Incorporate agentiality into the design process for digital pain assessment using a flexible framework instead of user requirements

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ABSTRACT

This paper offers a comprehensive new approach to design research in the field of digital health, by describing the development of a novel pain assessment tool based on the haptic-visual modelling of interactive graphics. The project is developed in cooperation between the Faculty of Art and Design of the Bauhaus-Universität Weimar and the Department of Anaesthesiology and Intensive Care Medicine at Jena University Hospital. Methodologically, a series of action design research studies are carried out in which stakeholders (patients and health care professionals, HCPs) are involved. The distinctive approach of this project is the use of a framework, which guides the design process. In contrast to the definition of user requirements, which is common in the development of (medical) software products, this framework addresses the pain concept emerging in the use of the assessment tool as an ‹agentiality› of the design. In doing so, aspects of pain medicine are taken into account in shaping a certain agentiality. As a result, for the first time, a pain assessment tool is developed that does not adress pain in a positivist sense, but rather reflects the agentic properties of the tool in its use.

KEYWORDS

- pain assessment
- digital medicine
- design research
- design methods

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FULL PAPER

INTRODUCTION – DEFICITS AND POTENTIALS OF DIGITAL PAIN ASSESSMENT

Medicine has been strongly influenced by digitalisation processes in recent years (Engemann, 2019). Under the label of ‹data-driven medicine› (BAG, 2017, p. 4; Cirillo & Valencia, 2019; Shomorony, 2022) the search for patterns in medical data offers great potential for improving diagnosis and therapy. To this end, medical data is correlated to calculate statistical probabilities of the individual chances of therapeutic measures being successful – on which basis clinical decisions can be made (Clinical Decision Support, CDS. Mills, 2019; Muhiyaddin et al., 2020). The prerequisite for this however is the definition of treatment goals. Here, a second important trend of recent decades comes into play, the attempt to identify and pursue holistic therapy goals such as general quality of life – as opposed to focussing solely on the disease's elimination (Zill et al., 2023). The assessment of one's individual experience is therefore important, as these ultimately determine the choice of therapy. Standardised questionnaires about Patient Reported Outcomes (PROMs) (Churruca et al., 2021; Pérez-Alfonso & Sánchez-Martínez, 2021; Weldring & Smith, 2013) and Patient Reported Experience (Benson & Benson, 2023; Ferreira et al., 2023; Scher et al., 2020) (PREMs) are used for this purpose.

PAIN ASSESSMENT AND PAIN MECHANISMS

An important category within these PROMs is pain experience (Breivik et al., 2008; Dansie & Turk, 2013; Fillingim et al., 2016; Karcioglu et al., 2018). Pain is assessed for the purposes of diagnosis, treatment adjustment, and evaluation (Weldring & Smith, 2013). However, pain assessment faces significant challenges because pain is a very complex construct. For a long time (and often still today) reduced to a purely mechanistic conduction of stimuli, it has been clear since the 1960s at the latest that the experience of pain arises from a complex interplay of the central and peripheral nervous system (Melzack & Wall, 1965). The way in which pain is perceived can only to a limited extent be directly attributed to a specific stimulus but depends heavily on a person's previous experiences and the existing context. Overall, pain has to be understood as a holistic experience with physical, psychological, social and spiritual aspects. As a process in the central nervous system, there is also always a risk of chronification, resulting in persisting pain, as repeatedly established nerve connections are stabilised. This means that if a patient is exposed to pain repeatedly or over a long period of time, the nerve pathways involved in the pain experience may become stabilised – the pain is «learned». This can lead to increased sensitivity or even permanent pain, even if the original physical injury has already healed (Cervero, 2014, p. 117). In such ‹chronic pain› conditions, the pain itself is the disorder. It is not uncommon that persisting pain leads to avoiding behaviour, such as social withdrawal, which may be followed by depression and an increased focus on the pain, which in turn leads to intensification and further withdrawal. One of the central goals of chronic pain therapy is therefore to convey to patients that they can influence their pain themselves – the experience of self-efficacy as a therapeutic goal (Arnold et al., 2009). It is essential for this to emphasise that pain can be influenced in a self-determined way. A variety of different instruments are used to assess pain, ranging from simple (intensity scales of 0 to 10) to complex questionnaires (questions on type, duration, course, functional impairments) (Karcioglu et al., 2018). Notably current digital pain assessment tools place patients – interactionally speaking – in a passive role, they represent rigid categories that cannot be influenced by the patient. Although it can be considered common knowledge that the form and content of questions implicitly (or explicitly) influence the answers and thus the overall research outcome (being, for example, critically discussed in social science and/or science and technology studies), this has not been extensively explored in the field of chronic pain therapy and its digital translation.

