INAUGURAL LECTURE
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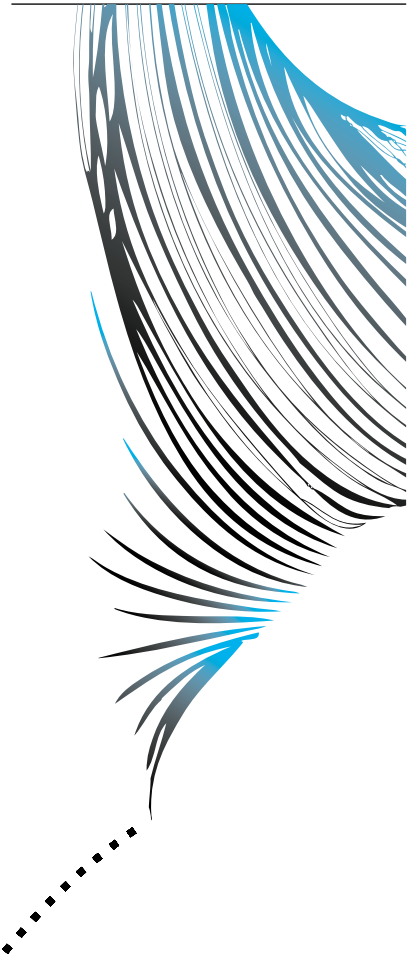

BIOMEDICAL DEVICE DESIGN & PRODUCTION TECHNOLOGY *INTEGRATION OF OBJECTIVITY AND SUBJECTIVITY*

PROF. DR. IR. GABRIËLLE TUIJTHOF

UNIVERSITY OF TWENTE.

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istinguished board of directors of the University of Twente, Dear mister rector magnificus and dean of my faculty Engineering Technologies, dear professors from all over the country, and dear colleagues, friends, family and interested audience both here on-site and on-line.

Welcome to my inaugural lecture!
This marks a significant milestone in my life, and I am truly happy that you are willing to share this moment with me.

ESSENCE

In this lecture, I will share my thoughts, ideas, and strategies for the chair 'Biomedical Device Design & Production Technology'. The essence of my lecture is threefold:

1. As an academic designer I recognize the necessity of integrating objectivity and subjectivity to generate solutions that are meaningful for society and can be used in clinical practice.
2. Based on my active lifestyle and fascination with the musculoskeletal system, my focus lies within the realm of orthopedics. Within this domain, osteoarthritis stands as the leading chronic disease, demanding multidisciplinary collaboration to enhance patients' quality of life. However, a one-size-fits-all approach is insufficient! Therefore, we are working towards personalized solutions.
3. My ambition is to take my responsibility of becoming a 'good ancestor' by considering healthy living in a broad sense, and by sharing my knowledge and expertise in engineering design and education.

Ultimately, technology is merely a tool, and the most effective strategy is prevention.

MY PROFILE: PASSION FOR HUMAN MUSCULOSKELETAL SYSTEM

As indicated, I, Professor Gabrielle Tuijthof, am passionate about the human musculoskeletal system, as it is capable of fascinating complex actions such as opening a bottle of water. The human musculoskeletal system is also vital for quality of life and social engagement, as it facilitates mobility. However, much like other systems, the human musculoskeletal system can break down due to dysfunction, wear, or trauma.

My driving force is to make a meaningful societal contribution by applying my background in biomechanical engineering, and academic design to the field of orthopedics. Throughout my academic career, I have contributed by focusing on minimally invasive diagnosis and intervention. I have aspired to design medical devices that seamlessly align with the user's capabilities, often surgeons. By enhancing their vision and dexterity, they can execute surgeries more effectively and with a higher quality. The outcomes of my research encompass novel mechanical surgical instruments, integrated hard- and software tools and training methods (1-8). My approach is 'clinically driven', which implies to cover the entire trajectory from idea to clinical evaluation (9). This entails not just prototyping and testing but also attending to the business case and the Medical Device Regulation (MDR) (10). The latter, a novel European legislation, aims to enhance patient safety in using medical devices. As the chair of Biomedical Device Design & Production Technology (https://www.utwente.nl/en/et/be/research/BDDP/), my aspiration is to evolve the 'clinically driven' approach by integrating personalized and circular elements into medical device design. Aligning with the trend due to the growing shortage of medical professionals, this design approach will also be extended for medical devices in home use (11, 12).

I highly value the sharing of my knowledge, evident through my active involvement in education and supervision of students. I have also contributed to developing various bachelor and master programs at Delft University of Technology, Zuyd University of Applied Sciences and Maastricht University, and presently at the University of Twente. These accomplishments make me proud, and I aspire to continue them as an academic leader in biomechanical design engineering with my own distinct signature.

Let’s start.

INTEGRATING OBJECTIVITY AND SUBJECTIVITY

The title of my chair is 'Biomedical Device Design & Production Technology', but I added an essential subtitle: 'Integration of Objectivity and Subjectivity'.

While science is typically perceived as an objective pursuit, my narrative will reveal that subjectivity plays an equally significant role. Both are pivotal in achieving results that are relevant to society.

First some definitions. The on-line dictionary of Merriam-Webster defines ‘objective’ (1647) as ‘expressing or dealing with facts as perceived without personal interpretation’ (13). To give you an example related to my engineering domain, consider the well-known Pythagorean theorem from high school mathematics. Another example is Newton's third law, which states that ‘for every action (force), there is an equal and opposite reaction’. In other words, when I push a wall, the wall pushes back with the same but opposite force. Do not worry; I will also touch upon Newton's first and second laws in a moment. Interestingly, ‘subjective’ was defined earlier (15th century) and does concern ‘the personal interpretation’, inherently colored by individual perspectives, culture and background (14). Examples include art and taste preferences for coffee. Stacks of balanced stones could be considered as art or not, and whether you enjoy a particular type of coffee is a matter of personal preference.

Now, transitioning to my chair, we are aided by the Medical Device Regulation (MDR), which objectively defines ‘(bio)medical devices’ (10):
‘Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.’

This elaborate definition precisely describes what constitutes a medical device. There are over 500,000 different medical devices available on the European market alone (15). Some recognizable examples include thermometers, syringes, and stethoscopes.

However, from this objective definition, I must already make a subjective choice, as I certainly cannot be an expert in all these medical devices. As mentioned, during my mechanical engineering studies in Delft, I became fascinated by the musculoskeletal system. This fascination was nurtured by my own active sporting lifestyle, and especially by the late Prof. Jan Cool and Dr. Plettenburg, who, during my first year of studies, taught a course that focused on designing arm prosthetics (16). They ignited my interest in the complexity of the human body, how it functions so naturally, and how challenging it is for an engineer to design something that seamlessly integrates with the body and is operated intuitively.

Unfortunately, similar to all other systems, the musculoskeletal system can breakdown, such as due to a sports injury. The guiding principle of my scientific career is that, from my technical perspective, I aim to contribute to restoring the mobility of the musculoskeletal system after such injuries or traumas. Which I have been doing for over 20 years in close collaboration with Amsterdam University Medical Centre.

