check complications				X		
Key limitation	FR13: Process data			X	X	X	
	FR2: Inform on process						X

5 Reduction of information content

The SMC is a data-driven device. Therefore, the main purpose is collecting correct data. The focus of the information content is therefore to enhance the quality of this data and

to verify if the sensors can measure with the required accuracy. Two iterative tests were executed and are described in this paper.

5.1 First test: Protocast 1.0

The first test, with a complete measuring system, is conducted with Protocast 1.0 (prototype cast); as shown in Fig. 4. The following sensors are included in this test:

- PT100 temperature sensor
- PPG heart rate sensor and BPT IC
- FSR cast pressure sensor
- FSR muscle activity sensor

All data is processed by an Atmega2560 development board and stored on an SD card. For power, a 10000 mAh power bank is used.

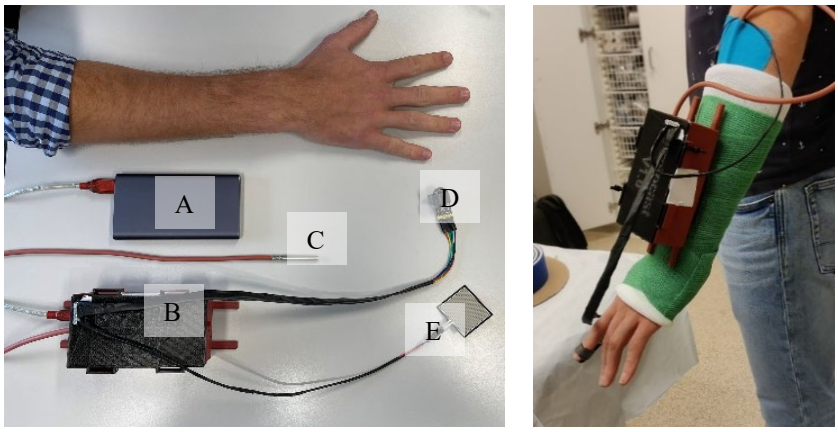


Fig. 4. Protocast 1.0 test setup. A. Power bank, B. Processing unit, C. PT100 temperature sensor, D. Heart rate monitoring sensor, E. FSR pressure sensor, Muscle activity sensor is not shown in the image.

The cast was applied at the UMC Utrecht by an orthopaedic technician. This way, incorrect installation of the cast was prevented which could influence the data. The sensors were placed on the lower arm and fixed in place with physiotherapeutic stretch tape.

Objectives of the first test

The Protocast 1.0 test took a total of eight days. This is the first duration testing with all sensors. The following goals for this test were set:

- Evaluating the wearing experience from both sensors and the added weight of the SMC.

- Feasibility of the sensors and how this represents the measurables.
- Validating if the data in the current setup is sufficient to give information on biomarkers.

Results of the first test

Wearing experience
In a normal casting process, the first layer that is applied is a cotton stocking. This is to prevent any skin irritation from any of the following layers. With this test, the sensors were directly attached to the skin which caused skin irritation as can be seen in Fig. 5.

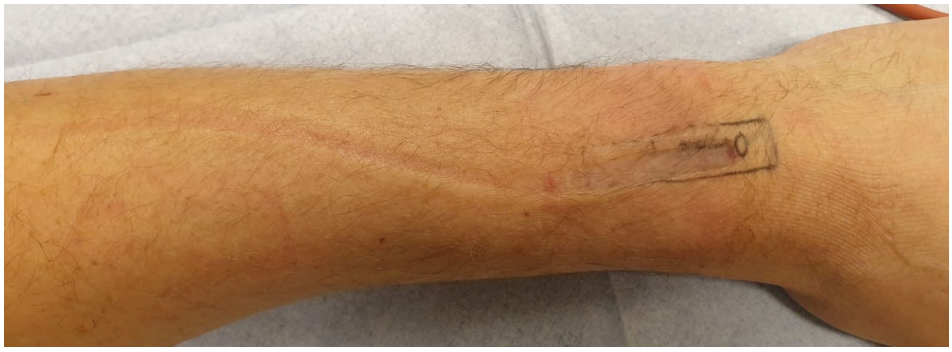


Fig. 5. Skin irritation caused by the PT100 is visible after removal of the SMC.

In addition to the PT100 irritating the skin through direct contact, the FSR sensors also collected moisture which was not able to vaporize. This was due to the large area of plastic material that contacted and covered a patch of the skin.

Software.
Due to software problems, the SMC could not measure for longer periods. It was, however, not clear from outside the cast, if the sensors and processing unit were properly working. Therefore, it often occurred that no data was recorded. Because of this, it was not possible to properly compare data.

Sensor feasibility and data validation.
For every sensor, the measuring range was defined by comparing it to with the validation data. The measured values during testing were compared to the actual sensor range. This determines if the sensors were correctly specified and if the measured data was useful. These results are shown in Table 6.

Table 6. Measured values compared to sensor range.

	Measured			**Sensor range**	**Ok**
	Min	Max	Res.		
PT100	28	37	0,03	-100-200	Yes
Systolic blood pressure	110	130	1	-	Yes
Diastolic blood pressure	69	90	1	-	Yes
FSR cast pressure	0	480	1	0-24000	Yes
FSR muscle activity	130	151	1	0-24000	No

Two sensors stand out from this table. These are both the FSR sensors used for cast pressure and muscle activity. The cast pressure only used a limited range of the complete sensor. The muscle activity sensor didn't show any real results, besides temperature drift.