CHALLENGES AND DEFICITS OF DIGITAL PAIN ASSESSMENT

Overall, the current assessment tools are in stark contrast to a context-variable and multidimensional concept of pain. This reductionist form of questioning can be understood in the terms of interaction design as the use of «resources», i.e. the selection of one or more options[1], in opposite to interaction elements called «directly manipulative systems», i.e. the parametric manipulation of one or more dimensions (Herczeg, 2006). This applies not only to paper questionnaires, but also to digital forms of pain assessment. Digital tools are often just adaptations of analogue methods (Rao et al., 2022). To conclude, digital pain assessment in its current form faces a number of challenges. Present assessment tools can be characterised as ‹reductionist› since they ask about different dimensions of pain separately (e.g. pain intensity) and offer only a choice between a few and/or predefined parameters and query options. Besides this, the abstract form of recording and visualisation must be regarded as problematic, as body-specific (i.e. local, regional and/or global) pain references/representations are often excluded. This means that pain as a holistic experience with physical, psychological, social and spiritual aspects is not adequately captured. The performance of digital, data-driven medicine based on these categories must therefore also be regarded as correspondingly limited. This is despite the fact that digital assessment systems, due to their multiparametric, multimedia and multisensory input and display options, would certainly be suitable for assessing individual patient experiences in the dimensions described while still delivering analysable information. In principle, they are able to translate a broad – and at the same time customisable – spectrum of experiences in unique data points (Breuer et al., 2022; Swanston et al., 1993, p. 384) and thus generate machine-readable data patterns for evaluation in the sense of preventive medicine (Zaveree & Keshavjee, 2015).

From a therapeutic point of view, it must be emphasised that framing pain in a fixed form is diametrically opposed to the aim of to convey self-efficacy. This is despite the fact that studies such as that

1 For example buttons, choices, checkboxes.

by Richter and Weiß show how pain words can trigger acute pain in chronic pain patients and that there is therefore a direct interaction between the verbal representation of pain and the experience of pain (Richter & Weiß, 2018).

