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FOXPAT

APPENDIX

Foxpat

Training simulator for
Cementless Oxford Partial Knee Replacement Surgery

4745736
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Thesis appendix

MSc in Industrial Design Engineering with specialization in
Integrated Product Design(IPD)

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APPENDIX

A - MICROPLASTY INSTRUMENTATION

Patient selection
The first and foremost important part of the procedure is patient selection, that is, making sure that the patient is eligible to undergo oxford cementless partial knee replacement. There are well defined circumstances in which the Oxford medial arthroplasty is appropriate and certain criteria must be fulfilled for success. In principle, the soft tissue components of the joint and the articular surfaces of the lateral compartment must all be intact. The operation is most suitable for the treatment of anteromedial osteoarthritis.
Few of them include,

- Having anteromedial osteoarthritis
- Full thickness cartilage loss on both sides of the medial compartment with bone on bone contact
- Both cruciate ligaments must be functionally intact
- Intra-articular varus deformity must be passively correctable

1. Preoperative X-ray Template
A true lateral radiograph is used to accurately choose the right size of femoral template preoperatively. By placing the central peg in 10 degree with the femoral shaft, right size of template is picked. Medial template suits for most of the patients.

2. Positioning the Limb
The leg is placed on a thigh support, with the hip flexed to about 30 degrees and the leg dependent. The knee must be free to flex fully and the leg should hang with the knee flexed about 110 degrees.

3. Incision
With the knee flexed to 90 degrees, a medial parapatellar skin incision from the medial margin of the patella to a point 3 cm distal to the joint line is made. Usually the length of incision varies from 7 to 9cm based on the experience of the surgeon.

4. Osteophyte Excision
All osteophytes are removed from the medial margin of the medial femoral condyle and from both margins of the intercondylar notch. A narrow chisel (6 mm), is used to remove the osteophytes from beneath the medial collateral ligament and from the posterolateral margin of the medial condyle.

5. Tibial Plateau Resection
A femoral sizing spoon is inserted medially on the condyle to confirm the femoral size. A tibial saw guide shaft is used to position the saw guide and attach a G-clamp. G-clamp serves as a guide for horizontal tibial resection. A vertical tibial cut is made after the horizontal cut and
the cut tibial biscuit is pulled out.

6. The Femoral Drill Holes and Alignment
Having the knee in about 45 degrees flexion, a hole is drilled in the intramedullary canal of the femur with a 4 mm drill. Intramedullary (IM) rod is pushed until it stops against the bone. A femoral drill guide to the same setting as the G-Clam is attached to facilitate the drilling of holes
in the femur. These holes are made of the insertion of femoral component pegs into femur

7. Femoral Saw Cut
A posterior resection guide is inserted into the drilled holes to help remove the posterior condyle of femur using a saw.

8. First Milling of the Condyle
A spigot 0 is inserted into the drilled holes to help mill the femur using a spherical cutter. Spigot is removed and any protruding bone structures due to milling are cleared off.

9. Equalizing the Flexion and Extension Gaps
Now that tibial an femoral cuts are made, trial implants are inserted and a feeler gauge is inserted between both the trial components to check the tension. It is important to make sure that the tension is same in both flexion and extension position of the leg. If the gaps are not similar in both postures, next size of spigot is inserted to extend the femoral cut 1mm at a time accordingly.

10. Confirming Equality of the Flexion and Extension Gaps
Having the tibial and femoral templates placed position, flexion and extension gaps are reconfirmed using a feeler gauge again. This size is confirmed to the team to prepare for the right size of implant to be implanted.

11. Preventing Impingement
An anti-impingement guide is used to trim anterior and posterior condyle of the femur to reduce the risk of impingement of bone against the bearing in full extension and full flexion. At this point, a chisel is used again to remove any posterior osteophytes.

12. Trial implantation
A tibial trial and twin peg femoral trail component are inserted into the resection and trial bearing of right size is inserted between the trial components. This is a trial test to make sure no impingement of bone against the bearing.

13. Final Preparation of the Tibial Plateau
If the trial bearing is too tight, a tibial recut of another 1mm is made and ensured to have clear and flat surface. Having a right size tibial template in place, a keel cut saw blade is used for keel cut slot. Keel slot is cleared off bone residue and washed thoroughly. A trial implant is inserted into the tibial cut and pressed with fingers to reconfirm the resection.

14. Implanting the Components
The tibial implant is assembled into the introducer/ impactor by locating it into the recesses on the underside and tightening the thumb wheel. The knee is flexed fully and, using the Toffee Mallet, the component is then carefully impacted, with the keel passing obliquely at an angle
into the keel slot. Before it is fully seated, the introducer/impactor is removed by unscrewing the thumb wheel.

15. Final impact
Final impaction of the tibial component is achieved with the Toffee Mallet and the standard impactor placed centrally over the keel. If the component does not fully seat it is better to accept this rather than impact it with a heavy mallet, it will subside into place in time. The femoral component is inserted and an impactor is used to completely push in the tibial component in the bone . Both components are examined to ensure they are fully seated. A trial bearing is inserted
again to reassure the flexion and extension tension. Once thickness is confirmed, complete the reconstruction by swapping the chosen bearing into place.

