DESIGN4 HEALTH

Extract of the

Proceedings of the 3rd European Conference on Design4Health

Sheffield 13-16th July 2015

Editor: Kirsty Christer

ISBN: 978-1-84387-385-3

Sheffield Hallam University | Art and Design Research Centre

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Yorkshire & Humber Academic Health Science Network

Cutting Edge: understanding advanced surgical processes for total knee replacement through design research

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Abstract

Osteoarthritis (OA) is the leading cause of musculoskeletal disability worldwide. A total knee replacement (TKR) is a proven surgical intervention that can help reduce pain and restore function on osteoarthritic knees. However, the traditional TKR approach – Mechanical Alignment – has a low satisfaction rate amongst patients, aiming to achieve a straight leg after surgery even when most patients do not have straight legs naturally. Conversely, TKR procedures based on replicating the natural anatomy of the individual's knee are emerging. This study focussed on recording and understanding these new approaches aiming to uncover design implications for TKR. Research followed a double-diamond process, starting with literature review of knee anatomy and TKR procedures. Methods were developed to map out and record surgical processes and techniques during in-depth interviews with surgeons [n=19]. Observations in theatre [n=7] to compare the described surgical procedure with the one used in practice were performed. Outputs resulted in a series of technique maps and a surgical technique matrix combining alignment approaches for the tibia and femur. The combinations obtained through the matrix were presented back to users for feedback. The most viable combinations are now being used to inform future product development in the TKR field.

Keywords: user-centred design, design research, design approaches, total knee replacement, total knee arthroplasty, orthopaedics

ISBN 978-1-84387-385-3

Introduction

Total knee replacement (TKR) surgery, otherwise known as total knee arthroplasty (TKR), involves the removal and replacement of the articulating surfaces of the human knee joint. The aim of this surgical intervention is to reduce pain and improve function, however, current patient satisfaction rates are poor, with 1 in 5 patients reporting being unhappy with the result of their surgery (Baker *et al,* 2007).

This study focussed on understanding and mapping an emerging TKR approach based on replicating the natural anatomy of the individual's knee. The hypothesis behind this new philosophy implies that better patient outcomes may be achieved by preserving the supporting soft tissue structures surrounding the knee joint as much as possible (Dossett *et al,* 2012). As a result, the geometry of the "new" knee would be closer to what the patient had before the operation. It is in stark contrast to the Mechanical Alignment philosophy, which prioritises the survival of the prosthetic implant above all else, with the soft tissue structures being routinely compromised to conform to the replacement knee, and thus changing the patient's natural leg geometry.

Total Knee Arthroplasty

Osteoarthritis (OA), the leading cause of musculoskeletal disability worldwide, is a degenerative disease that causes joints to degrade (Rosenthal, 2012). Cartilage can wear away and bony growths called osteophytes can develop. This degeneration can cause unbearable pain, impede function and can significantly reduce quality of life. A TKR is a proven intervention that can help reduce pain and restore function (Scuderi, 2002).

In TKR, the damaged surfaces of the joint are replaced by new, metal and polymeric prosthetic components. These prosthetic components come in many different forms, from 'fixed bearing' to 'rotating platform' describing the relationship between the tibial implant and the polyethylene bearing; which can be composed differently, from 'all polyethylene' tibial components, to metal backed tibial components with a polyethylene insert; from implants that are designed to work with the posterior cruciate ligaments to those that are designed to replace it and with different methods of securing them in place, including 'cemented' or 'un-cemented'. Despite the large amount of variation within TKR, the current premise behind the intervention remains the same – to remove the damaged surfaces of the joint and replace them with artificial smooth surfaces (Williams, Garbuz and Masri, 2010).

The replacement of the surfaces is done by cutting the proximal end of the tibia and the distal end of the femur, in such a way that the bones are shaped to fit the attachment surfaces of the prosthetic components. The angles and planes at which the bone cuts are made is crucial (Sikorski, 2008) as they provide two important definitions:

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- The position of the prosthetic components relative to the joint surfaces
- The resulting post-operative geometry of the leg and replacement joint line position

Mechanical Alignment

Traditionally, a Mechanical Alignment philosophy has been widely adopted. It aims to achieve a specific post-operative geometry, defined by a straight line from the femoral head, through the centre of the knee, to the centre of the ankle [Figure 1]. Even when 98% of limbs are not straight (Eckhoff, 2005), this alignment method takes little account of the patient's natural pre-operative anatomy and can result in one leg being longer than the other, a change in the position of the joint line, instability, proprioception issues, diminished confidence and pain.