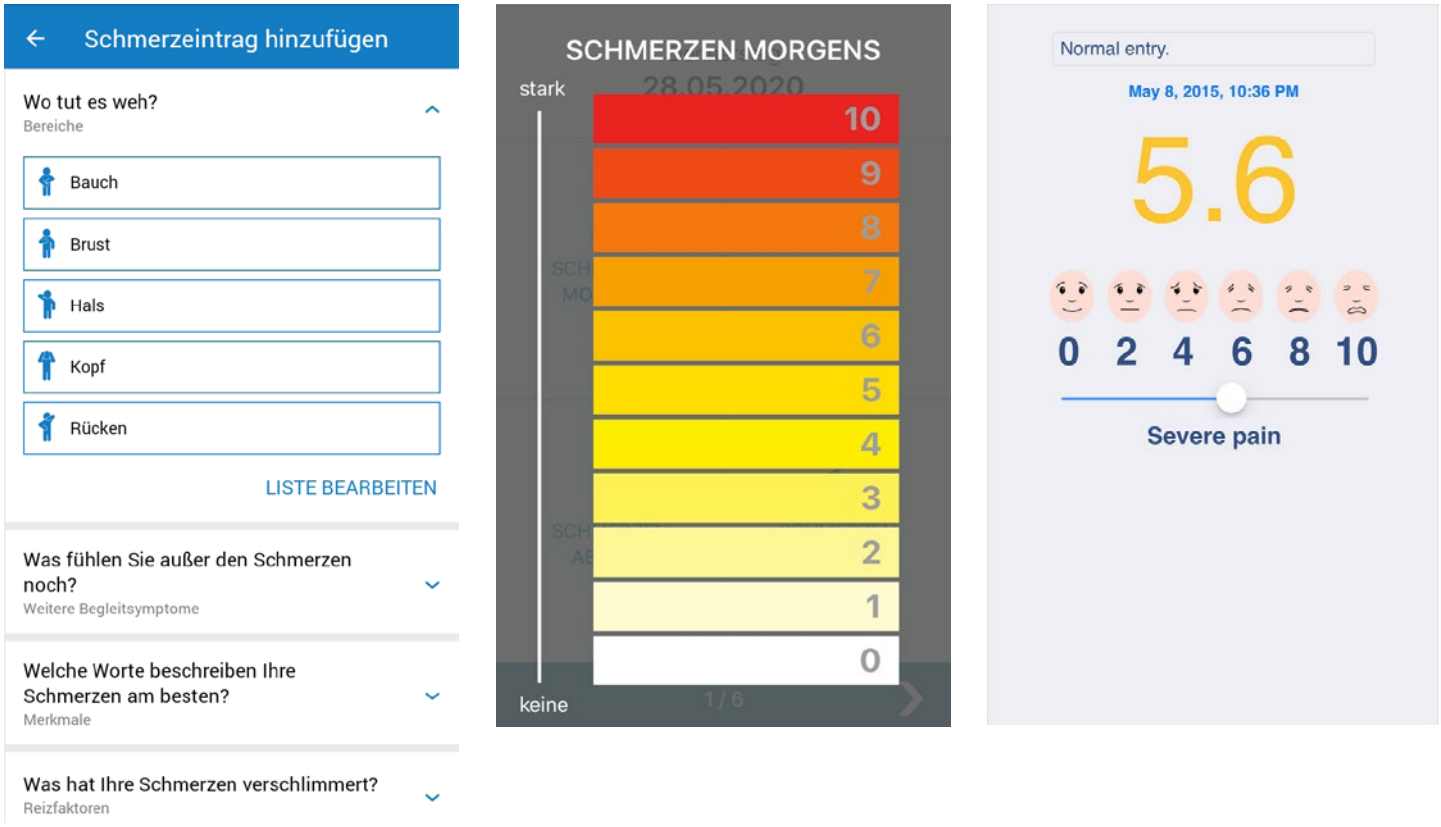


Fig. 1: Examples of mobile applications fo of pain assessment (Daman, 2020; Gruenenthal, 2018; Healint, 2020; Softarch Technologies, 2020; Track & Share Apps, 2018)

DESIGN AND DEVELOPMENT PROCESSES FOR MEDICAL SOFTWARE

The question that arises from a design perspective is: How the existing tools for digital pain assessment were designed, when they are so deficient? It is worth taking a look at the publications on the development processes of such applications. Although there are only very few publications on the development processes of digital health systems (Nilsen et al., 2012), these are nevertheless informative. From these, it is apparent that the process of choice is «human-centred design» based on the principle of human-computer interaction (HCI). Rarer projects can also be identified in which approaches such as participation and co-design are used – but usually limited for the identification of requirements at the beginning of the project (Noorbergen et al., 2021). It can be stated that the concept of design in medical software development is primarily thought of in terms of the implementation of an existing (medical) approach and less as a questioning of existing practice[2]. The inclusion of users is limited to an evaluation and validation of usability by the target-defined functions, which leads to a reproduction of established forms of pain assessment in digital applications. It can therefore be stated that in development projects for digital pain assessment – with a few exceptions[3] – the form of assessment is not the subject of the design at all.

2 In this sense, design should not be seen as something that creates optimisations in existing categories or thinks in terms of existing cultural practices, but rather design artefacts should be thought of as alternative approaches to the world, society and nature, an «Andersmöglichsein»(Geiger, 2018) or tests the options of counterfactual action (Oulasvirta & Hornbæk, 2021).

3 Published projects include the project by Rao et al. in which items from the McGill pain questionnaire were translated into interactive graphics (Rao et al., 2022), the dolography by Affolter and Rüfenacht (Rüfenacht, 2020), in which various images were developed which the patients can select to describe their pain. Or the project by Mathew and Kant, where a communication tool was developed with which people suffering from pain can pass on their experience to their relatives (Mathew & Kant, 2021).

Since the discipline of design – especially when postulating being ‹human-centred› – claims to represent «human interests» (Gasson, 2003) which undoubtedly also applies to medicine (Gerabek et al., 2005), therefore the question arises, as to why the form of assessment is researched on so little and why the deficits of the current form of pain assessment are not recognised. One reason, for sure is the prerequisite of validation of a new assessment tool – to proof that it fulfils criteria of validity and realibility (Moosbrugger & Kelava, 2020, p. 37). This makes it – in theory – difficult to develop an individualised form of assessment. However, digital assessment automatically provides clear datapoints, which makes validation much easier. Furthermore, many projects (such as individual symptom diaries) do not claim to use statistically valid instruments and still use the same discrete forms of assessment. So, the question is, why do the deficits not become apparent in the design process itself? To answer this, we take a look at the specific design of HCI software engineering. Various frameworks for the development of software products are known and are discussed in the context of medical software development (Al-Bashayreh et al., 2013; Yusof et al., 2008). What they usually have in common is the identification of user requirements that define the requirements for the necessary functionality of the product. A user requirement contains generally formulated requirements as to which work tasks the user should be able to perform with the system; they are therefore «requirements of the context of use» (cf. DAkkS, 2010, p. 6). These are derived from a context analysis, e.g. an interview (cf. ibid. p. 3), and are then prioritised and implemented. The aim of the successful realisation of the user requirements is the creation of usability in the sense of the development process according to ISO standard 9241.

For software that is subject to medical device regulations, a standardised procedure (starting from requirements identification until testing the system's compliance) is essential, as the development process itself has to be certified by the Medical Device Regulation (MDR) (in addition to the software itself) (Walitschek, 2018). Discrete requirements can be evaluated in a standardised manner, for example through use errors[4], as is common in usability evaluation. The user requirements therefore address the functions that should be realised with the system without taking into account the possible consequences of the use of the system. As already repeatedly discussed in the critique of functionalism (Mareis, 2014, p. 90 ff.), this approach neglects the fact that user requirements are by no means ‹objectively› or ‹naturally› necessary functions, but mostly an identification of established techniques and behaviours. This leads to two problems: 1. Problematic actions can also be evoked, since a problematisation of embedded systems is excluded from the outset (cf. Norman, 1999) and 2. possible problematic consequences of use are not taken into account in the evaluation, since the focus lies on the usability itself. Both are due to a fundamental problem of human-computer interaction (HCI) that applies both to medical pain assessment and to work (solely) with user requirements in general: it's the passive concept on the user (Hartley, 2012, p. 113), with their hurting bodies on the one side and ‹objective› assessment categories on the other, which need to be synchronised by the design process. The obvious answer to this challenge is the vibrant and diverse practices of user experience design and UX research that exist for several decades; here, the user experience (and its explications) defines the design process, its relevance and impact (Diefenbach et al., 2014). In turn, this requires the involvement of the user at the earliest stage, whereas instrumental needs are explored, prototypically tested and optimised in iterations (Gray, 2016) whilst also evaluating non-instrumental qualities using standardised metrices and routines (e.g. Thüring & Malke 2007). However, such approaches have not been transferred yet to the field of (digital) pain assessment research and respective settings and methods (with the exception of a few projects, see footnote 3).