ENGINEERING DESIGN

My fascination with the musculoskeletal system goes hand in hand with my passion for designing, which brings us to the next term of my chair: 'design'. I am active in the domain of engineering design, which I can explain - quite objectively - through a series of steps (Fig. 1). The core idea is that you start with a problem and ultimately develop a technical solution for it. To get there, several distinct steps are necessary. First, an analysis is conducted to derive requirements, which we quantify and express as objectively as possible. From there, the creative process begins: the synthesis phase. Once the idea takes shape, we seek to simulate the technical solution's behavior, in other words: can we predict the system's behavior? This helps us to determine whether the technical solution aligns with our set requirements. Next, we refine the technical solution into an actual artifact. Again, tests reveal whether the system's behavior matches our predictions and whether all requirements are met. If they are not met, we must go back to the drawing board. If they are, then we have a technical solution.

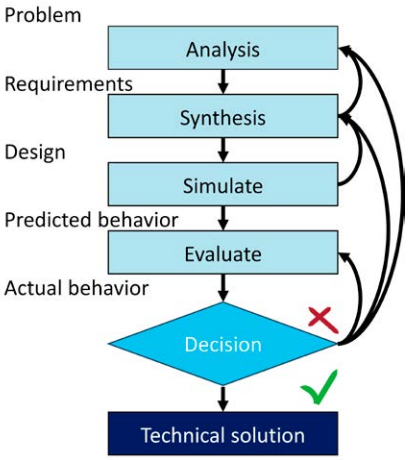

Fig. 1 Generic engineering design scheme. © GJM Tuijthof printed with permission.

Now, you might think: great, we know what to do! Objectively follow those steps. But… given the shear amount of design books - some of which I use in my courses or have been taught from (16-20) - and the over five million

hits when you Google design methods in my mechanical engineering domain, it turns out that it is not quite the case. Once again, my subjective interpretation is needed to make sense of all this information, methods and approaches. I believe that a perfect design method does not exist and that adhering to a single methodology will not necessarily lead to desired technical solutions. The choice of which method is suited depends on the nature of the problem. An experienced designer can navigate throughout the design process more quickly, having already learned to avoid certain pitfalls from experience. Creativity - a highly subjective aspect of design - plays a huge role in this, and since it is elusive, many methods have been developed to try and grasp this aspect.

To end this section, I have applied various engineering design methods in the biomedical domain, resulting in a series of prototypes that all were a collaborative effort with colleagues and students (e.g. Fig. 2) (6-8, 21-24).

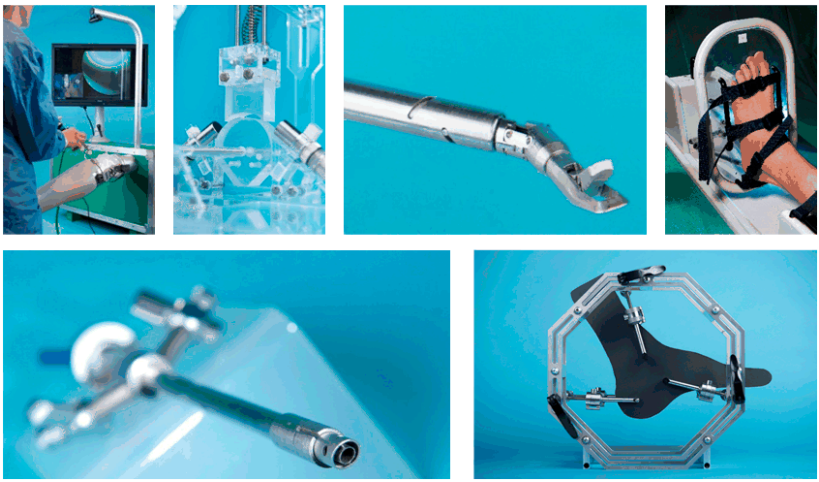

Fig. 2 Various prototypes of medical devices that were design throughout the years.
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SCIENCE

Now, let us shift our focus to science. After all, I work at the University of Twente for a reason. We can apply a fairly similar objective step-by-step process as for the design process, with two major differences (Fig. 3). First, our starting point is an observed phenomenon, something we observe in our surroundings; and second the endpoint is generation new knowledge (25). Starting from a phenomenon, we make observations to deduce a common denominator, which we bundle into a hypothesis: this aids in establishing predictive (cor)relations. The hypothesis is tested for its predictive nature, with the aim of obtaining a clear 'yes' or 'no' answer. To collect precise and replicable evidence, we conduct these tests in a controlled environment, such as a lab, where we can minimize environmental influences and vary only the aspect we are investigating (26-31). This approach contributes to the repeatability of the experiment, so others can verify the hypothesis. The strength of this scientific approach lies in its broad applicability. Even in the medical domain, where the clinical (objective) counterpart to lab tests is a randomized controlled trial (RCT) (e.g. (32)). In this case, the patient population is carefully defined using inclusive and exclusive criteria, and patients are randomly distributed to an intervention. This way, the RCT aims to minimize bias and measures as objectively as possible the hypothesis.

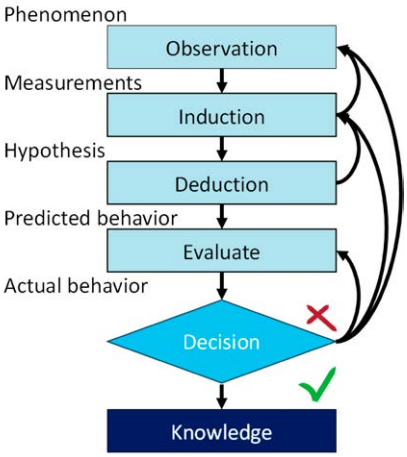

Fig. 3 Generic science scheme. © GJM Tuijthof printed with permission.

Another important aspect of the scientific approach that I want to emphasize is that hypotheses or a set of hypotheses can lead to a theory, which is applicable in a wide range of situations. And there they are. As promised, Newton's first and second laws are examples, respectively they state: 'If an object is at rest or moves with a constant speed, the object will remain at rest' and 'Acceleration of an object times its mass equals the summation of unbalanced forces'. These laws are applicable to almost all mechanical systems in our everyday lives. Again in analogy, in the medical field, we have evidence-based medicine (e.g. (33)), which accumulates all the available evidence and determines what treatment works best for a patient population. Through science, we have achieved significant results, including the theses of the PhD candidates I have had the privilege to guide throughout my career, and I am incredibly proud of them (34-40). However, based on the characteristics I just discussed, I cannot claim that we have developed new theories or revolutionized science. So, how do we measure the impact of all this hard scientific work?