16. Closure
The wound is closed in a routine manner.

B - FIELD TRIP TRANSCRIPTS

OBSERVATION OF LIVE SURGERIES AT HAGA ZIEKENHUIS

Surgery 1 – cementless Oxford partial knee replacement
Osteoarthritis - Left knee medial compartment
Patient: Male, 72 years old

The patient already has a total knee replacement before for the right knee. Now the left knee has medial cartilage loss. Based on the x-ray the surgeon was able to make a decision for partial knee as the later side has a good thickness of the cartilage. The same way during the surgery it was identified that both ACL and PCL are quite good, which is a good indication for patient selection for the Oxford PKR. Right after the incision, the surgeon removed the osteophytes on tibia and femur first. The surgeon chose to do tibial cut first and then femur. Once both the cuts were made, the surgeon inserts the templates to make sure the flexion and extension gaps are same by using a in feeler gauge. There was one millimeter difference between flexion and extension gap. The surgeon got the next size of spigot to remove one millimeter on the femur and check the gaps again. Both flexion and extension gaps are 3mm and before placing the twin peg template, impingements were prevented by removing the posterior and anterior condyle in full flexion. Now the tibial template and twin peg femoral trial component and 3mm trial bearing were inserted to check ligament tension. The surgeons confirms the sizes to the team and proceeds to prepare for the tibial plateau. Having the right size tibial template the slot for keel was cut and tibial trial component with keel is placed to check the position. Then the tibial implant was placed with an introducer by impacting in two directions. The tibial impactor was used finally to impact the tibial component into the bone. The femoral component was placed on the femur and impacted with the femoral impactor and hammer. Finally the bearing is inserted and checked the ligament tension in full flexion and extension. All in all the procedure was straightforward without any complications. The incision was stitched and the wound was closed in a regular way. The surgeon mentioned that he is going to flex the knee of the patient in a couple of hours to see the result, which was one of the advantages of PKR.

Surgery 2 – cementless Oxford partial knee replacement
Osteoarthritis - Right knee medial compartment
Patient: Male, 61 years old

The patient didn't have any previous knee replacements.. The medial side of the right knee had significant cartilage loss, which made the patient eligible for oxford PKR. As the incision was made and tissue is cleared the medial side of lateral compartment has a kissing lesion due to cartilage lost on medial compartment. Due to the cartilage loss on the medial side, the tibial tip touches the femur and caused the lesion. The surgeon commented that once the procedure was completed, the issue would be resolved as normal joint alignment would be restored. He continued with the procedure as normal. The patient has a very high bone density which has made it difficult for the surgeon to mill and cut both on the tibia and femur. Further the tibial plateau was bigger than usual and size F trial implants are tested and confirmed on tibia. Just as the tibia the femoral trial was tested and confirmed with flexion and extension gaps differ in two millimetres. The femur is milled further and finalized the sizes of implants. The tibial implant is placed with the introducer but with a great difficult due the high bone strength that caused the resistance in the keel interference. Eventually the impact was used the position the tibial component flush to the bone. The femoral component was also placed and hammered and followed by inserting the bearing. Overall the procedure didn't have any major complications except the high bone strength.

OXFORD VISIT

Nuffield Orthopaedic Centre, Oxford
The second in-field was in Oxford, UK. Reaching the Nuffield Orthopedic Centre, we straight away headed to the operation ward and changed ourselves into scrubs to visit Mr William Jackson who's already operating an MCL replacement. I got to observe the tibial fracture
correction and there was an artificial MCL implanted to the patient.

Right after the procedure there was a small discussion with Mr Will. I gave a little introduction of the project. Will thinks its not the tibial impact that is solely responsible for the peri prosthetic tibial fracture. The way the implant is inserted and positioned is the crucial step. This was something new for the project as the brief talks completely about the tibial impact. But Mr Will says that since they make a small incision at the joint, the surgeons have a very small working space and a constrained visibility of the working area. During the insertion only the anterior portion of the implant is visible. The surgeons will have a hard time predicting the position of the implant posteriorly. Also, Will has observed some of his fellows during the time of insertion of the inserter with implant on, they insert with a higher angle from horizontal plane of tibial plateau. This causes the implant tip to hit the tibial plateau instead of sliding over and as they start hammering the inserter to push forward, the impacts transfer to the lateral and posterior tibial zones. Although there was never a fracture recorded intraoperatively due to this act, it is not recommended to avoid possible peri-prosthetic
fracture.

Nuffield Health Oxford, The Manor Hospital

Mr. Dodd was operating two surgeries during this visit. It was a left knee lateral compartment arthroplasty, which is very rare. The patient has a good thickness of cartilage on medial side and complete loss of cartilage on the lateral side, which is a perfect condition for lateral UKA. Lateral side UKA is slightly different from medial side. The lateral implant is not a mobile bearing implant. IIt is a standard Oxford femoral component with a monoblock tibial component. Mr Dodd mentioned the reason they had it so is the lateral side has a large movement of femoral component both linearly and horizontally. Although there is a large linear movement in medial UKA, there is not much of horizontal. To avoid the complications of bearing overhang, the lateral side implant has fixed bearing design. So the top surface of the tibial component has a fixed polyethylene bearing on which the femoral component slides directly.

During a short break between the two surgeries I had an opportunity to discuss about the most crucial things for reducing the learning curve of new surgeons. He added to the point Mr Jackson mentioned earlier that the workspace is limited and the constrained visibility making it difficult to assess the positioning of the implant. For the training purpose it's good to give the real experience of the surgery by simulating the constraints and may be having some kind of window on the back of the knee simulator to reveal the workspace visibility during implantation.