Fig. 6 and Fig. 7 respectively show the cast pressure and muscle activity output. The cast pressure does not give clear results over time. As mentioned, the data was not recorded sufficiently and thus, cannot be used properly. Looking at the muscle activity, almost no change is recorded. After further testing, there was not a real change when the muscle was contracting and expanding. Appendix B shows all the results from the first test.

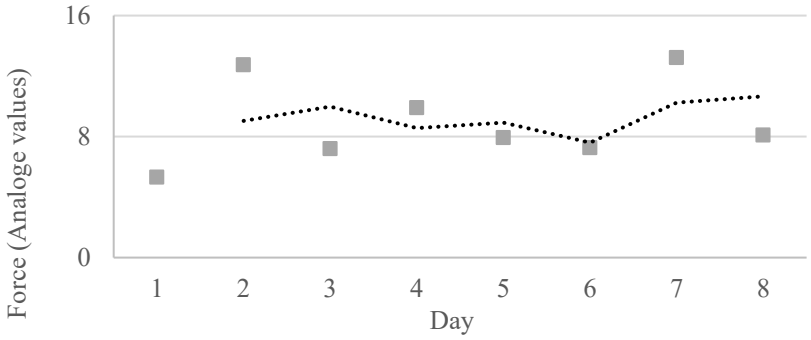


Fig. 6. Average daily cast pressure over 8 testing days. Moving average indicated by the dotted line.

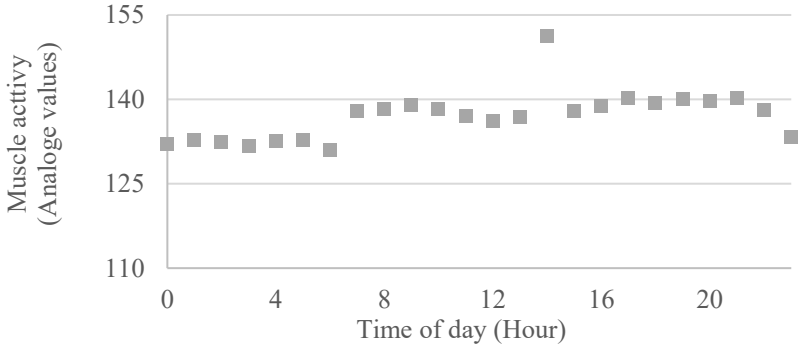


Fig. 7. Average hourly muscle activity over one day

Conclusions on the first test.
The direct contact between the skin, sensors, and cables caused skin irritation. Therefore, a new constraint is set that there may not be any direct contact with the skin.

The cast pressure sensor should be more optimised for the available measuring range. Since the sensitivity can be adjusted with the same sensor, this is an optimisation that can easily be implemented. However, the FSR used for the muscle activity, cannot be adjusted and thus needs to be replaced.

With the current dataset, it is hard to determine any trends in the biomarkers. From the measured data, it became clear that the average data between days should not be compared, but rather the trends during the day. Some biomarkers are influenced by activity. To eliminate any daily rituals the patient may have, changing data points should be compared to data points at the same time on a different day.

Finally, to know for sure that the SMC is measuring correctly, the status should be visible to the user. This is an additional FR.

5.2 Second test: Protocast 2.0

With the findings from the first testing, changes were implemented, resulting in Protocast 2.0. This includes a display for visual feedback, optimised wearability by using a sensor mat above the stocking, and a new muscle activity sensor. To test the new Protocast, the following objectives were defined:

- Test how the application of the Protocast affects the current casting process.
- Asses the wearing experience, such as sensor placement and skin irritation.
- Determine how the measured data correlates to the monitored process.

Test expectations.
The purpose of this test is to verify that the prototype can monitor the measurables correctly, despite the design changes. The first major change was applying one cotton layer on the skin before the sensors were applied. Therefore, the proper functionality of

the sensors had to be tested again. Besides this, the cast wearing experience and the usage of a Quick start guide (QSG) were tested. This was done so the orthopaedic technicians will know how to implement the SMC in the cast and to test how big of an impact the added steps have on the current casting procedure.

Fig. 8. Prototype of the SMC installed on the left lower arm.

Test results.

Implementation.
During the application of Protocast 2.0, the orthopaedic technician only used the QSG, which can be found in Appendix D. A normal casting procedure takes around 10 to 15 minutes. With Protocast 2.0 and the QSG as a guide, it took an extra time of one and a half minute. This translates to a 10-to-15% time increase.

Wearing experience.
With the new sensor mat and placement above the cotton stocking, no more skin irritation occurred at the sensor location after longer periods, as can be seen in Fig. 9.

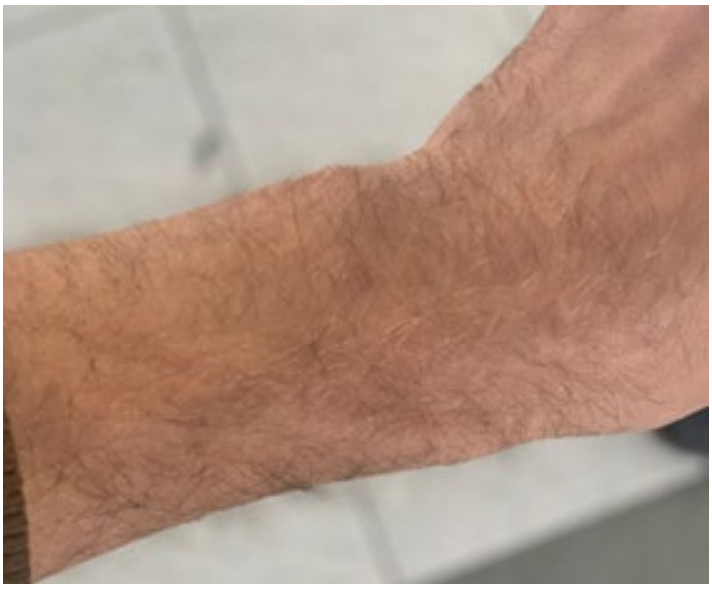


Fig. 9. No sign of skin irritation after removing Protocast 2.0

Measurements

The aim of the new data collection method is the ability to compare measurements at different periods of the day. As stated earlier, activity during the day has an impact on the data.