The impact of scientific publication is measured by impact factors, which as they are numbers can be considered as objective. This brings me to a first point of discussion. Analyzing my specialization - mechanical engineering and orthopedics, the musculoskeletal system - we can see that the impact factors of both domains score low. For mechanical engineering, designs that are purely mechanical without sensors or actuators are apparently considered as 'less complex' and therefore less advanced. Moreover, mechanical engineering has been around for a few thousand years. In the field of orthopedics, patients usually do not die; instead, their quality of life's are 'merely' enhanced. Apparently, the scientific community considers this to hold less value than saving lives. It is a difficult ethical discussion that I will not delve into here, but I do believe that as scientists, we should be aware of these underlying subjective patterns when considering impact factors. It is akin to a talent show, where the majority's subjective opinion rises to the surface. The question is what the value of such generic scientific impact factors is, when evaluating individual researchers throughout the early stages of their careers. For sure they do not cover societal impact.

FROM IDEA TO CLINIC

This brings me back to my intrinsic motivation. My goal is not merely to achieve an academic track record, as important as that might be, but to genuinely assist medical professionals or patients in the real world. I provide the example of an innovative steerable cutter to treat meniscus tissue in the knee joint. The cutter is truly innovative, protected by a strong patent that we have claimed (4). Through a cadaver study involving surgeons, we have also demonstrated, in a thorough scientific manner, that the cutter outperforms existing ones (24, 41). The nice journal publications end the scientific journey. However, to really get the steerable cutter in the operating room in the hands of surgeons, a complex process involving many stakeholders and steps is needed. To name a few step: formulating a business case, making the prototype robust and manufacturable, ensuring that this medical device adheres to the MDR to obtain a CE mark. This is only possible within a team of different backgrounds, skills and expertise that trusts each other and has embraced this common goal of using the medial device in clinical practice.

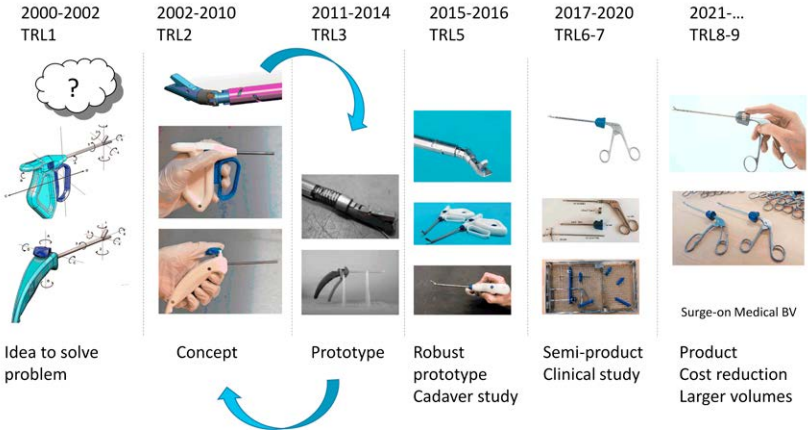

Fig. 4 Example of the steerable cutter from idea to clinic.
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To emphasize that this is not straightforward, the timeline of the steerable cutter spanning about 20 years from idea to clinic is shown (Fig. 4). Even a

startup was launched. Market scans indicate that there are 500-700 Small and Medium Enterprises in medical technology in the Netherlands, and that surgical devices have a market share of roughly 5-10% (42, 43). Unfortunately, the startup did not make it to launch the steerable cutter. So, reality is more challenging than we might wish, and the person-hours invested are immeasurable. A consolation is that the patented mechanism is also suitable for other medical applications. Therefore, the project continues in a domain with a larger market.

At the start of a technology development, the risks are high because of the many unknowns, making it hard to predict whether the new technical solution will exhibit the desired behavior. As the idea and time progress, risks are reduced by accumulating more evidence about the behavior of the technical solution, proving that it does show the desired behavior (Fig. 5). This process evolves in waves, which brings me to my second point of discussion: the Dutch funding landscape. Here are three remarks from my side - subjective of course (Fig. 5):

First, when we reach the first 'valley of death' all the risk but also the potential reward lies solely with the startup. This is straightforward but does not fully acknowledges all stakeholders, encompassing all those who invested time and knowledge to even get to this stage. From various discussions with colleagues in the field, the following proposition emerges. Why not create an ecosystem where the researcher, the clinician, and all other stakeholders - who must play a part in the journey to the clinic - have some form of joint ownership? And collectively share in the eventual revenues and the associated risks, until a certain maturity is reached within the startup to stand on its own. By securing this buy-in, all participants form a solid foundation to survive that first valley of death, which in the medical field can take quite a long period due to the MDR and the required clinical studies. The government can play a distinct facilitating role in this proposition by defining ground rules and truly bringing parties together.

Second, the government is adept at stimulating startups but not as skilled at facilitating the growth into scale-ups - more stable companies that can offer their products in the market over the long run. Currently, an enormous effort must be put to secure even small grants to continue valorization. These teams must repeatedly prove that they are truly knowledgeable, solid and trustworthy, spend more time to secure the funding than to continue

valorization. My plea is to make set up an investment fund that ensures that once teams embark on a path to valorization and shown their capabilities, they can finish it. And yes, not everything succeeds; failure is also part of this game. Ultimately, this benefits the economic viability of the Netherlands as a whole

Third, the current funding landscape compels us to develop complex technology within academia. Consider what I mentioned earlier about making an impact in the scientific field. Developments need to be advanced, pushing humanity forward. A potential underlying - again, partly biased - notion here might be that simpler designs do not require a university but can be handled just fine by the industry. I genuinely believe this is a misconception. Because for many medical needs, to arrive at a simple design that provides the desired synergy between user and medical device, thorough research must first be conducted. Especially when considering technical solutions for home settings, where simplicity is a crucial driver to engage hard-to-reach people. I strongly advocate to consider this into account within the funding landscape.

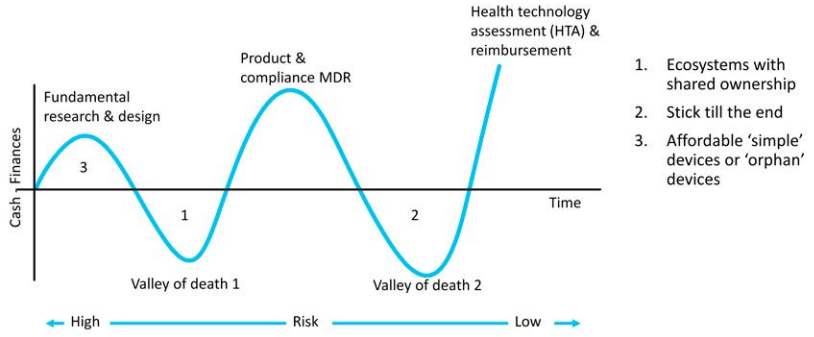

Fig. 5 Valleys of death regarding finances to bring medical devices to the market.
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With this outlined, I return to my chair, where I certainly do not operate alone. I applaud the team, of which I am immensely proud, also because together we have defined the following mission for the chair:

'Generating knowledge and expertise to cover the **entire trajectory** from a

clinical need via innovative designs to clinical evaluation of a **biomedical device** including manufacturing, verification of **Medical Device Regulation** demands and **circularity**.'