A push and pull study of the tibial component with variable interference was published from the researchers at Botnar. We had a meeting with Prof. David Murray and development team of Zimmer Biomet. The meeting ended with Prof Murray answering few questions about the most important factor that are responsible for peri-prosthetic tibial fracture. He mentioned the first most important thing as the keel slot, making the right size of keel slot and making sure all the bone residue is cleared off the keel slot. Secondly, during the keelcut saw, the long pin that holds the tibial template in place needs to be held firmly. Any possible slip of the template will lead to extended keelcut damaging the posterior cortex. Lastly the tibial trial implant needs to be tested in the tibial cut with flinger and making sure it fits correctly. Although these three points are discussed mostly in the microplasty, Prof. Murray says these are easily over overlooked.

During the dinner that followed the meeting at the Botnar, Prof Murray summarised the situation as, 'The procedure seems a lot easier than it does. They don't realise the most important part of procedure until they make a mistake. All you need to do is to get these to their attention'. This portrays the summary of the project very well. It is quite possible with the new surgeons that they do not realise these steps as important because the same steps when done in a cemented procedure are not that important.

VISIT TO RESEARCH & DEVELOPMENT, SWINDON

Dr. Imran Khan, the director of research gave us a short tour of the Research & development facility. The ground floor is spread with 4 testing labs and the R&D engineers. The microbiology lab is equipped with all types of equipment to test the organic residuals on specimen. Mechanical labs have equipment for high tensile tests and wear analyses. Inorganic lab has equipment to separate organic and inorganic substances from the implanted specimens. The robotic lab is currently involved in the research of a new technique to plasma coat the shell implant of hip implant.

Discussion with Duncan

Duncan Ridley, the development manager at Swindon R&D office was available have been involved with oxford partial knee development for about 10 years now. He was one of the key persons involved in the development of tibial component keel design. Duncan is leaving Zimmer Biomet at the time and that was the last and most valuable chance to understand different development facts about the oxford partial knee from someone involved in this for such a long time.

After a short introduction about the project the meeting kicked off with discussion points from design surgeons in Oxford. When Will Jackson at Nuffield Orthopedic Centre(NOC) said it's not only the impact that is majorly responsible for the tibial fracture, but it is more of the insertion technique. Will observed some of his fellows hammered the inserter with a very steep angle which makes the implant hit the tibial plateau with huge impact. So the way of insertion is important in reducing the learning curve as well. Duncan agrees and have never thought about that so.

PCF20

Duncan has confirmed about the choice of using PCF20 sawbones as a simulation of actual bone for testing. It was chosen because it was approved by regulatory that if an implant is tested on PCF20 sawbones, it is approvable. Secondly, since they do a lot of comparison tests of the new design with the proven existing designs, it is fine if the sawbones does not completely simulate a real bone. The results are acceptable as long both the designs are tested an same type of specimen. But Duncan suggests that it is still good idea to relook into the sawbones densities to evaluate the exact simulation of real bone.

Simulation

From the discussion with designer surgeons, it is evident that there are two things to incorporate in the trainer to achieve the desired simulation. Simulating the interference for force measurement and simulating the workspace.

To simulate the interference a basic thing to do is to use a power saw to make the keel slot and let the users insert the implant. Since it is not possible to get the saw blade, to simulate the interference in the sawbones Duncan used to mill the slots with variable widths and test it. Duncan suggests to use a slip gauge to measure the width of the slot to get the accurate values.

Secondly, to simulate the visibility constraints, and workspace accessibility, it is crucial to simulate the soft tissue around the joint. Duncan has never used any soft tissue like materials, but he thinks silicon must be the reasonable option to simulate the soft tissue.

Measurement & Assessment

Besides simulating the conditions it is important to measure how the surgeons perform the procedure and analyse. Probably a hybrid prototype that can measure both the insertion and impact steps needs to be developed and let the designer surgeons perform the procedure on it. From the results of thes 4 surgeons if an ideal surgical procedure is developed, it will be helpful to assess every time a young surgeons(user) performs the procedure. Duncan thinks every time a surgeon performs a procedure, the value will be different and there is a possibility that the values of novice surgeons will never match with the ones from designer surgeons.

To track their insertion procedure and impact, the first thing is to find out where they place the impactor on the implant by using the some contact detection may be by placing an electronic film over the implant. Duncan thinks it's a really good thought to think about the placementof the impactor placement, cause sometimes the you surgeons keep placing the impactor end at the posterior and impact many times and the impactor head is also bigger when you compare with smallest size implant, so some of it might overhang if not placed correctly. MeanwhileImran Khan suggests something like contact detection Fujifilm can detect the placement of metal conductor electronically. Duncan has never used one but thinks that such a film will be useful for this purpose as well.

And when it comes to measuring the impact some force sensors can be placed in the implant or somewhere below it. But Duncan has never done such an experiment in the office to test the hammering effect on the implant. One of his colleagues shared few literature studies on the effect of hammering in hip replacement.

Impacting force
Also regarding the amount of force to be applied on the implant to during impacting, one of the papers featuring push in and pull-out paper published from Botnar, Oxford has used a force of 905N. But it was a constant force applied, it is not a hammering like impact. Another paper featuring a cadaveric study on tibial fracture. Testing 6 cadaveric samples they found out that an average of 645 times of the body's weight can fracture the tibial plateau. Which is like 2.6 to 3.9kN which is way higher than that of surgeons apply intraoperatively. But Duncan himself thinks there cannot be a definitive value of acceptable range of force for impacting. This range of force is different from patient to patient due to different bone mineral density. And there has never been a study on finding this range of force.