In current practice, for example, a concept of affordance – which has to be considered outdated from a current UX design perspective – is used. According to this design must fulfil pre-defined goals (cf. Alshawmar, 2021) and not the effects that arise from the use itself[5]. Thus, the agency[6] of the assessment tool both a) in terms of the level of detail (multidimensional instead of unidimensional) and b) in terms of the mediated pain assessment (e.g. variable instead of rigid) cannot be formed in such kind of design process.

DEVELOPMENT AND UTILISATION OF A FLEXIBLE DESIGN FRAMEWORK

2.1 BACKGROUND

The starting point of the present project was the recognition of the deficits of current pain assessment instruments (see introduction) and thus the goal of developing an alternative method that does not passivate the patient in the query, and which is able to display pain in its multiple dimensions. The requirements for the design therefore do not relate to the use, but to the effect that results from it. A conventional approach with use requirements does not allow for this focus of the design. This is because the current practice aims on optimizing an existing instrument into a digital product and not to develop a new practice of pain assessment that addresses the influence of the system in the design. We therefore need a UX-Design framework, as described above, that focuses on the agential properties of the system – the way pain is conceptualized in its use.

4 In those, the defined user requirements are assigned to the testers as tasks, which they are then asked to solve with the system presented. If this succeeds, the development process is complete; if not, iteration continues until the system is designed in such a way that the tasks can be fulfilled by the users.

5 Apart from malfunctions in terms of usability, of course.

6 The term ‹agency› describes the (unintentional) influence of human and non-human actors on an environment. (Latour, 2019). This «agentive realism» (Barad, 2015) conceptualises matter as active and influential. The approach builds on the decline of materialist approaches of the 1970s and 1980s and the rise of post-structuralist theories (Hoppe & Lemke, 2021). In relation to the present project of pain experience, this relational perspective of agency is crucial, as it follows that the ontological and epistemic properties of the virtual and material prototypes must be included as ‹agency› in the design process.

We argue that design should be understood as something becoming and agential, as it influences not only the way it is experienced and used, but how it is conceived and pursued. This agential capacity, as formulated in Latour's actor-network theory, outlines an epistemic shift and represents a central position within the design theory discourse (Mareis, 2014, p. 143).

Latour describes the (non-intentional) influence of an environment by both human and non-human actors (Latour, 2019) further elaborated within Barad's relational perspective of ‹agential realism›, according to which ‹reality› is constituted on the basis of the properties of aperatures (Barad 2015). With regard to pain assessment, this implies, that the design of the apparatus, queries certain aspects of pain while ignoring others – forming a certain ‹reality› in dependence of the agentiality of the assessment tool. In this way, the articulation of pain and also the conceptualization of pain are influenced (Fig. 1). With regard to design in medical contexts, this effect can also be unterstood as ‹health effectiveness› (Rehn, 2019) – referring to the behaviour evoked by the artefact. In design theory, this constructivist argument has also been used from an ethical perspective (Borries, 2017) and in contrast to functionalism (Geiger, 2018, p. 44), but it has not yet played a role in the development of digital pain assessment so far.

Our aim is to carry out a development process on the basis of a framework that defines certain actions in relation to pain assessment as goals (e.g. to be able to visualize pain in a changeable way, for all criteria see also the next chapter) and thus to achieve a certain concept of pain during use. Therefore, we aim in our Instrument to create a certain type of agency for a certain concept of pain. Considering the overall design development and design process as agential, it cannot be formulated and pursued through (fixed) use requirements or hedonistic properties. Contrastingly, our approach is based on user experience design by placing the conceptualization, testing and observation of prototypes at the centre of development, while, at the same time, arguing that in pain assessment, the user experience has also (and foremost) a medical-therapeutic function – being a category that has so far only been considered from a usability perspective. Accordingly, this agential condition should be defined as prerequisite of the design process, and thus allowing the UX design research to be adaptive and affective. For this, we used our flexible framework that served as a guideline for the design and concretised the realization of the goals along the process.