This expertise is crucial to contribute with societal impact.

SO, DESIGN VS. SCIENCE? NO, DESIGN & SCIENCE

In summary, I have discussed science on one hand and design on the other hand, which can sometimes appear to be conflicting in nature (Fig. 6). Design inherently involves that subjective, creative aspect that remains elusive to science. My interpretation is that the formation of a hypothesis in science is equally subjective. It is always colored by personal observation, and that is fine if we recognize that. A second point, I want to make is the formulation of design requirements, which have to be set objectively using the scientific method as demanded by the MDR. The verification of these set criteria, during the evaluation of the developed artifact is also executed according to the scientific methods, where we can view the artifact as part of the experimental setup. This how the integration of objectivity and subjectivity emerges, which naturally intertwines design and science. The way forward in my view.

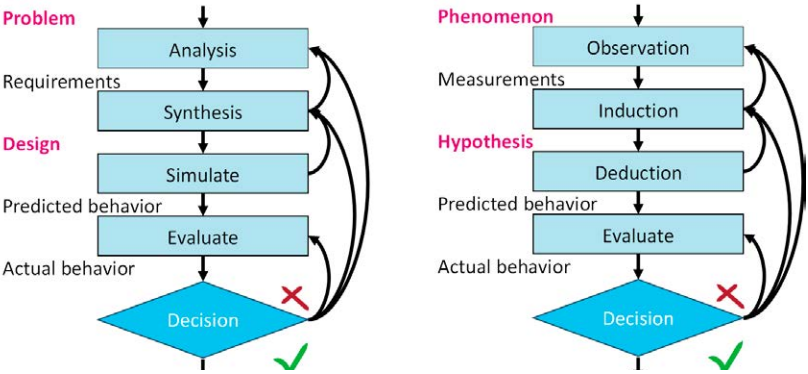

Fig. 6 Engineering design and science scheme with differences highlighted.

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As indicated engineering design has subjective aspects, so how were they shaped for me personally? what is my distinct approach? From the start of my PhD, I have witnessed hundreds of surgeries in the operating room. Because the opportunity arose, because I had an interest, and (only later) I discovered it is a methodology from anthropology - participant observation (e.g. (9, 44-47)). You essentially become part of the whole, and being so close, you develop a holistic perspective. Alongside the observations, I have experienced the culture, social interactions, and dynamics within the

operating room. I incorporate all of this in my designs.

Additionally, it is in my nature to perform an in-depth analysis. Once I am presented with a problem, I cannot let go. I keep (re)viewing the problem from every perspective possible and want to unravel precisely what lies at its core. This way of analyzing turned out to be a theory: the theory of synectics (48). In this approach, you conduct an extensive and detailed analysis of the situation to map out all critical points. The significant advantage is that, by delving so intensely into the problem, you simultaneously conduct a sort of brainstorming session toward a potential solution. This is undoubtedly a specific trait of mine, as both an individual and a professor.

Lastly, an approach I have adopted from my mentors Prof. Cool, Stassen, and Herder: 'You need to ensure that the open-loop system, the foundation, is solid before even considering other solutions like measurement and control.' As an illustration (Fig. 7): an irrigation system is used to rinse a joint - in this case, the knee - during surgery, to clear away bleeding and improve visibility (49). Saline flows from the bag, through the tubes and scope, into the knee, and is suctioned out. We can schematically represent this system with fluid resistances symbolizing the components through which the saline flows. To improve this irrigation system, an option is to implement a control system. However, I first examined how the components functioned, meaning I mapped their behavior both in theory and experimentally (46, 50). This led me to the conclusion that the scope was the bottleneck, as it had by far the highest fluid resistance. Subsequently, I designed a new solution specifically for that component, which already solved 80% of the problems (51, 52). I did not need to think about measurement and control at all, because I took care of the open-loop system.

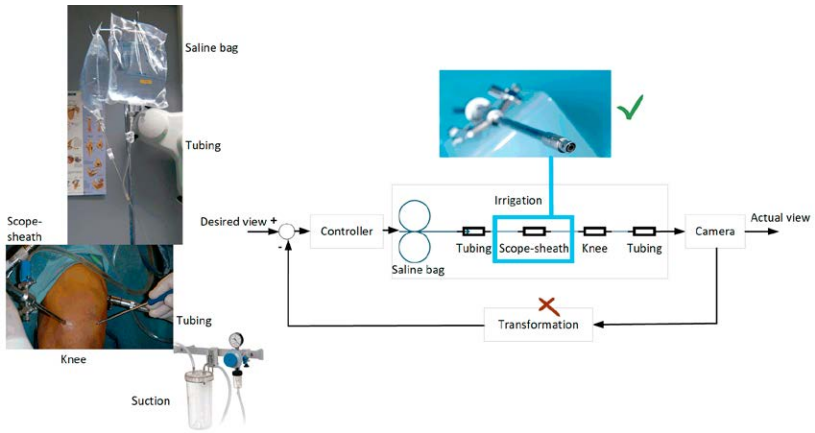

Fig. 7 Scheme of an irrigation system for arthroscopy, highlighting analysis and improvement of the open-loop system instead of adding a control system

Despite all the impressive diagrams and the amount of design methodologies, the revelatory reality is that the design process is chaotic. You are simply going back-and-forth, continuously switching between all the steps (Fig. 1).

And, even though two colleagues were educated the same way I was, they employ a completely different approach to design than I do. I just could not grasp how that was possible. Until I entered the Design Education Network at Delft University of Technology, where design educators defined design independently of a domain or methodology. Design is (53):
1. Working with a guiding theme or qualities
2. Working in domains
3. Using a frame of reference or a library of examples
4. Exploring, analyzing, deciding or experimenting
5. Using a language of sketching and modelling

This way of describing design, still intrigues me tremendously. For me, it made all the puzzle pieces fall into place. Especially the first one - design is working with a personal theme. In this, the subjectivity shines through once again. Because this theme is by nature different for every single person. My personal theme is that I always try to design medical devices that seamlessly align with the user's capabilities, in my case that were primarily the surgeons. I also aim to ensure that we only treat the tissue that needs treatment, perform early and precise diagnoses, and strive to work from out-of-the-box perspectives.

ONE SIZE DOES NOT FIT ALL

Returning science and its highly regarded generalizability also in the medical domain, it does not necessarily align with my approach or what I see is needed. Patients and their symptoms cannot be fully protocolized into the clinician decision making trees and diagrams. Fortunately, facilitated by new upcoming technologies such as 3D printing, within the medical domain the realization start to sink in that 'one size does not fit all'.