E - DISCUSSION WITH DR. KEITH R BEREND MD

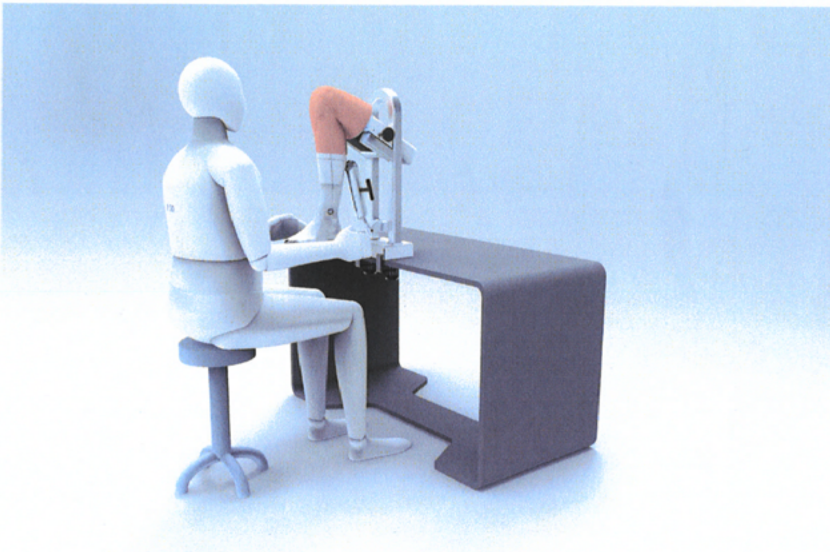
Keith Berend, MD, founding physician of Joint Implant Specialists in New Albany, Ohio, is among the initial surgeons advising the development of oxford partial knee replacement. Dr. Berend implanted several oxford partial knees using cementless technique. He was one of the
few surgeons to bring up the topics of solution for per-prosthetic tibial fractures. Dr. Keith R Berend has some different perspective of solution to this problem. As none of the peri-prosthetic fractures happened intraoperativel, he says the problem is not with the surgical technique or
the surgeon. It has something to do with the design on the implant. The bone-implant interference causing the internal stress post operatively leading to the fracture few weeks after the surgery. That implies that there is no fault either with the surgeons impacting the impactor with heavy mallet or with the surgical technique. So in his opinion, making a simulator and training the surgeons to apply right amount of force may not be the ideal solution for solving this problem. There wouldn't be an ideal solution than a right design of the tibial component.

C - USER INTERVIEWS

DR. SANDER SPRUIJT

Foxpat training simulator for cementless Oxford knee replacement

You will be briefed about the improvements made to the prototype since the last test. You will have a pre-cut sawbones set to test the implanting procedure. During this test I want to know how realistic do you think the process is and how helpful is the device to train the new surgeons.



1. **How well do you think Foxpat is simulating the insertion and impaction steps?**
   Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Low	◯	◯	◯	◯	◯	◯	◯	✓	◯	◯	High

2. **How well do you think Foxpat is simulating the whole surgical process?**
   Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Low	◯	◯	◯	◯	◯	◯	◯	✓	◯	◯	High

3. **How ergonomic is it working with Foxpat?**
   Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Low	◯	◯	◯	◯	◯	◯	◯	◯	✓	◯	high

4. **How realistic is the flexion and extension?**

Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Low	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	High

5. **How realistic is the bone resistance of sawbones compared with real implantation.**

Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Low	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	High

Interview questions

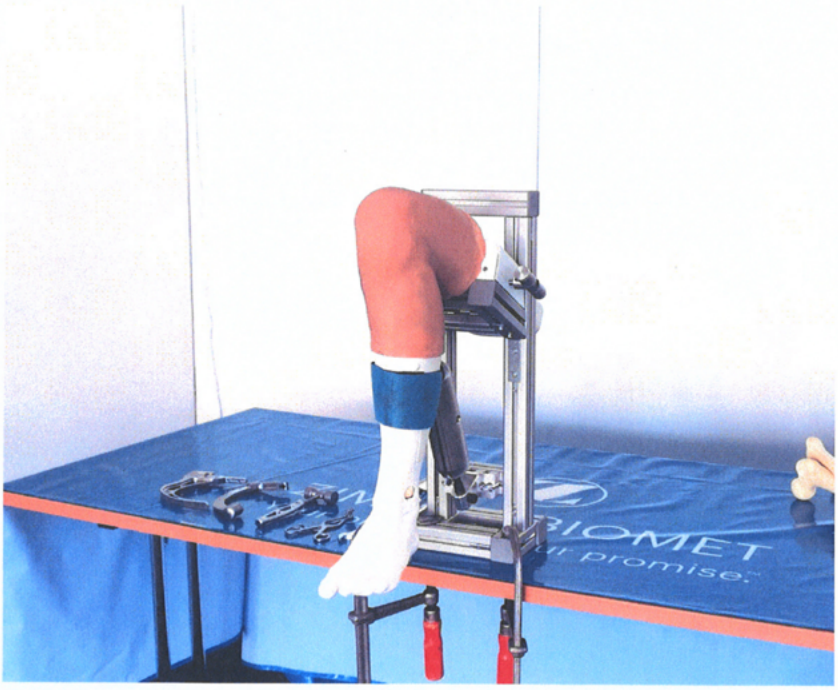
The leg fixture helps a surgeon to move the lower limb and lock in a convenient position to insert the tools. What value do you think it adds for a surgeon to work independently?