Comparing data from the temperature sensor in Fig. 10 with data from the cast pressure in Fig. 11, the pressure readings show more fluctuations during the day due to activity. The temperature readings are more stable but known to change due to the influence of outside temperature.

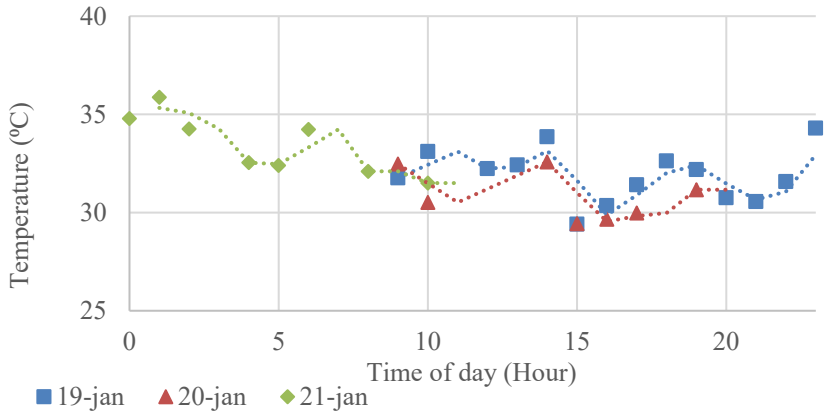


Fig. 10. The average hourly temperature during the day. The moving average is indicated by the dotted line. Data compared per day.

When looking at the cast pressure in Fig. 11, there are a lot more changes in values during the day. At first sight, the peak on January the 20th around 18:00 looks like compartment syndrome, but during that time, the temperature rises in the cast, and the peak disappears fast.

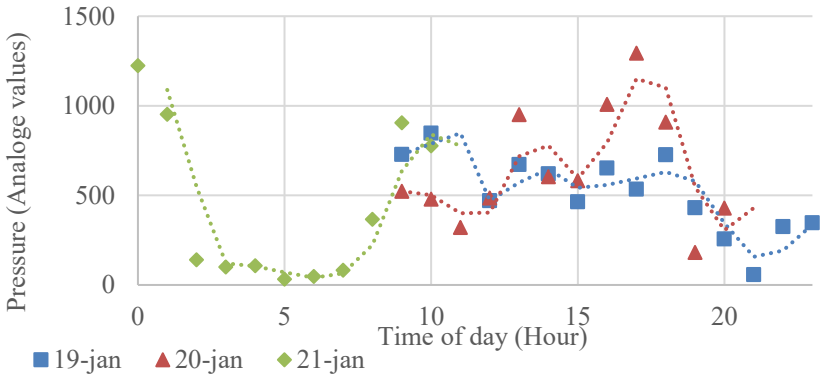


Fig. 11. Average hourly cast pressure during the day. The moving average is indicated by the dotted line. Data compared per day.

During testing with Protocast 1.0, the muscle activity sensor did not respond to muscle activity. Fig. 12 shows the average values from the muscle activity sensor which shows that the sensor is working correctly.

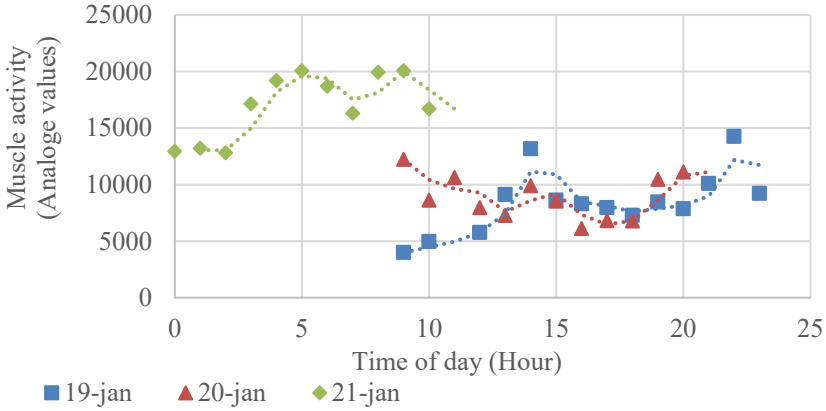


Fig. 12. Average hourly muscle activity during the day. The moving average is indicated by the dotted line. Data compared per day.

The complete overview of measurement data is shown in Appendix C.

Testing of the manual.

The application of the SMC in this test was done through the QSG. The physician did not receive any input from the research team. The application of the full cast with

SMC took roughly 12 minutes, which is comparable with the standard casting procedure. The QSG did therefore provide the right amount of information for applying the SMC.

5.3 Results of the second test

The QSG helped with applying the SMC during the casting procedure. During testing with the prototype, only 10 to 15% of application time was added, which will be optimised in the future.