Therefore, personalized orthopedic treatment is one of the goals we are pursuing in the chair. This is subjectivity in a pure form. Ongoing projects include personalized preoperative planning of surgeries, design of personalized surgical guides for orthopedic interventions, and personalized splints for fracture management. In collaboration with OCON Orthopedic Clinic in Hengelo, we are investigating patient-specific management of malaligned wrist fractures as well as the personalized treatment of osteotomies of the knee joint (54, 55) (Fig. 8). For instance, if you have bowlegs or knock-knees, it is quite helpful if the anatomic reconstruction is tailormade considering the shape of your own bones. In collaboration with the Medical Spectrum Twente in Enschede, we are exploring how to perform patient-specific fusions for the hard-to-reach sacroiliac joint located in the pelvis (56). In collaboration with Maastricht University Medical Centre (57), we take this a step further towards design. By detailed characterization of the local variation of cartilage surface in the knee joint, we can design novel small cartilage resurfacing knee implants that are better matched to the local bone shape within the knee joint (58). This is accomplished through advanced statistical shape modelling techniques that also indicate the location with highest damage to tailor these new knee implants.

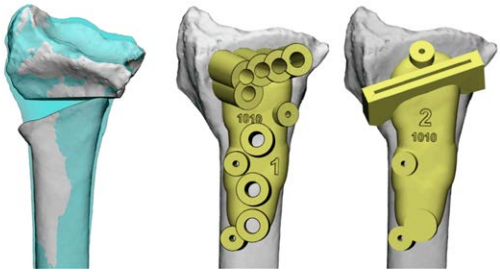

Fig. 8 From left to right: surgical planning of required correction of a wrist fracture, two personalized surgical template to assisted the correction in the operating room. © C Smees, A. Vochteloo 2023, printed with permission.

All these new personalized treatment steps take a lot of time and manual effort. With our own team, we are preparing a roadmap to create an open-source platform, where users can upload CT images and depending on their need can indicate what type of processing they desire. Using these specified criteria, the CT data will automatically be processed via available AI algorithms, taking away the burden of performing all steps manually, as they are often highly repetitive and time-consuming. An example is automatically identifying anatomical bone features or translating a CT image into a CAD file (NURBS). We hope this initiative will gain significant traction to make a contribution to implementing these technologies in clinical practice at a faster pace.

One final example in this series, initiated by my predecessors here in Twente, is the continued development of a smart implant for scoliosis correction in collaboration with the University Medical Centre Utrecht (59). We have now progressed to the point where we have an implant called DSR that allows a teenager some degree of mobility while growing (60). In a new project, we want to make the implant so intelligent that it can adjust itself to continuously provide the optimal correction, so that the scoliosis finally might be completely cured.

In short, there are plenty of challenges ahead in which objective engineering methods are integrated to tailor subjective needs of patients.

HOLISTIC APPROACH TO PATIENTS

Now, I would like to return to the drawing board. Our Western modern science is based on Greek philosopher Plato's concept of a mortal 'body' and eternal 'mind'. He considered reason to be the purest aspect and thus closest to the gods. The body was perceived troublesome - it could succumb to all sorts of earthly temptations and only served as a vessel to house the mind (61). If we make a giant leap to the Renaissance, this distinction between body and mind was adopted into Western scientific tradition, where everything including the living species - humans, animals, and plants – were perceived similarly. In fact, the deductivism theory stems from the idea that we view everything as machines. If, we are capable of completely dissecting the machines in their tiniest elements, they will reveal exactly how they work (61). This approach has brought us tremendous wisdom, such as the discovery of DNA and the initiation of tissue engineering.

However, spoiler alert: living species (us included) cannot be fully grasped as such. By solely breaking everything down to its tiniest elements, we do not encompass the essence of life. This has already been acknowledged for many centuries by other cultures, including Asian and Indigenous. Characteristically, these cultures do not make such a sharp distinction between body and mind (61). More recently, Western scientists start to embrace that additional theories are needed to investigate certain phenomena. Although this is certainly not my expertise, I would like to mention the complexity theory, as its core concept has given me the insight needed to extent my distinct design approach from surgeons in the operating room towards patients in their home setting.

To illustrate the complexity theory, I present two examples naturally adapted from nature. Think of starlings flying in large numbers. These flock of birds can create all sorts of unique patterns. Scientists have shown that these birds follow just three simple rules when flying in groups (62). When you observe the patterns they create, you quickly realize that studying just one individual starling is meaningless; it is the entire system of all starlings together that generate these patterns. The internet - the World Wide Web - has a natural precursor that exists for millions of years: the Wood Wide Web. The interaction between trees and fungi in the woods occurs similarly to how humans have formed the World Wide Web (internet) (63). Again, it

is pointless to study a single tree, when you want to understand the entire network of interactions. And this holistic approach is crucial, when designing for patients in their home setting while living their own lifestyle. We must look at the patient in their entirety or holistically, not just as that small piece of tissue that is damaged or as the user of part task that your product can offer.

To quote Ted Hunt's Twitter post (64): 'Users are… vs. People are…'.

This quote clearly reflects that people are no ideal users, let alone machines. People are complex and unpredictable. They deal with problems, seek opportunities and recognition, produce alternatives, and invest in relationships. Users act logically and predictably. They generate continuous metadata, require products and services, and are satisfied with binary choices. We as engineers need to be more aware of this. That is why I integrate the holistic perspective more and more in my design classes and look forward to joining the scientists that have already recognized this. Especially because healthcare is facing a significant personnel shortage (11, 12). One solution is to care for and/or monitor people in their home environment. A massive challenge. To make this transition, we really have to take into account the individual person in his/her home environment into account. The ultimate form of subjectivity. Particularly for pathologies of the musculoskeletal system, this is by no means a simple task. There are no good sensors yet that can concretely measure what is truly clinically relevant and assist patient in self-management. Symptoms such as pain and fatigue play a significant role when dealing with conditions like osteoarthritis or rheumatoid arthritis. How on earth do you measure that, and how design we the technology in such a way that patients embrace the technology and use it?

Still, we want to tackle this challenge as part of a broader program 'Care is coming home' with many experts from the field, under the leadership of Prof. van der Helm. Personally, I find this a challenge, as I am familiar with the ins and outs of an operating room, but the much more varied home environments are exciting to explore. It really calls for the holistic approach I just outlined.

A BRIDGE TO SUSTAINABILITY

The realization that we should not only treat people in hospitals but also in their homes automatically bridges the gap to promoting a healthier living environment. We are all aware of the harsh realities of climate change and the massive waste production in which the operating room has a significant share (65, 66).

Fortunately, more attention is being paid to this. In Maastricht, I had the opportunity to pilot a project to make an inventory on the surgical waste produced during a single surgery. I am glad that my former colleague Dr. Ir. Tim Horeman was the one who took up this initiative and recycles the polypropylene material from surgical waste into new medical products within the consortium of GreenCycl (67). I contribute to continue this initiative on a European level. In preparation, we are examining how we - as designers - can adapt our design strategies to use recycled materials to develop reusable medical devices (68).