Figure 1: Post-operative Mechanical Alignment (left) versus patient's natural anatomy (right)

To achieve this type of alignment, significant leg geometry adjustments may need to be performed. The surgeon may require altering the ligaments around the joint by releasing (lengthening) them. This finely tuned envelope of soft tissues holds the joint together and allows motion by varying the amount of tension dynamically through the range of flexion. Compromising

ISBN 978-1-84387-385-3

the soft tissues in this way is believed to be one of the leading causes of high dissatisfaction rates with TKR (Dossett *et al,* 2012).

Philosophy, Algorithm, Technique

In order to aid discussion amongst the team, a hierarchical classification of the different levels of surgical thought was defined [Figure 2]. It is important to note that these are not universal definitions but were used in the context of this project to allow a consistent terminology throughout the research program.

At the top of the surgical hierarchy, there is the governing thought or surgical philosophy, defined as the over-arching school of thought that determines a surgeon's goal for TKR. For example, a surgeon might say, "I will restore mechanical axis alignment in extension, but let the soft tissues guide my femoral rotation". One level down is the surgical algorithm, defined as the protocol or method adopted to achieve the surgical philosophy – e.g. 'gap balancing' versus 'measured resection'. And finally the surgical technique, defined as the detailed steps of surgery including the order in which the steps of the algorithm are completed and the instrumentation settings.

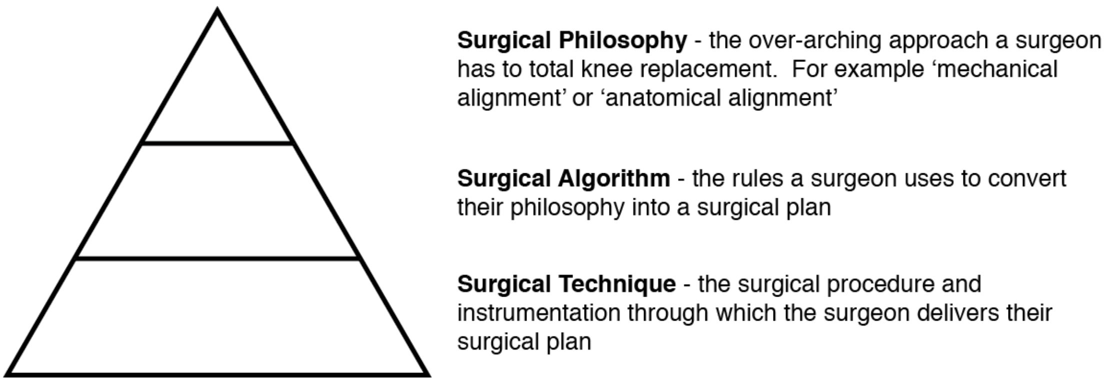

Figure 2: Surgical approach hierarchy

Methods

A double-diamond design process was followed (Design Council, 2015) to structure the programme over 18 months. The project was conducted as an evaluation of surgical practice in TKR involving interviews and workshops with clinicians and as such did not require approval by the National Research Ethics Service.

Initial research

The initial phase of the project comprised of a familiarisation period for the design team. Research included review of literature surrounding lower limb and knee anatomy, creation of kinematic

ISBN 978-1-84387-385-3

models to explain knee motion and the functions of various ligaments, understanding of the TKR procedure, alternative knee operations, a review of implant types, types of surgical imaging, complications of surgery, and an understanding of surgical theatre staff roles and the surgical process.

A review of the arguments against and in favour of Mechanical Alignment versus new alignment philosophies resulted in the following table:

Table 1. The debate in Alignment Philosophies

Argument against Mechanical Alignment	Argument against new philosophies (kinematic)
20% of patients are unsatisfied with the result of their TKA	Not fully proven to be better for patients as clinical trials are lacking
98% of limbs are not mechanically aligned	Kinematic alignment not yet accepted by FDA
Resulting in unnatural kinematics of the knee	Worries about component survivorship - mechanical belief is that departing from 3° will cause asymmetric loading leading to premature failure
Patella maltracking	Logistics and costs of scans and manufacturing guides
Transepicondylar and AP axes have no relation to the actual kinematics of the native knee joint	Don't know true geometry and mechanics until osteophytes are removed
Bony landmarks inherently unreliable	Inconsistencies - some ligament releases apparently acceptable (depending on surgeon)
Identifying bony landmarks intra-operatively consistently is unreliable	Main opposition due to varus and valgus extremes
Requires ligament releases as standard	Not repeatable for all types of knees and deformities - only suitable for 'normal' knees - but not possible to set upper and lower limits without data
Requires compensatory change in axial rotation of femoral component	Varus / valgus - issues with restoring constitutionally varus and valgus knees to their un-diseassed varus/valgus states. Huge loads on one side, and stretching of ligaments on the other
In some cases 'impossible' to balance the knee correctly in varying degrees of flexion	Not suitable to return flexion contracture back into same environment it was in before
Changes obliquity of joint line	Doesn't allow for large amount of wear / wear of bone - it's guesswork
Raises joint line	Unpredictable cuts - especially tibial when referenced from the femoral cuts. Worries about tibial plateau failure