Could you please mention few things that the Foxpat is missing when compared to the real surgical setup?

What value does the Foxpat training simulator add to the current Oxford training process?

Do you see the advantage of having the device in hospital besides having at Oxford training course?

Is Foxpat also going to be helpful for experienced surgeons to try new techniques?



How well do you think Foxpat is simulating the insertion and impaction steps?
I think it's very well simulated these tibial components impaction and insertion process. Much more better than old fashioned sawbones model.

How well do you think Foxpat is simulating the whole surgical process?
Well I would say it's much better and much more realistic simulation than the old models

How ergonomic is it working with Foxpat?
In terms of ergonomics I think if you would be able to change the height it would be perfect.

How realistic is the flexion and extension?
Well I think the flexion and deep flexion of this model is very good but in extension I noticed that there's some problem with silicon plastic If you would improve that even further then that would be perfect.

How realistic is the bone resistance of sawbones compared with real implantation.
Well I it's certainly improved. Because when we testing the former models then it was sometimes very stiff and got fractures of sawbones. This is I think more realistic but the feeling is still little bit different compared to real bone. I don't know if the real bone is different or is it because of all the soft tissue and ligaments are different I don't know why it is but there is some difference but it was improved a lot. The leg fixture helps a surgeon to move the lower limb and lock in a convenient position to insert the tools.

What value do you think it adds for a surgeon to work independently?
For training purpose this is a good edition. You don't have to instruct the people how to hold the leg. You can fully focus on implantation and insertion process, making saw cuts, so that's a great improvement.

Could you please mention a few things that the Foxpat is missing when compared to the real surgical setup?
I think it's very realistic . You did a very good job. Off course it's always a proximation of reality. You can't fully copy the reality. But I think because in the real situation you have tendons muscle sand ligaments. They are all tension little bit different than this model does. If there would be any improvement that would be the things to pick up. Off course in real situation you have blood and things like that and also you have off course different dimensions in legs, so you have big people small people muscular people fat people, I think for training that would go too far to go to these variations.

Do you see the advantage of having the device in hospital besides having at Oxford training course?
I would love to have it in my hospital. Because during the workshop you can only use it for may be for one hour or 2 hours or may be for half a day. But if you have such a model in your hospital you can let your surgical trainees practice again n again a again. That would be great if that's possible.

Is Foxpat also going to be helpful for experienced surgeons to try new techniques?
Well since its more realistic and the approach is more like in real situation, it might perhaps can be used for new tricks, not sure which tricks. They might be helpful

What value does the Foxpat training simulator add to the current Oxford training process?
Certainly its more realistic model than the old fashioned sawbones, I think everybody would be enthusiastic if there were tables full of this setup.

DR.FRANCOIS HARDEMAN

Foxpat training simulator for cementless Oxford knee replacement

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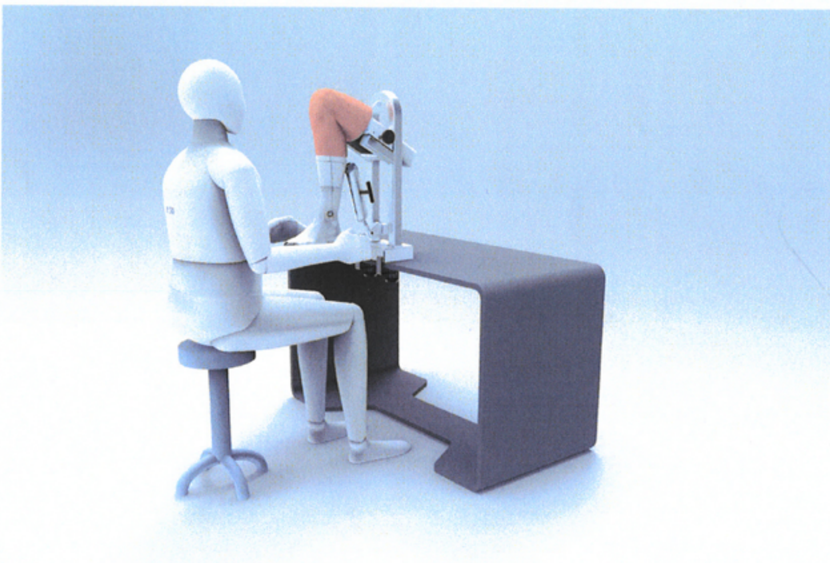

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	1	2	3	4	5	6	7	8	9	10	
Low	◯	◯	◯	◯	◯	◯	◯	◯	X	◯	High

2. **How well do you think Foxpat is simulating the whole surgical process?**

   Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Low	◯	◯	◯	X	◯	◯	◯	◯	◯	◯	High

3. **How ergonomic is it working with Foxpat?**

   Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Low	◯	◯	◯	◯	◯	◯	◯	◯	X	◯	high

DR. SANDER SPRUIJT

4. **How realistic is the flexion and extension?**

Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Low	○	○	○	☒	○	○	○	○	○	○	High