In parallel with this, we are collaborating with the Radboud University Medical Centre to assess the environmental impact of alternative materials, including 3D-printed braces as a replacement for plaster casts. We do this by performing Life Cycle Analyses, which encompass the entire lifecycle of a product - from raw material through production, usage, and end-of-life. We identified that in the case of 3D-printed braces the environmental impact does not come from their use in hospitals, but rather from the production of the material. This illustrates the complexity of the topic of sustainability. We will further explore how we, from a clinical perspective, can generate roadmaps for sustainable implementation, influence manufacturers and generate eventually a true circular additive manufacturing pipeline (69).

Reflecting on sustainability, rather than developing new surgical instruments made of stainless steel, I should concentrate on developing alternative technologies. Such as the two projects I will highlight. The first involves the use of optics - light - to see, feel and sense tissue properties, presumably with less material required as these devices use light. In a public-private project together with the Maastricht University Medical Centre and Amsterdam University Medical Centre we explore this technology of hyperspectral imaging to assist surgeons performing safer operations (26). Another project, in collaboration with the latter institute, which has been ongoing for ten to fifteen years, involves drilling holes in

bone using waterjets to treat cartilage (6, 8, 29, 70). This technology combines personalization with the potential for using less hardware. That is theoretically, water jets could replace all orthopedic drills, saws, and chisels, and which requires much less material as the waterjets do the job using a single device (Fig. 9).

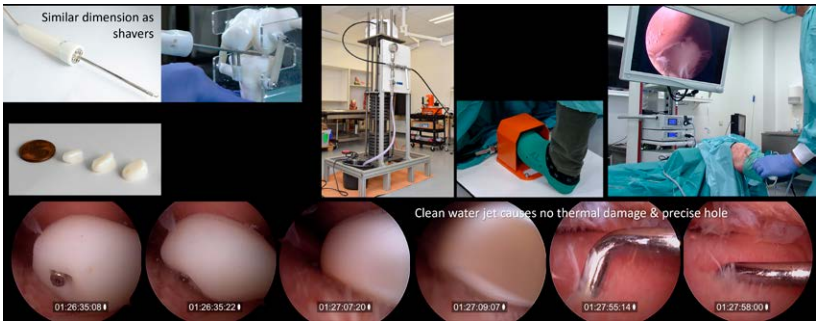

Fig. 9 Results of the WaterjetDrill project, showing the handheld prototype and pump, custom-made discs to hold the tip in the joint, test and its result when performing a simulated surgery in a cadaver knee. © GJM Tuijthof, SD den Dunnen, L Smeets, P Laeven, PE Emans, GMMJ Kerkhoffs 2022, printed with permission.

Unfortunately, the translation from prototype to clinic remains challenging. We have demonstrated the feasibility of minimally invasive waterjet drilling in cadaver tests with surgeons. Yet, some challenges remain to be solved before we can bring this technique into practice. However, I am convinced of the potential of this technology as being disruptive, so we will continue to pursue new funds.

As I have said: one size does not fit all. Now, I add the term ‘towards inclusivity’. In a slightly different sense than currently discussed in the news. Let us go back to the Medical Device Regulation (MDR). Of course, this law exists for a reason. We all want patients to be treated safely and effectively. Unfortunately, the MDR does hamper innovation in medical technology.

I do feel the responsibility to contribute to finding ways to navigate this challenge, bringing the last term in my chair to the forefront, 'Production Technology'. Here are two approaches that we will explore in coming years, which hopefully facilitate medical innovation:
The first approach involves a typical real-world example with patient groups

being very small. A thumb prosthesis has been developed, the T-Grip, that could potentially help a thousand people with spinal cord injuries become more independent (71). This thumb prosthesis needs to be tailored to each individual hand, so it is custom-made, as well as tailored for mode of operation to the individual patient. The logical conclusion is that creating a business case for just a thousand individuals requiring such level of customization is not feasible. In a project with Hankamp Rehab and Roessingh Research and Development, we are exploring alternative options to create a business case. The first is the traditional approach of enlarging the target group so that this solution can also serve other patients. The second is to bring the motor and sensor component of this prosthesis to the market as a standalone product for other applications. This could generate the steady cash flow needed to offer the entire thumb prosthesis at affordable prices. The third is the most exotic. To explore whether we can offer only the components and leave the assembly to medical professionals and/or users to reduce costs. Still the truth is, that it will be challenging to formulate the business case to generate a breakeven point. But does that mean we should not pursue it, because it truly helps a subset of patients? That is a discussion we need to have.

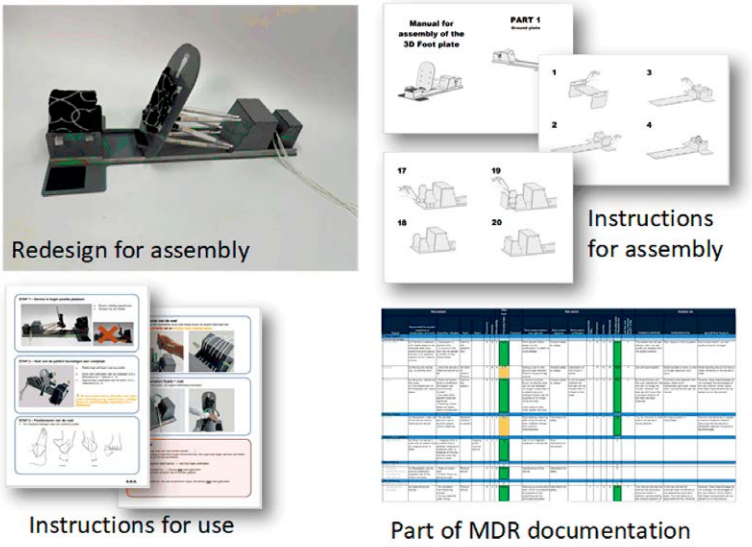

Fig. 10 The 3D stress footplate, an example of a Medical Device Class 1 made ready for open source distribution.
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The second approach, is an even more extreme variant, which concerns a medical device that can be used in combination with a CT scan to study complex hindfoot problems (72). This 3D stress footplate simulates a conventional clinical stress test in the CT scanner. The CT scans made in stressed conditions, allow quantitative assessment of alterations in the ankle's mobility. This 3D stress footplate is typically interesting for specialized university medical centers, as such detailed diagnosis is not needed for the regular patient with an ankle sprain. So, you can imagine that the demand for the 3D stress footplate is even lower than for the T-Grip, making its introduction to clinical practice challenging. As compliance with the MDR is necessary to be used in another hospital, we have redesigned the footplate into an 'IKEA-style' product. This implies that all components are off-the-shelf or require minimal effort to produce them as we provide the engineering drawings that can be outsourced to manufacture them, a compact manual with instructions for assembly as well as instructions for use. Finally, we generated documentation as for as we could, to comply with the Medical Device Regulation. Currently, we are discussing with MDR experts whether we can offer the entire package of design, instructions and MDR documentation open source in line with global initiatives (73). This approach could boost innovation of 'rare' or 'orphan' medical devices and make medical devices affordable. Also, education on the MDR is important for biomedical engineering students as well as medical professionals (e.g. (74)).