There was a significant decrease in skin irritation due to the implementation of the sensor mat and moving the sensors on top of the cotton stocking. Simultaneously, this did not influence the measurements.

The data showed that all the included measurables are now detected within the correct measuring ranges and thus, useful. Finally, the muscle activity sensor worked in this test.

6 Discussion

The SMC was thoroughly tested on a healthy person and the key limitations, stated in chapter 2.2, are addressed as follows. The SMC shows promising results in the measurement of biomarkers associated with the complications during the fracture healing process. Due to the inability to test on a patient with a fracture, the monitoring of the healing process has only been tested in theory on a healthy person. The gathered information can be used to provide the physician with sufficient information to make informed decisions on the course of the healing process, as well as inform the patients.

Applying the Axiomatic Design approach clarified the process of mapping CAs, FRs, DPs and their mutual relations. Specifically, the decoupled setup of measurables and therefore ability to monitor each biomarker separately resulted in uncoupled data. This also reduced the information of the system since every biomarker was monitored independently.

The application time of the SMC showed to have little impact on the casting procedure, as tested during the casting process. Though, this time might change, when Protocast 3.0 is implemented.

The SMC can collect lots of data. This data can be used to create an AI algorithm that can make predictions on the monitored processes. Besides this, the data can be used for fracture-related research, but also other medical research. The design of the SMC is independent of the cast it is implemented into. Therefore, it can be implemented into different kinds of casts, splints and perhaps even future cast types like 3D printed casts.

The effect of internal (and mechanical external) fixation on a fractured bone is not researched. When a bone is stabilised with a surgically inserted pin, the measurables might be heavily impacted. However, within this group of patients, complications are more likely to arise. Therefore, the implementation of the SMC might be beneficial.

Also, the monitored processes can be made more specific. For an athlete, muscle atrophy has a higher impact on life after immobilisation. With diabetic people, overall

monitoring of the complications is most important since they have an increased chance of complications [46].

No data has been collected on a patient with an actual fracture. Therefore, it is currently not possible to verify the correlation between the researched measurable trends and actual changes in biomarkers, during the fracture healing process. This is a recommended next step.

7 Conclusion

The goal of the project was to design a product that could monitor the healing status of a fractured bone and three complications. As discussed, the measurables have all reached a certain level of robustness. None of the measurables, and therefore none of the monitored processes, reached the final level. However, no restrictions were found during testing to prevent this from being realised in the future.

On a lower level, it is already shown that the SMC can be implemented in the current medical process without too much interference for the patient. Since the design is even more optimised after testing, this will only improve further.

From a medical standpoint, the SMC would be a very interesting addition to fracture healing. Possible research can be done with this device to gain knowledge and collect new data throughout the healing process.

The value of Axiomatic Design showed its strength in the strong foundation formed by the independence axiom. The correct formulation of FRs made sure that the correct measurables were applied, allowing a substantiated sensor selection. The testing of the SMC from part- to system-level made it possible to quickly evaluate results and adjust the design were necessary. This resulted in narrowed specifications for the sensors, which ended up being used.

8 Author contribution

Tim Heijne, Mitch Kruijer, Jakub Kylar, and Lennard Spauwen all contributed equally to the project and this paper as part of a student project. Karin Thomassen supervised the project. Erik Puik supervised the development of this paper.

9 Acknowledgement

We would like to thank Ms Saskia Volders from the UMC Utrecht for the help with applying the cast during the testing procedures.

References

[1] Axiomatic Design Research Foundation, “Axiomatic Design,” Axiomatic Design Research Foundation, 10 2021. [Online]. Available: https://www.axiomaticdesign.org/. [Accessed 16 02 2022].

[2] C. van der Werken, H. J. Klasen, S. de Lange, R. K. Marti, A. J. G. Nollen, E. J. F. B. Raaijmakers, L. S. de Vries and P. R. G. Brink, Letsels van het steun- en bewegingsapparaat, Maarssen: Elsevier gezondheidszorg,, 2000.

[3] V. Saskia, Interviewee, [Interview]. 25 October 2021.

[4] Ministerie van Volksgezondheid, Welzijn en Sport, “Nieuwe prognose verwachte personeelstekort,” Den Haas, 2022.

[5] M. Psatha, Z. Wu, F. M. Gammie, A. Ratkevicius, H. Wackerhage, J. H. Lee, T. W. Redpath, F. J. GIlbert, G. P. Ashcroft, J. R. Meakin and R. M. Aspden, “A Longitudinal MRI Study of Muscle Atrop hy During Lower Leg Immobilization Following Ankle Fracture,” *Journal of Magnetic Resonance Imaging,* vol. 35, pp. 686-695, 2012.

[6] E. I. Gover, N. Yasud, M. A. Tarnopolsky, A. Abadi and S. M. Phillips, “Little change in markers of protein breakdown and oxidative stress in humans in immobilization induced skeletal muscle atrophy,” *Applied Physiology, Nutrition and Metabolism,* vol. 35, pp. 125-133, 2010.

[7] A. P. Fitzpatrick, M. I. Mohanned, P. K. Collins and I. Gibson, “Design of a Patient Specific, 3D printed Arm Cast,” in *The International Conference on Design and Technology*, 2017.

[8] D. Faegnell, “3D Printer Chat,” 23 January 2022. [Online]. Available: https://nl.pinterest.com/pin/732890539330175035/.