2.2 DEVELOPMENT OF CRITERIA FOR THE FRAMEWORK

For our project, we developed criteria that describe the interactional goal of the design, i.e. which agent properties the system should have, and which concept of pain should derive from its use. In order to define these criteria, we first conducted extensive research on the topic of pain, pain assessment and pain therapy, e.g. interviews with people suffering from pain and HCPS. In a way, this procedure is similar to the context analysis of usability engineering (see previous chapter), with the difference that we didn't formulate requirements in terms of functionality, but rather a) which dimensions of pain should be possible to visualize in the tool and b) which concept of pain should emerge from these for the users. In formulating generalistic goals which has to be specified during the process, the interaction of the users is interpreted and moderated in the design process, not a certain knowledge applied (cf. Koskinen, 2023, p. 13). As described in the introduction, the patient's experience of self-efficacy is one of the factors that is of considerable importance. An evident visual and interactive conversion, which is formulated as criteria, is therefore a) to visualise the pain in a fluid form (criteria 1) and b) to make the visualisation itself modellable (criteria 2). The ability to influence the visualisation of pain means that pain can be experienced as changeable. Assessment by means of modelling also leads to a shift in roles between the querying authority (assessment tool) and the user. The experience is no longer ‹queried› but articulated by the user. To further emphasise this effect, a) the articulation is not further translated (e.g. into a graphic), but the self-modelled representation itself is the result of the assessment (criteria 3); b) the assessment itself or its visualisation is free from a quantifying evaluation by the system – the meaning (in terms of *better/worse*) is determined by the users themselves (criteria 4). We foster an integrative perspective on pain as a physical, psychological, social and spiritual construct in equal measure. The experience of pain should therefore neither be isolated from the body nor differentiated in terms of intensity and quality. For the interactive-visual realisation, this results in the need to a) implement the assessment in a multidimensional, multi-layered and body-related way (criteria 5) and b) strive for an integrated assessment of aspects such as intensity and quality (criteria 6).

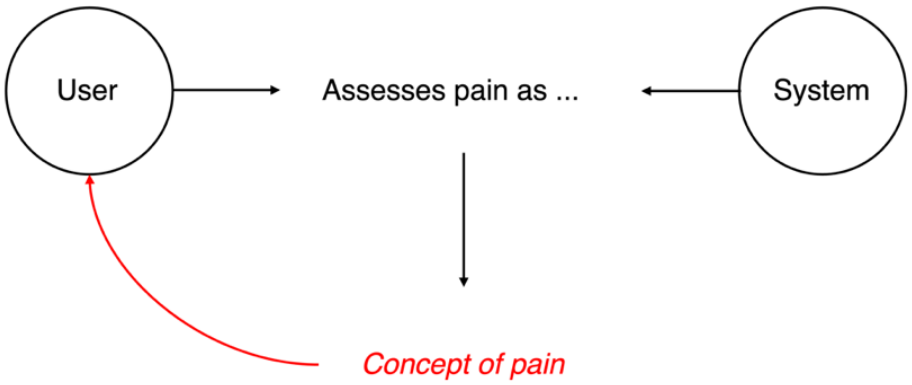


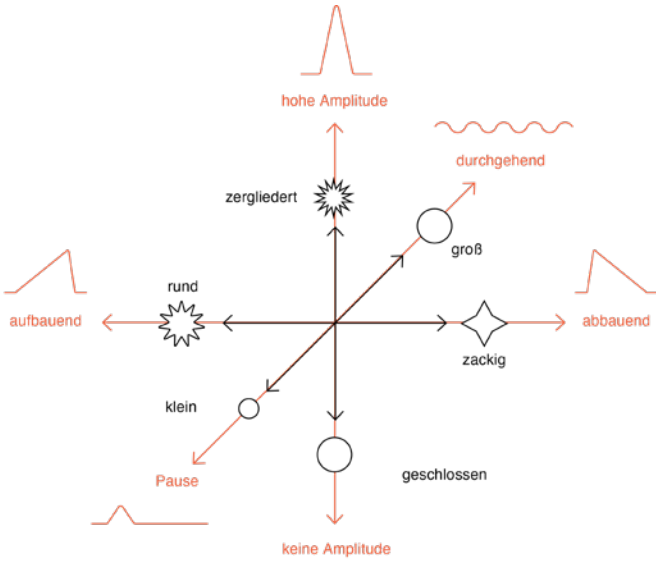
Fig. 2: Based on Latour's actor-network theory, in this project is assumed, that the design as a material artefact determines the type of pain communication and that, in the case of pain assessment, a certain concept of pain arises in its use.

Table 1: Collected criteria as a framework for concretizing a haptic-visual pain recording system

Criteria 1:	Illustration of body information only in motion. Conveying change and changeability.
Criteria 2:	Empowerment of users through action-reflection mechanics. Fluid and modellable parameters instead of static choice.
Criteria 3:	Keep the relationship between the articulation and the form of presentation comprehensible.
Criteria 4:	Avoidance of judgement-implicit iconography and notation logic. Subjective evaluation through individual creation of meaning.
Criteria 5:	Experience in its complexity and in relation to the body.
Criteria 6:	Merging intensity and quality – the two cannot be separated in the perception of those affected.
Criteria 7:	Organic and pictorial collection and visualisation of body data. Creating ‹perceptual proximity› – image instead of sign.
Criteria 8:	Radical subjectivity of pain: Approximation using pictorial metaphors.