TOO LITTLE ROOM FOR TINKERING

As promised, I get back to the five characteristics of design (53):

1. Working with a guiding theme or qualities
2. Working in domains
3. Using a frame of reference or a library of examples
4. Exploring, analyzing, deciding or experimenting
5. Using a language of sketching and modelling

But, not before a cheer to all students I have mentored. Thanks to you folks, I have been able to shape new ideas about education and create many beautiful prototypes.

The second aspect is the ability to work in different domains. For the track Medical Device Design that I coordinate, knowledge is required of the engineering design, MDR, the human body, and health technology assessment. Without this, you cannot qualify for the domain of design of medical devices. This track is structured with a job profile in mind to allow the generation of a coherent study program. This somewhat similar to five other study programs, where I have had the pleasure to collaborate with colleagues who value education highly.

The third aspect is the need for a library of examples. You must build on the shoulders of the giants who exist before you. Examples from my own library are force-driven design (form follows force) and statically balanced mechanisms, with which I would like to honor such a giant who has been my mentor, Prof. Herder (75-77).

The fourth aspect is about exploring, analyzing, deciding or experimenting: in short 'tinkering'. You learn the most by quickly failing and build upon that experience. Unfortunately, our education system is not really set up for that. There is too little room for tinkering. Yet, this is essential for developing refinement and listening to your intuition, and developing the skill of being versatile. That is why we are developing in collaboration with the Free University a new course called 'Medical Device Prototyping,' where students have to work hands-on to perform tissue characterization measurements which they later transfer to a surgical tool prototype (Fig. 11). Only by hands-on experience and tinkering you develop a sense for what could or could not work, as the real world is more challenging than theory.

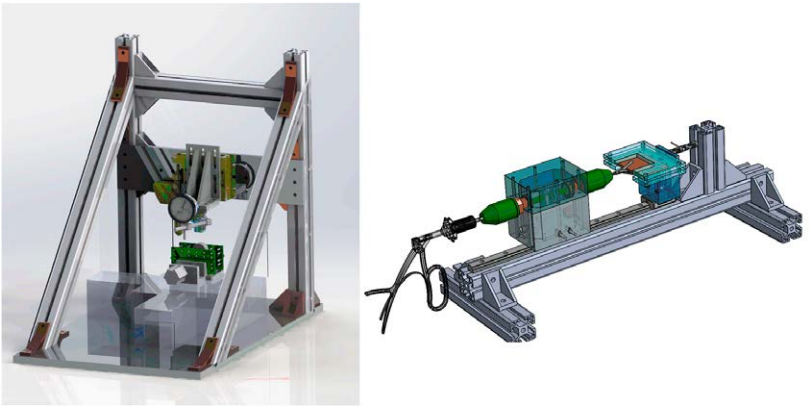

Fig. 11 Two of the setups to perform experiments for human tissue characterization in education.
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The fifth aspect is using a common language of sketching and modelling to convey your ideas as designers. This brings me to my major ambition for education in the years to come: Develop a course where all engineers regarding their discipline learn the five styles of communication styles: sketching, presenting, (scientific writing), mathematical formulas, and programming. It is strange that we always tell engineers that they should be able to communicate with the customer and with engineers amongst each other, but for each and every program we offer different course teaching them about communication.. My ambition is to start within the Faculty of Engineering Technologies, then continue to create a ripple effect throughout the entire UT and preferably all technical universities in The Netherlands, and beyond .

I hope that this latter ambition conveys my sincere desire to have a positive influence on future generations, to becoming a good ancestor (78).

ALL GOOD THINGS COME TO AN END

It is time to conclude. In this lecture, I have outlined my thoughts and approach regarding my chair 'Biomedical Device Design & Production Technology'.

I hope that my narrative has taken you along on this journey and emphasized the importance of two aspects:

1. Bringing an idea to the clinic is challenging and complex and requires the integration of objectivity and subjectivity, but it is worth the ride; and
2. A healthy living environment is crucial for future prospects. This is a tremendous challenge, especially considering the growing global population.

Objectivity and subjectivity are intertwined in everything. We must embrace that. Particularly in this era where personal approaches and individualism are increasing. A holistic approach is vital, as well as collaboration, simply because issues are so complex that you cannot solve them alone.

ACKNOWLEDGEMENTS

This is the moment for a word of gratitude. As indicated, quite of few of you already were acknowledged by the pictures in the lecture, but there is always a risk that I forgot to mention you. If I did, please keep in mind that people tend to forget those closest to them.

First and foremost, I sincerely thank all of you for coming to Enschede and showing interest in my lecture. I express my gratitude to the University of Twente's Board of Directors for their trust in me.

Professors Stassen and Valstar, dear Henk and Edward
How wonderful it would have been if you could have been here with us. Henk, I try to be an inspiration for the students as you were, and I hope you still watch my enthusiasm that you appreciated so much. And, Edward, I am continuing the direction we set, focusing on the well-being of our colleagues. Since there is more in life than science.

Professor Herder, Dear Just
De Professor of Excellence granted to you this year, shows your merit. You laid the foundation for what I am today as a designing researcher, guided me through crucial steps in my career, and above all, you are an incredibly loving person. Thanks!

Dear colleagues from the orthopedic field, more specifically professor Kerkhoffs, Kruyt, van den Bekerom, Doornberg, and doctors Emans, Stirler, Vochteloo and Hoogeslag.
They say collaboration between engineers and surgeons is not straightforward. Between us, it is. We have mutual respect and you guys are fantastic lads.

Dear Tim Horeman,
It is so gratifying to brainstorm and devise great plans with you as a friend. Time might be limited to execute them all, but we will keep moving forward. Thank you!

Dear colleagues of the department of Biomechanical Engineering of University of Twente,
Thank you for the warm welcome and embedding. I will try to my best to establish amazing things that serve the department as well.

Dear colleagues from the departments I was appointed at TU Delft, Academic Medical Centre Amsterdam, Zuyd University of Applied Sciences and Maastricht University, I still work with many of you and intend to continue these inspirational collaborations.

Dear students,
Education is an active process. Each time, I learn as much as you do. It is a privilege to supervise you.

Without the support of my friends, I would not have been in this position. Lianne, Marte, Luise, Therese, Constance, Anne Stijn and Jos. Thank you!

Dear Dad,
I know you watch over me and are present at important moments such as now.

Dear Mom,
Such a strong woman and source of inspiration. You definitely are a good ancestor.

Dear Sis Michelle,
What a rollercoaster year. A shock when we heard your diagnosis. Thanks to our Dutch healthcare and your superior drive, you can attend this event. I am really proud of you.

Dear Eric, Saartje Bo, Jesse James,
Continue on your paths and remain the pillars of support for your wife and mother.

Dear Annie,
Thank you for doing all laundry and providing meals when we are too busy.