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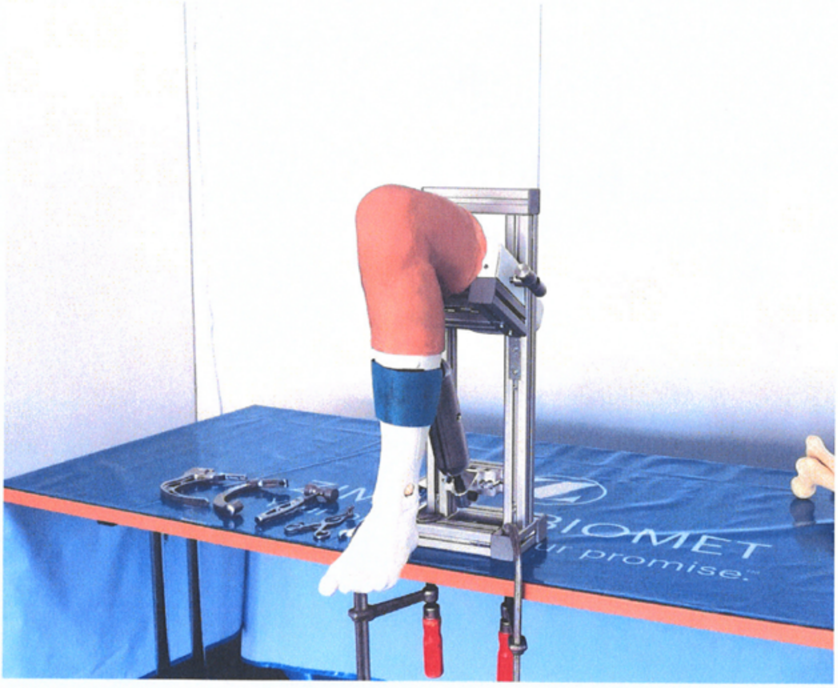

D - MANUFACTURING DETAILS

BARANA RAPID

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E-MAIL: baranarapid@baranarapid.com WEB: www.baranarapid.com

COMMERICAL INVOICE

BILLING TO:	SHIPPING TO:	INVOICE INFOR	
Nithin Gurram	Nithin Gurram	Invoice Date:	01.08.2019
Leeghwaterstraat 5,	Leeghwaterstraat 5,	Quotation #:	20190725-C-01-V3
2628 CA Delft, The Netherlands	2628 CA Delft, The Netherlands	PO #:	N/A
		Delivery Date:	13.08.2019
		Tracking #:	N/A

No.	Part Infor				CNC RP	Silicone Mold	Vaccum Casting		Subtotal (USD)
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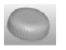
2	knob final		2	AL 6061 Anodizing Silver	70.00				140.00
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5	buttom pad final		1	Yellow ABS Paint Silver	15.00				15.00
6	top dome enclosure 2 final		1	Yellow ABS Paint Silver	85.00				85.00
7	30 degree flange		1	SS304 Paint Dark Grey	60.00				60.00
8	bone holder plate with clinch nuts assembly		1	SS304 Debur	150.00				150.00
9	main shell bottom final		1	Yellow ABS Paint Dark Grey + Light Texture	80.00				80.00
10	static wall		1	SS304 Debur	20.00				20.00
11	clamp face 1 final		1	AL 6061 Anodizing Silver	15.00				15.00
12	moving wall protector flange		1	SS304 Debur	30.00				30.00
13	main shell top final		1	Yellow ABS Paint Dark Grey + Light Texture	125.00				125.00
14	U arm final		1	AL 6061 Anodizing Silver	550.00				550.00
15	swivel holder final		1	AL 6061 Anodizing Silver	30.00				30.00
16	ball final		2	AL 6061 Anodizing Silver	35.00				70.00
17	swivel arm 1 final		1	AL 6061 Anodizing Silver	40.00				40.00
18	swivel arm 2 final		1	AL 6061 Anodizing Silver	40.00				40.00
FREIGHT	FREIGHT COLLECT								0.00
LEAD TIME	12 Days				TOTAL(USD)				1645.00
					DISCOUNT TOTAL(USD)				1600.00

Information of Beneficiary's Bank (ONLY FOR USD)

Beneficiary's Name	BARANA RAPID TECHNOLOGY LTD
Beneficiary's Bank Name	OCBC WING HANG BANK LIMITED
Beneficiary's Bank Address	161 QUEEN'S ROAD, CENTRAL, HONG KONG
Beneficiary's Bank Account Number	035-815-742971-831
Swift Code	WIHBHKHH

For and on behalf of
BARANA RAPID TECHNOLOGY LIMITED
佰瑞納快速製造技術有限公司
Katherine Liang
Authorized Signature(s)