[9] Y. Chen, H. Lin, Q. Yu, X. Zhang, D. Wang, L. Shi, W. Huang and S. Zhong, “Application of 3D-Printed Orthopedic Cast for the Treatment of Forearm Fractures: Finite Element Analysis and Comparative Clinical Assessment,” *BioMed Research International,* vol. 2020, p. 12, 2020.

[10] T. Chaudhry, G. Ruiz, J. d. Vergara and Z. Siddiqui, “SMART-cast,” Department of Biomedical Engineering, New Jersey Institute of Technology, Newark, NJ, USA, New Jersey, 2017.

[11] M. N. Charles and D. Yen, “Properties of a Hybrid Plaster-Fiberglass Cast,” *Canadian Orthopaedic Association,* vol. 43, no. 5, pp. 365-367, 2000.

[12] R. T. Loder, “The influence of diabetes mellitus on the healing of closed fractures,” US National Library of Medicine, 1998.

[13] D. N. Retzepi M., “The effect of diabetes mellitus on,” The effect of diabetes mellitus on, London, 2010.

[14] L. Claes, S. Recknagel and A. Recknagel, “Fracture healing under healthy and inflammatory conditions,” *Nature Reviews Rheumatology,* vol. 8, pp. 133-143, 2012.

[15] University of California - Davis Health System, “A fracture anywhere reduces bone density everywhere: New UC Davis Health studies help explain why one break can lead to others,” ScienceDaily, 2018 September 24. [Online]. Available: https://www.sciencedaily.com/releases/2018/09/180924095727.htm. [Accessed 2021 October 26].

[16] C. Lu, M. Rollins, H. Hou, H. M. Swartz, H. Hopf, T. Miclau and R. S. Marcucio, “Tibial Fracture Decreases Oxygen Levels at the Site of Injury,” *Iowa Orthopedic Journal,* vol. 28, pp. 14-21, 2008.

[17] S. Fuegener, P. Hoff, A. Lang, T. Gaber, A. Rakow, P. Simon, G. R. Burmester, C. Perka and F. Buttgereit, “SAT0090 Analysis of Potential Risk Factors for Delayed Fracture-Healing,” *Annals of the Rheumatic Diseases,* vol. 73, no. 2, pp. 622-623, 2014.

[18] M. F. Bastos, V. F. Brilhante, P. J. Bezerra, C. A. Silva and M. P. Duarte, “Trabecular bone area and bone healing in spontaneously hypertensive rats. A histometric study,” *Brazilian Oral Research,* vol. 24, no. 2, pp. 170-176, 2010.

[19] U. Tarantino, I. Cerocchi, A. Scialdoni, L. Saturnino, M. Feola, M. Celi, F. M. Liuni, G. Iolascon and E. Gasbarra, “Bone healing and osteoporosis,” *Aging Clinical and Experimental Research,* vol. 23, no. 2, pp. 62-64, 2011.

[20] R. Barkmann, P. Laugier, U. Moser, S. Dencks, F. Padilla, G. Haiat, M. Heller and C.-C. Glüer, “A method for the estimation of femoral bone mineral density from variables,” *Bone,* vol. 40, no. 1, pp. 37-44, 2007.

[21] J. Saulgozis, I. Pontaga, G. Lowet and G. v. d. Perre, “The effect of fracture and fracture fixation on ultrasonic velocity and attenuation,” *Physiological Measurement,* vol. 17, no. 3, pp. 201-211, 1996.

[22] V. Kilappa, “Ultrasound Measurements in Bone Using an Array Transducer,” Department of Physics University of Jyväskylä, Jyväskylä, 2014.

[23] E. Camus, “Analysis of the axial transmission technique for the assessment of skeletal status,” *The Journal of the Acoustical Society of America,* vol. 108, no. 6, p. 3058–3065, 2000.

[24] M. Gerlanc, D. Haddad, G. W. Hyatt, J. T. Langloh and P. s. Hilaire, “Ultrasonic study of Normal and Fractured bone,” *Clinical Orthopaedics and Related Research,* vol. 111, no. 1, pp. 175-180, 1975.

[25] K. N. Malizos, A. A. Papachristos, V. C. Protopappas and D. I. Fortiadis, “Transosseous application of low-intensity ultrasound for the enhancement and monitoring of fracture healing process in a sheep osteotomy model. Bone,” *Bone,* vol. 38, no. 4, p. 530–539, 2006.

[26] V. C. Protopappas, D. A. Baga, D. I. Fotiadis, A. C. Likas, A. A. Papachristos and K. N. Malizos, “An Ultrasound Wearable System for the Monitoringand Acceleration of Fracture Healing in Long Bones,” *Transactions on Biomedical Engineering,* vol. 52, no. 9, pp. 1597-1608, 2005.

[27] L. E. Claes and J. L. Cunningham, “Monitoring the Mechanical Properties of Healing Bone,” *Clinical Orthopeadic Related Research,* vol. 467, no. 8, pp. 1964-1971, 2009.

[28] J. Rittweger, H. M. Frost, H. Schiessl, H. Ohshima, B. Alkner, P. Tesch and D. Felsenberg, “Muscle atrophy and bone loss after 90 days’ bed rest and the effects of flywheel resistive exercise and pamidronate: Results from the LTBR study,” *Bone,* Vols. 1019-1029, p. 36, 2005.

[29] J. W. Andrushko, L. A. Gould and J. p. Farthing, “Contralateral effects of unilateral training: sparing of muscle strength and size after immobilization,” *Applied Physiology, Nutrition, and Metabolism,* vol. 43, pp. 1131-1139, 2018.