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Insight gathering tools

Methods for insight gathering included interviewing surgeons followed up by live surgery observations. This drove the research team to test and iterate tools to facilitate the conversations with surgeons aiming to explore their surgical philosophies, algorithms and techniques in depth. The research tools included:

- **Questionnaire** – The first iteration of the questionnaire asked a very broad range of questions, ranging from the surgeon's training history, to how often they see patients pre and post op, what imaging they use in what instance, and other information aiming to gain a more complete understanding of the system surrounding TKR surgery. The nature of this "shotgun" approach reflects the exploratory nature of the project at that point. The information gathered helped the team iterate the questionnaire to a much more focussed version that centred on surgical procedures and techniques.

- **Procedure cards** – This method invited surgeons to draw each step of their surgical technique. The approach encouraged the surgeon to think about their technique in finer detail without missing steps. It acted as a visual narrative in time and as a record of the steps the surgeon takes – effectively, a surgical recipe. The method proved to be much more effective for getting the level of detail the team required as opposed to simply asking a surgeon to describe their technique, which might have elicited one-sentence answers. Using the procedure cards allowed for more information to be coaxed from the surgeon – in fact, it invited disclosure of finer details, from tourniquet use, to bony landmarks utilised, to what cocktail of drugs were preferred.

- **Case studies** – When it comes to TKR, there are many variations from patient to patient, including age, physiology, disease progression, condition of soft tissues, aspirations, etc. All these may have an impact on the surgeon's (or hospital's) choice of implant, instruments, and approach. The quantity of variables to be considered prompted the team to create a series of patient case studies with the aim of understanding and comparing how different surgeons would approach a specific case. The first set of case studies was based on the team's limited knowledge of leg deformities and clinical conditions, but was quickly iterated to create more extreme and detailed cases that would prompt surgeons to reconsider their approach.

- **Technique table** – The technique table was borne out of previous interviews and research methods. Having better understood the level of detail required for the project aims, the table was the culmination of the iterations of the previous methods – simplifying the surgeon's technique into discrete steps and values in a table. This allowed the technique to be captured quickly, without leaving out any crucial information or steps. The technique table does not provide the narrative element that the procedure cards do; however it is a

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more analytical tool that made referring back to the surgeon's technique easier at a future date.

Applying the research tools

Three separate workshops resulted in a total of 19 surgeons interviewed using the research tools. The team was able to follow up some of the interviews by observing seven surgeons in theatre.

This methodology showed that surgeons often did things differently to the way they would describe them during the interview, highlighting a mismatch between theory and practice. Furthermore, surgeons often employed a combination of surgical techniques showing that some are willing to combine or amalgamate techniques as long as they help them fulfil their specific surgical goal.

After completing the interviews and observations, a surgeon categorisation emerged based on their openness to change and attitudes towards new philosophies, algorithms and techniques.

Table 2. Surgeon categories according to perceived attitude towards change

	Description	**Quantity** (from interviews)
Mavericks	These surgeons are the developers of new ideas and new instruments, they are at the forefront of the discussion leading the pack and breaking new territory. Some of these surgeons are often questioned for their approach	n=2
Early Adopters	These surgeons are not necessarily developing new ways of thinking but if the method and tools are available to them, they will be eager to try, with little or no clinical trial evidence required to convince them	n=4
Curious / Cautious	This group recognises that there is a way to increase patient satisfaction by changing their surgical approach, however they won't change unless they are presented with evidence of safety and favourable outcomes	n=12
Apathetic	Surgeons on this group believe their current approach is best practice and have no interest in changing or exploring different methods	n=1

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In this respect, the groups most likely to benefit from or engage with product development regarding new alignment approaches are:

- The Early Adopters, who may be happy to take part in early-stage trials.
- The Curious / Cautious, if they can be convinced of the benefits once sufficient evidence has been gathered.

Surgical Technique Matrix

From the interviews, observations and mapping exercises, a technique classification matrix was developed [Figure 3]. This helped the team visualise and communicate a landscape of theoretically possible surgical approaches. The matrix shows different combinations of approaches to the proximal tibial and distal femoral cuts, which include:

- Independent cuts made at 90 degrees to the mechanical axis
- Replicating the natural anatomy within arbitrary boundaries
- Truthfully reproducing the natural geometry
- Balancing tibial / femoral cuts off of the other, and
- Combinations of the above

In relation to the surgical philosophies discussed previously – combinations on the top-left corner of the technique matrix are closer to the Mechanical Alignment philosophy, whilst the bottom-right corner tends towards new philosophies attempting to completely reproduce the natural anatomy.

In theory, each of the combinations forming an entry in the matrix could become the starting point of a new surgical algorithm.