APPLICATION OF A FLEXIBLE FRAMEWORK IN THE DESIGN PROCESS

The flexible framework is developed for our transformative and generative design research process in which findings generated during the process are incorporated into the further development. In this ‹research through design› process (cf. Frayling, 1993), the criteria take on the function of guidelines, as abstract objectives that are concretised and materialised in the form of design hypotheses (sketches and prototypes) and observed in use which offers a productive Expansion of the HCI approach (Zimmerman et al., 2007). The criteria of our framework provide general objectives but are interpreted for the specific implementation – in other words, they are in a bidirectional relationship to the process itself. For example, in a first step, we develop an initial purely graphical concept study in which we derive from the critera «change and changeability» that it should be parameterised (e.g. modelling of the size of the representation, jaggedness, roundness) and that animation parameters (amplitude, continuity, direction) should be included into it. In a later study based on the same criteria, we work with experimental design methods to explore different visualization strategies. In that study we work with colors in water and derive the parameters resolution and sharpness/blurring for our final demonstrator. Aspects of change and changeability are thus implemented depending on the context and capabilities of the available design tools (see Fig. 3).



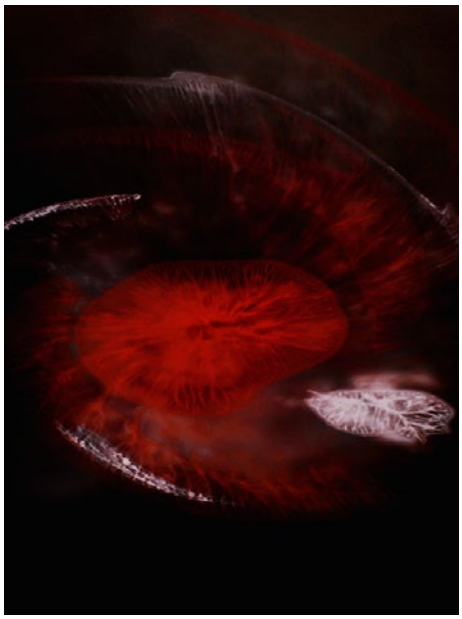


Fig. 3: Two different derivations of the same criteria (foster change and changeability) from the flexible design framework in different phases of the design process.

In this regard, the criteria are concretised processual and in interaction, i.e. they are not discrete requirements but remain interpretative and flexible. Another important differentiation from specific user requirements is the way in which the agentiality is addressed, i.e. the way in which the users assess their pain with the prototypes offered and which aspects of their pain are targeted. The inclusion of users is therefore an essential part of a design process with our flexible framework (and goes beyond the mere evaluation of usability). The designs developed on the basis of the criteria are iteratively implemented and tested as prototypes. In the test sessions, methods such as semi-structured interviews (Helfferich, 2014) and ‹thinking aloud protocol› (Konrad, 2010) are used and evaluated using a deductive code system. With that we explore the agential properties – i.e. the concept of pain that arises during use. To this end, the users are asked about their experiences during assessment with the prototypes. Two results derive from these: 1. the resulting perception of pain and its evaluation in comparison with the design criteria and 2. concrete suggestions or derivations from the statements on the design of the system. The users are thus actively involved in a co-creative manner (in contrast to a passive examination of discrete requirements according to a yes/no scheme). In this sense, a flexible framework of this kind is ideally based on UX Design and participatory methods in which the concrete result is defined in the process and with the involvement of the stakeholders.

To summarise, it can be stated that the framework is only indirectly aimed at the system design, but at the agentiality of the system in the interaction. The criteria therefore remain guidelines, and the refinement and differentiation are carried out flexibly according to actualising interpretations.

2.4 RESULT: DEMONSTRATOR FOR HAPTIC-VISUAL PAIN ASSESSMENT

As a result of our project, a ‹demonstrator› for haptic-visual pain assessment is developed, in which an individual pain picture can be modelled haptically and visually using a total of seven parameters (location, area, size, shape, material, colour and animation, see Fig. 3) (Breuer et al., 2023).

We tested the tool with chronic pain patients. As decriped in the introdcution, chronic pain often leads to avoidance behaviour, such as social withdrawal, which leads to depression and an increased focus on the pain, which in turn leads to reinforcement and further withdrawal (Arnold et al., 2009). One of the central goals of chronic pain therapy is therefore to teach patients that they themselves can influence their pain. Therefore, it is important to be able to visualise and document small changes in the pain experience, which is made possible by the high resolution of our assessment tool. The application scenario in chronic pain therapy would envisage generating a pain image at the beginning of the four-week therapy, in the middle and at the end, to visualise the course of the therapy and possible reinforcement of the therapy effect itself [7].