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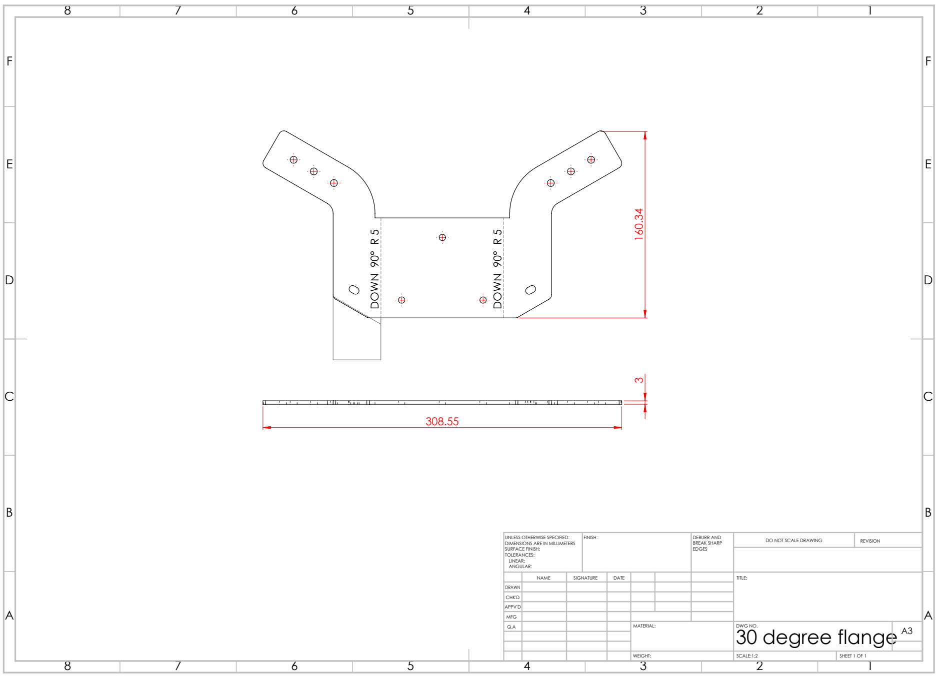
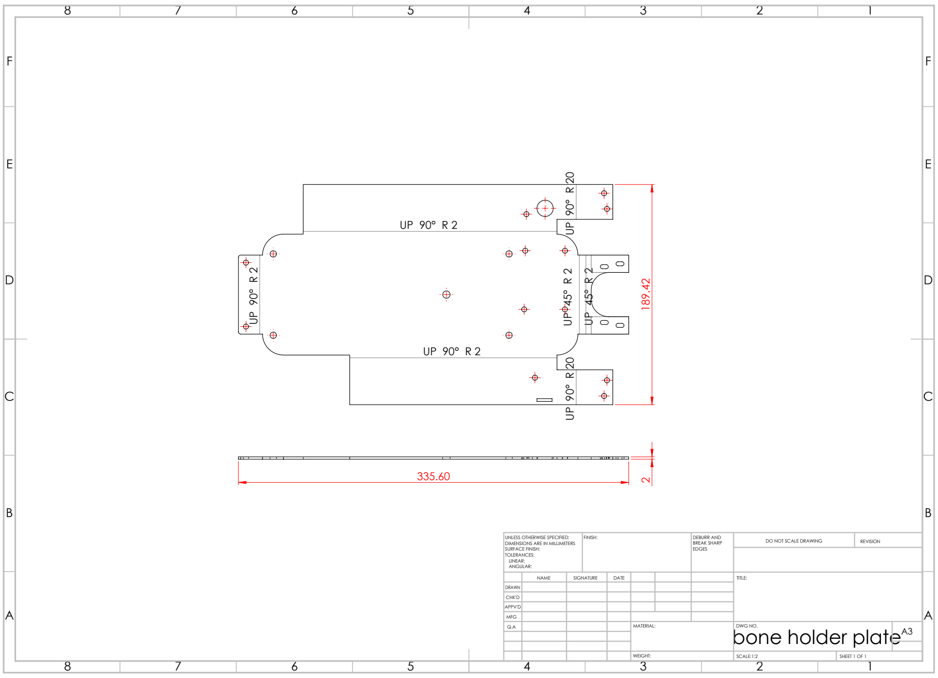
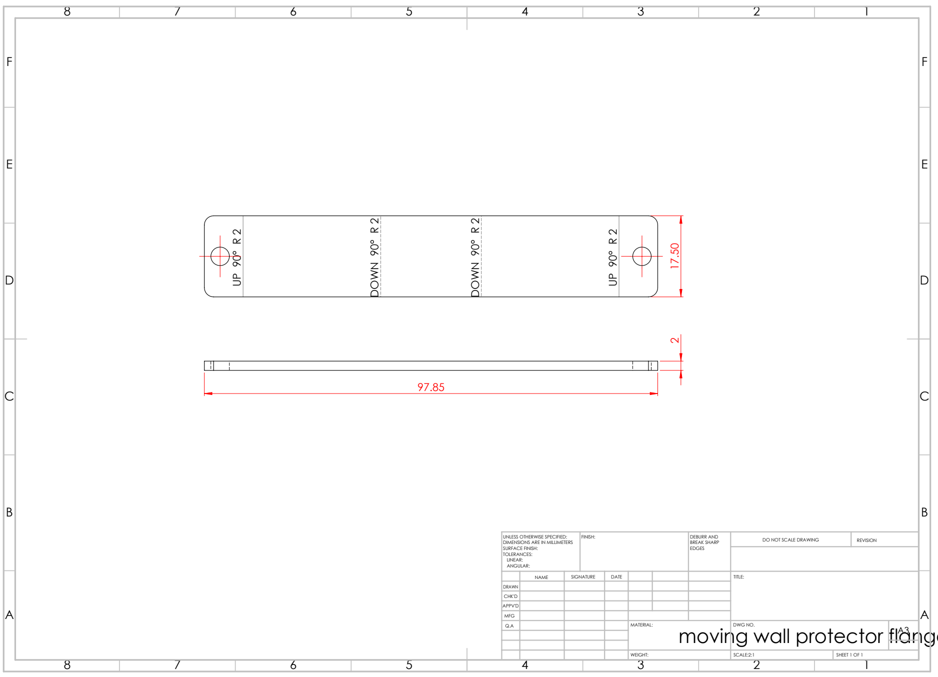
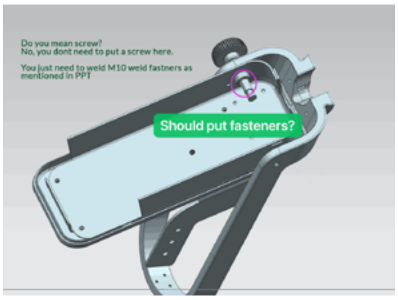
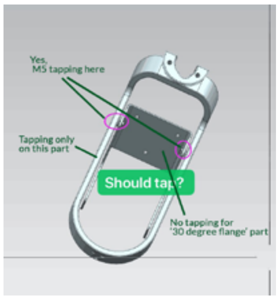
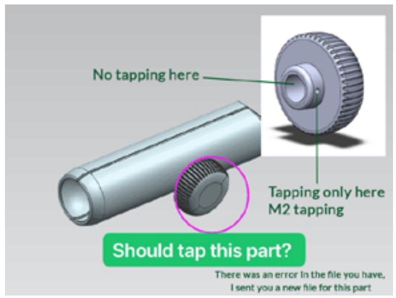