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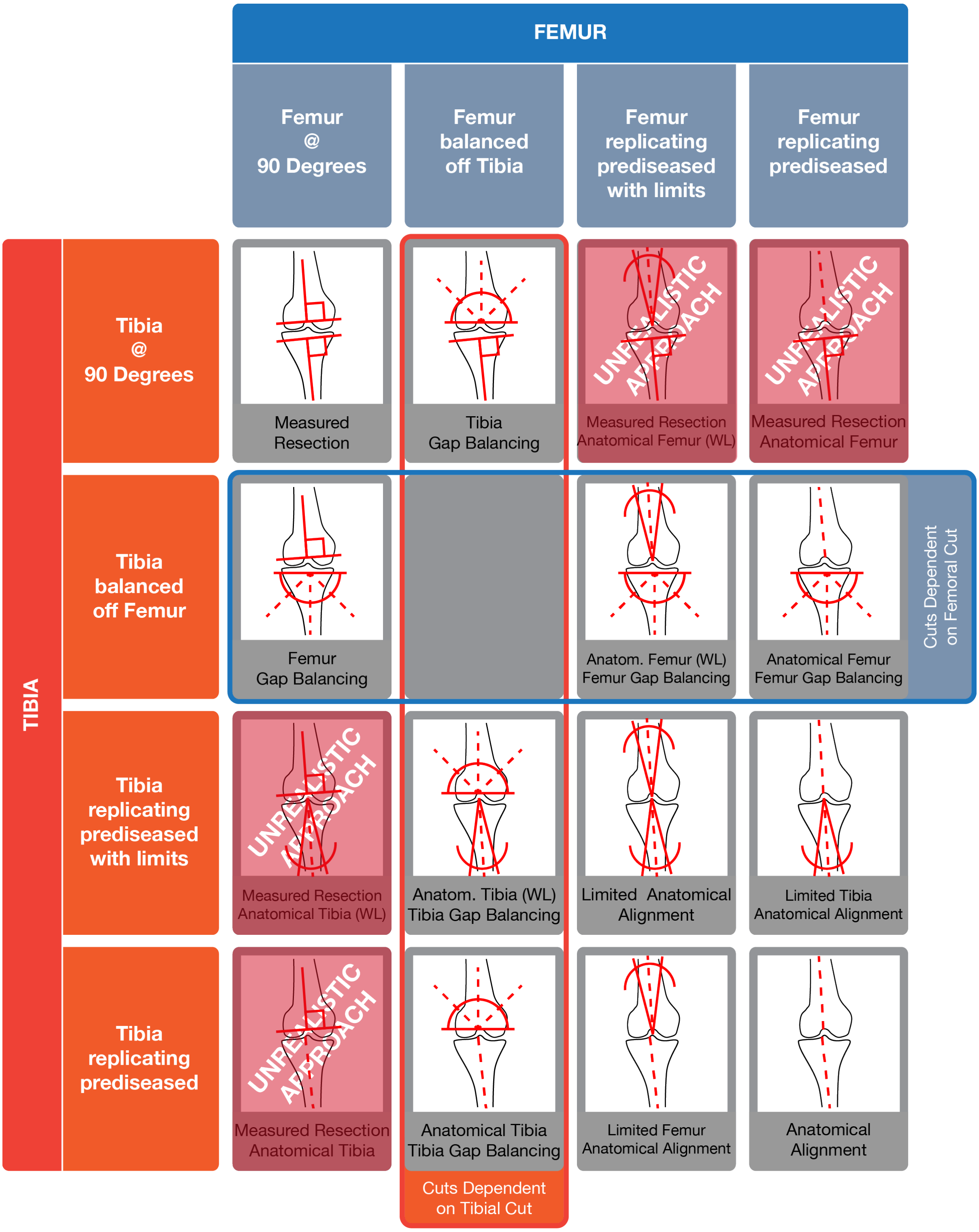

Figure 3. Surgical Technique Matrix

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Implications

The team used the technique matrix to obtain feedback from surgeons and biomedical engineers. It helped identify the combinations that have the potential to be developed into defined, step-by-step surgical algorithms. The work currently under development will take into account some of the concerns expressed by surgeons towards new alignment philosophies, for example reproducibility and reliability to accurately match the patient's natural anatomy whilst giving them the possibility to apply their surgical judgement on what they consider to be the safety limits for varus / valgus deformities. In other words, future work will focus on working closely with surgeons to develop a surgical method that can reliably and reproducibly create a bespoke surgical plan that matches the patient as well as the surgeon, creating a more personalised solution without compromising the safety of the patient.

Other design implications tied to the development of new surgical algorithms may include the design and development of new guidelines and instrument sets to support the appropriate delivery of the surgery. Additionally, new implant designs may also be within the scope of these new approaches.

ISBN 978-1-84387-385-3

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ISBN 978-1-84387-385-3