[30] J. E. Stevens, G. A. Walter, E. Okereke, M. T. Scarborough, J. L. Esterhai, S. Z. George, M. J. Kelley, S. M. Tillman, J. D. Gibbs, M. A. Elliot, T. N. Frimel, P. C. GIbbs and K. Vandenborne, “Muscle Adaptations with Immobilization and Rehabilitationafter Ankle Fracture,” *Medicine and Science in Sports and Exercise,* vol. 36, no. 10, pp. 1695-1701, 2004.

[31] M. Psatha, Z. Wu, F. M. Gammie, A. Ratkevisius, H. Wackerhage, J. H. Lee, T. W. Redpath, F. J. Gilbert, G. P. Ashcroft, J. R. Meakin and R. M. Aspden, “A longitudinal study of muscle rehabilitation in the lower leg after cast removal using magnetic resonance imaging and strength assessment,” *International biomechanics,* vol. 2, no. 1, pp. 101-112, 2015.

[32] K. Vandenborne, M. A. Elliott, G. A. Walter, S. Abdus, E. Okereke, M. Shaffer, D. Tahernia and J. L. Esterhai, “Longitudinal study of skeletal muscle adaptations during immobilization and rehabilitation,” *Muscle Nerve,* vol. 21, no. 8, pp. 1006-1012, 1998.

[33] R. E. Klabunde, “Skeletal Muscle Pump,” Cardiovascular Psysiology Concepts, 1 12 2008. [Online]. Available: https://www.cvphysiology.com/Cardiac%20Function/CF018. [Accessed 02 2022].

[34] R. Ozgun, “Non-invasive Blood Pressure Monitoring System,” 15 August 2019. [Online]. Available: https://www.maximintegrated.com/en/design/technical-documents/app-notes/7/7082.html. [Accessed 2021 October 28].

[35] Y. Torii, K. Kusunose, R. Zheng, H. Yamada, R. Amano, R. Matsumoto, Y. Hirata, S. Nishio, N. Yamada, I. Takayuki, K. Yamaguchi, T. Tobiume, D. Fukuda, S. Yagi, T. Soeki, T. Wakatsuki, Y. Okayama and M. Sata, “Association between Sarcopenia/Lower Muscle Mass and Short-Term

Regression of Deep Vein Thrombosis Using Direct Oral Anticoagulants," *International Heart Journal,* vol. 61, no. 4, pp. 787-794, 2020.

[36] R. Cooray and C. Lake, "Prevention of deep vein thrombosis and pulmonary embolism," *Anaesthesia and intensive care medicine,* vol. 22, no. 10, pp. 630-635, 2021.

[37] T. Heijne, M. Kruijer, J. Kylar and L. Spauwen, "Smart Medical Cast – Midterm Review," Utrecht, 2021.

[38] M. H. Walls and T. Landing, "Compartment Syndrome: an Ortheopedic Emergency," Elsevier, Baltimore, 2017.

[39] J. M. Kistler, A. M. Ilyas and J. J. Thoder, "Forearm Compartment Syndrome Evaluation and management," Temple university, Philadelphia, 2017.

[40] J. J. piotrowski, J. Alexander, C. P. Brandt, C. R. McHenry, J. P. Yuhas and D. Jakobs, "Is Deep Vein Thrombosis Surveilance Warranted in High-Risk Trauma Patients?," Excerpta Medica inc., Rancho Mirage, 1996.

[41] B. T. Wall, M. L. Dirks and L. J. van Loon, "Skeletal muscle atrophy during short-term disuse: implications for are-related sacropenia," Elsevier, Maastricht, 2013.

[42] L. Giangregorio and N. McCartney, "Bone loss and muscle atrophy in spinal cord injury: Epidemiology, fracture prediction, and rehabilitation," J spinal cord med., Waterloo, Ontario, 2006.

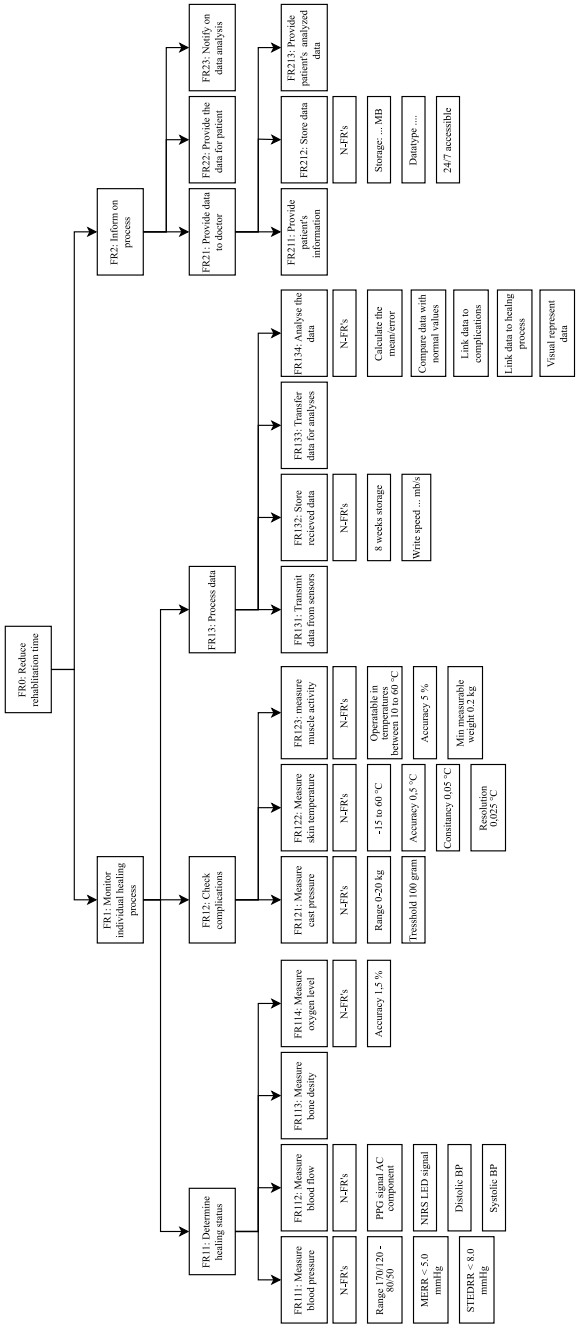
[43] M. S. Beerekamp, R. J. de Muinck Keizer, N. W. Schep, D. T. Ubbink, M. J. Penneman and J. C. Goslings, "Epidemiology of extremity fractures in the Netherlands," *Injury,* vol. 48, no. 7, pp. 1355-1362, 2017.