Dear Miranda,
My special buddy and partner. Let us continue the rest of our lives to inspire and to support each other to get the most out of our lives, and enjoy our walks, talks and nice dinners.

Let's celebrate life by healthy living and a toast. Ik heb gezegd.

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CURRICULUM VITAE

Prof. Dr. Ir. Gabriëlle Tuijthof was born in Teheran (Iran) in 1975. In 1998, she graduated cum laude in Mechanical Engineering at Delft University of Technology on a soft robotic arm design. She performed her PhD as a joint collaboration between Delft University of Technology (TUD) and Amsterdam University Medical Centre (AUMC) titled 'Technical improvement of arthroscopic techniques'. She remained affiliated at AUMC from 1998 till 2018 primarily performing research in ankle biomechanics and arthroscopy. For the latter she received a VENI grant to Optimize the arthroscopic view (2004).

Between 2006-2012, she combined her position at AUMC with an assistant professorship at TUD as tenure tracker. Still her focus was on the development of novel surgical instruments as well as training simulators. After successful acquisition of public funding such as TTW OTP Healing Water, TTW OTP Vibrant Vision, ZonMW Steerable Punch and a personal ASPASIA grant, she was appointed associate professor and formed her own group 'Joint Engineering'.

After a successful accreditation process in 2013, she was appointed director of education of the new BSc program Clinical Technology, a joint degree initiative of the Medical Delta offered by the universities of Leiden, Rotterdam and Delft. Gabrielle has been editor of the ESSKA education book 'Effective Training Arthroscopic Skills' published in 2015, has 90 peer reviewed journal publications, contribute to 5 books and is co-inventor on 5 patents.

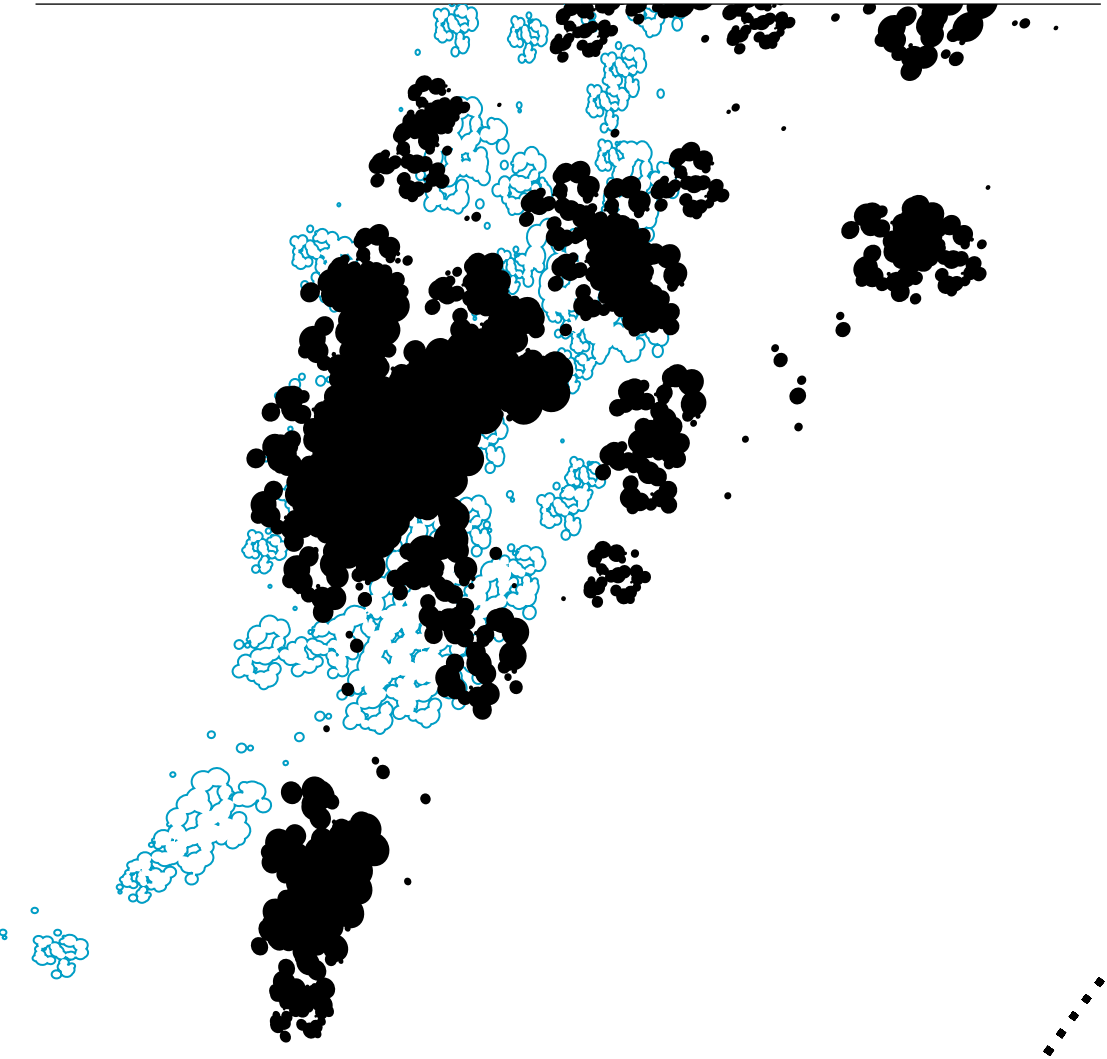
In 2016, she left the TUD to become university professor (lector) in Smart Devices at Zuyd University of Applied Sciences with a special focus on mobility in the home setting and self-management of patients via wearables, apps and biosensors. She raised a RAAK SIA Pro grant on Point-of-care scanning of surfaces for bacterial loads and a RAAK SIA Public grant on Anterior cruciate ligament rehabilitation, and co-developed the new BSc program Healthcare Engineering.

After a short break, she continued her career at Maastricht University at Research Engineering, where she was co-applicant in public-private grants

such as TKI LSH, TTW Demonstrator and TTW Take-off grants and established a network of innovative SME companies and extended her clinical network. Furthermore, she gained hands on experience in the Medical Device Regulation, and co-developed three new engineering programs: Business Engineering, Circular Engineering and Molecular Imaging and Engineering.

In 2022, she became Full Professor Biomedical Device Design & Production Technology at University of Twente. Her chair consists of 5 staff members with affinity to Orthopedics and Rehabilitation. She is supervising 5 PhDs in collaboration with hospitals in the Twente area OCON Orthopedic Clinic and Medical Spectrum Twente in the area of personalized orthopedic surgery. She is an active member at the TechMed Centre, CareTech and Interdisciplinary Consortium for clinical Movement Sciences & technology, track coordinator Medical Device Design of the MSc Biomedical Engineering, teaching courses in engineering design, and member of Mechanical Engineering BSc curriculum renewal.

Gabrielle does not stop once a nice publication has been achieved, but is committed to bring the new developments to the clinic, or to patients' at home.



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