The prototype was tested and analysed by a total of fourteen pain patients. In addition to quantitative questionnaires on the suitability of the system, semi-structured interviews and the thinking aloud method were used. Patients were first asked to describe their pain verbally, then to locate it in a pain questionnaire commonly used at our pain clinic and finally to enter it using the demonstrator and describe it again during that process. The results showed how the level of detail of the description increased significantly while using the demonstrator and how the patients adopted the categories of the demonstrator in their description. For example, in the verbal report, one patient initially states that the pain is felt «all over the body» and only as «impairment» and «continuous». In the interaction with the system, his description become increasingly differentiated, e.g. in relation to the «material – sharpness» tool: «That's what it is! There's no straight line in it» (test patient). When using the ‹material – dissolution tool›, which breaks down the pain points into multiple parts, the patient statet: «It's true it's completely mixed up – so at the moment I have the pain extremely here and it's possible that in the next 10 minutes I'll have it here»). Such ‹dialogues› between patient and system occurred repeatedly – as an interactive exploration of the patient's pain in interaction with the pain perception system and its specific agentiality.

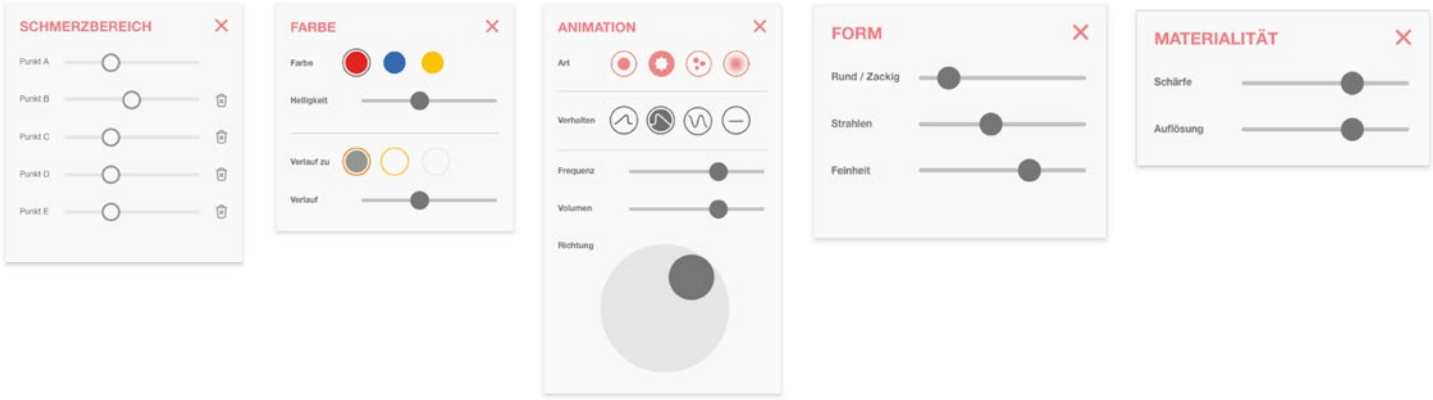


Fig. 3: The demonstrator's tools for pain visualization: (from left to right) area, size, shape, material, colour and animation (location tool not pictured)

7 The evaluation of the hypothetical therapeutic effects and added value is the subject of a planned follow-up research project.