[44] MRI Centrum, "Passantentarieven 2021 MRI," 11 January 2021. [Online]. Available: https://www.mricentrum.nl/sites/default/files/ckeditor/20210111_passantentarieven_mri_2021.pdf. [Accessed 1 February 2022].

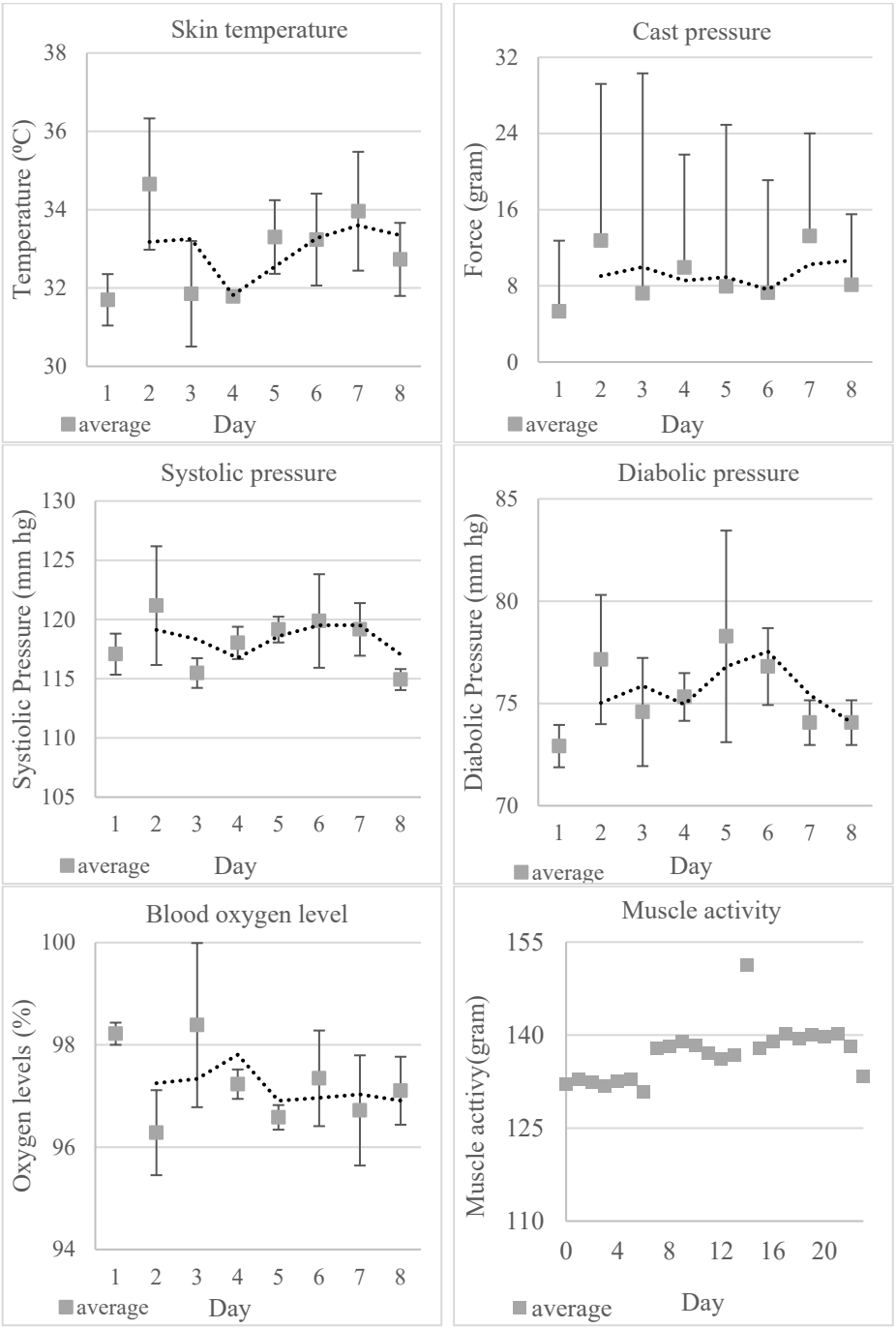
[45] D. M. Vossebeld, J. T. Foley and E. Puik, "The Complexity of Mapping Customer Needs... (and the Myth of a Unanimous Customer)," in *ICAD 2018*, 2018.

[46] H. Jiao, E. Xiao and D. T. Graves, "Diabetes and Its Effect on Bone and Fracture Healing," SpringerLink, Pennsylvania, 2015.

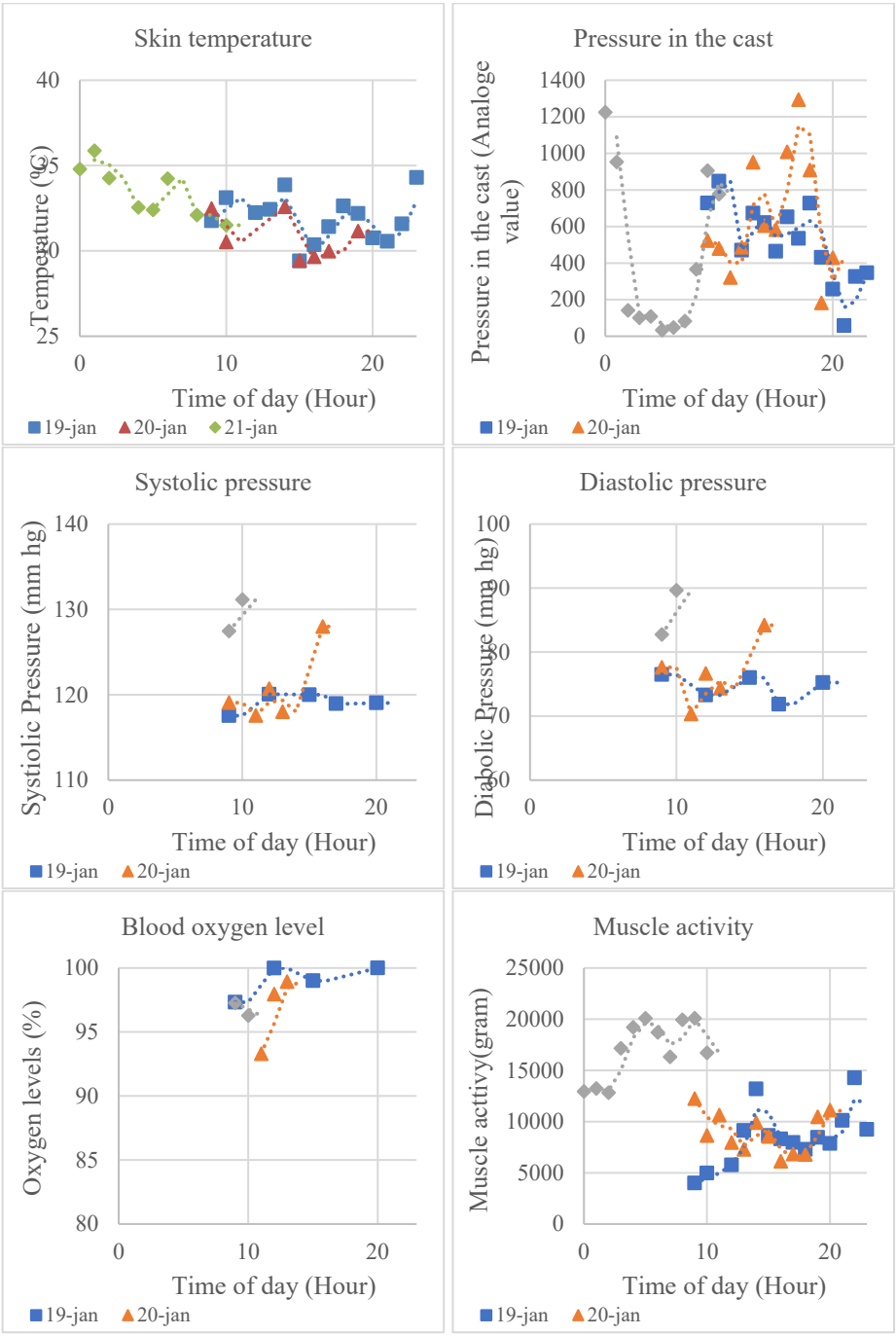
Appendix A - Functional decomposition



Appendix B – Measurements test one



Appendix C – Measurements test two



Appendix D – Quick Start Guide

Smart Medical Cast - Quick Start Manual

The Smart Medical Cast is a device that will be intergrated into the orthopeadic cast to measure the healing status of the fracture and check for the most common complications.

In this quick start manual the example is given on a forearm with a distal Ulna fracture, but the Smart Medical Cast can be used on most body parts

1

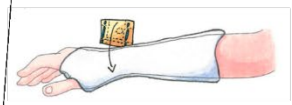
Place stocking on the body part

2

Spray the pre-tape on the three sensor mats to complete the preperation

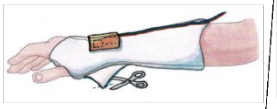
3

Place sensor mat 1, with the blue stripes across the fractured bone, on either side of the fracture and fold the rest of the mat over the body part



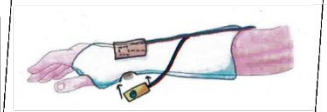
4

Locate indicated-artery according to the table on the back of the quick start manual and cut a hole through the stocking with a diameter of at least 0.5 centimeter



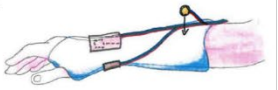
5

place sensor mat 2 with the blue dot on the indicated artery through the hole



6

Locate the idicated muscle with the table on the back of the quick start manual and place sensor mat 3 on the specified muscle



7

Continue casting

8

Attach the connector of the sensors to the main box and attach the main box to the ortopeadic cast using the provided velcro