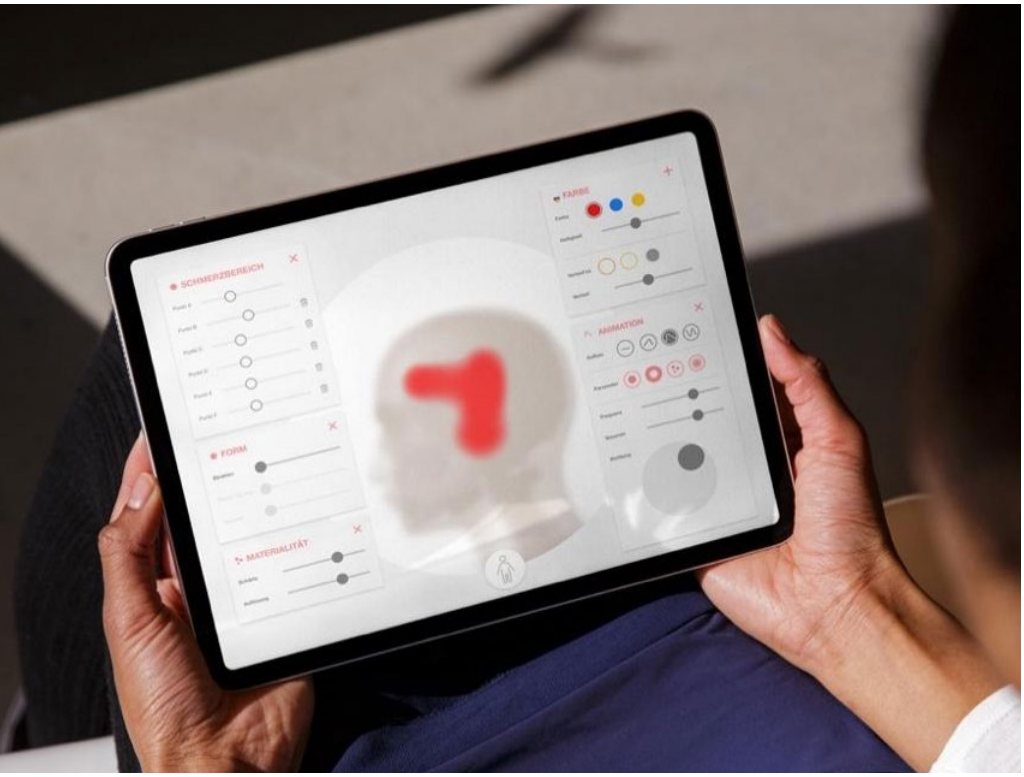


Fig. 4: Visual-haptic pain assessment using modellable parameters on a 12" tablet. The ‹tools› for modelling and animating the representation are arranged around the centrally placed body representation, which can be selected via the icon at the bottom of the screen.

Therefore, it can be stated, that tests with pain patients reveal that the initial design criteria for pain expression could be realised, that the desired form of agentiality is achieved which can be assumed to have therapeutic implications[8]. This type of system could not be designed on the basis of predefined user requirements, as the definition of the requirements for the ‹agential pain parameters› can only be identified during use and iteratively concretised using prototypes.

SUMMARY AND DISCUSSION

There is no doubt that the current digital pain assessment tools have considerable deficits. Firstly, they record different aspects of pain separately from each other and thus do not allow a holistic representation of pain with its physical, psychological, social and spiritual aspects – and are therefore limit the potentials in regard to digital medicine based on this data. Secondly, they have problematic properties regarding the therapeutic aims of chronic pain therapy: a) the patients are put in a passive role during the assessment and b) the pain is captured in a static, inflexible form, which can have a potentially negative impact on the patient's sense of self-efficacy. In a cooperation between the Bauhaus-Universität Weimar and the University Hospital Jena, a new form of pain assessment was developed in which the agentic properties of the system are considered as part of the design process. Traditional HCI design frameworks, relying only on use requirements are, not able to map these. In this article, we have focussed on describing the overall constraints and methodological approach; a detailed description and reflection of the research design (including the research setup and apparatus) is part of a more comprehensive publication[9].

We worked with flexible frameworks in our project. In contrast to usability engineering, no discrete user requirements are defined, but a flexible framework is used that considers the agentiality of the pain assessment procedure as design criteria. In concrete terms, hypothetical therapeutic implications of the pain assessment process are worked out (How should the pain be presented? How is the interaction organised? What expression options are offered?) These key criteria formed the guidelines for the realisation of the pain assessment tool – and are concretised and refined during the development process itself. This distinguishes the use of flexible frameworks from user requirements usually seen in the development of medical software: These aim to establish a defined usability that is external to the development process (or is initially explored and maintained). In the case of a flexible framework, goals are also defined, but these are geared towards the usage effect and can therefore only be concretised during development and testing (further differences are summarised in the following table in a generic comparison, see Table 2).

8 This refers to the general effect of influencing the pain concept of patients according to the situation – of course no statements can be made about a specific, measurable medical effect of the tool with our setup.

9 These aspects are described in detail in the forthcoming monograph «SCHMERZEN FORMEN – Agentielles Design in der Schmerzerfassung». Springer Viewig.

Table. 2: Comparison between user requirements and working with a flexible framework of design criteria

User requirements	Flexible framework
Context defined	Context open
Concrete	Processual concretisation
Normative	Interpretative
Requirements (define the design)	Guard rails (guide the design)
Function-related (‹usability›)	Experience-based (‹user experience›)
User is Defined	User is Agile
«... The user should be able to do XY»	«... The system should assess pain as XY»
Evaluated by Results	Evaluated in the process
Aimed at: Usability	Aimed at: Use effect

When developing medical applications, the definition and consideration of goals is of particular importance. In our article, we want to show how these can be defined and applied in «empathic and interpretive design research processes» (Koskinen, 2023) in the field of digital pain assessment. This approach faces certain challenges, for example, it must be clarified whether and in what way such a development process can be certified according to the guidelines of medical device regulation and how design research with flexible frameworks relates to this practice. It would be worth considering, for example, separating the development from the final optimisation and only carrying out the latter – after clarifying and modelling a certain agentiality – in the form of user requirements. Another approach would be to extend the user requirements from functional to agential goals and expand the methods of evaluation and validation regarding to them.

In any case it is clear, that the agentiality in relation to pain documentation can't be disregarded. Assessment tools and descriptive categories need to be developed with consideration of which options they open up and which they close off, as these categories potentially alleviate but also exacerbate the patient's experiences. Working with a flexible framework is a first approach to systematically integrate agentiality this into the design research process of a digital assessment tools.

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