DOWN 90° R 5
DOWN 90° R 5
160.34
3
308.55
30 degree flange
A3


UP 90° R 20
UP 90° R 2
UP 90° R 2
UP 45° R 2
UP 45° R 2
189.42
UP 90° R 2
UP 90° R 20
335.60
2
bone holder plate
A3

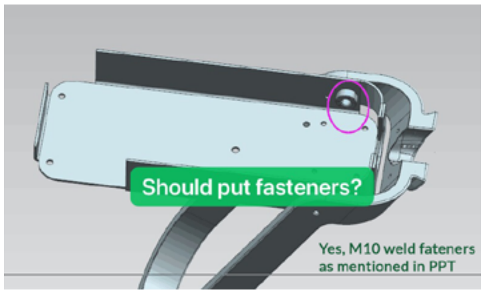

UP 90° R 2
DOWN 90° R 2
DOWN 90° R 2
UP 90° R 2
17.50
2
97.85
moving wall protector flange

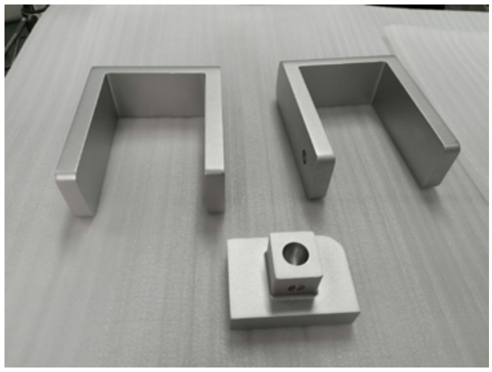

Do you mean screw?
No, you dont need to put a screw here.
You just need to weld M10 weld fastners as mentioned in PPT
Should put fasteners?

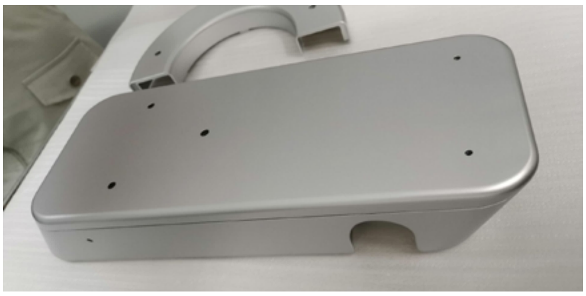

Yes,
M5 tapping here
Tapping only on this part
Should tap?
No tapping for '30 degree flange' part


No tapping here
Tapping only here
M2 tapping
Should tap this part?
There was an error in the file you have,
I sent you a new file for this part


Should tap this hole?
Yes, M10 tapping


Should put fasteners?
Yes, M10 weld fateners as mentioned in PPT





E - WEEKLY NEWSLETTERS

Weekly newsletter - Week 4

Recap of week 1,2,3 - Research

- Infield research - Hagaziekenhuis
- Call with Dr. Keith
- Literature research - cementless Oxford partial knee arthroplasty and post complications
- Oxford visit -Meeting with Oxford Knee group
- Swindon - Meeting with development engineer
- Bridgend - Manufacturing facility tour
- Literature research - learning curve, training sessions and impact forces
- Competitor study
- Infield visit - Existing products

Key points (Week 1,2,3)

Redesigning the surgical toffee mallet is not a feasible option for this 20 week project. It was decided that a training model will be developed that can help reducing the learning curve of novice surgeons.

A good measure to keep up with the surgical techniques is to perform the cementless procedure at least once in a month(12 procedures per year).

Besides impact forces, the angle of insertion is important to consider. A steep angle of insertion gives unwanted impacts on tibial condyle.

Impact patterns are different from surgeon to surgeon. Few use many strokes of small impacts and few use bigger impacts for less number of times.

There is not a specific range of force to be applied that is ideal for the cementless procedure.

The training model or the simulator needs to focus on the both the impact forces and insertion technique.

Studies on learning curve shows, 25-30 procedures for a new surgeon is a good number to reach good results.

Comparing the impact values and insertion procedure with oxford surgeons could be a good measure to assess the new surgeons.

Week 4 - Conceptualization & prototyping

Direction of focus - Mechanical setup

There are two directions to take, either use a haptic device to simulate the resistances and show a virtual reality visuals (Like all the other simulator are doing as of now) or use a true mechanical setup where a surgeon can operate with actual instruments.

There couple of options in virtual simulation, using haptic gloves and using other using table-top haptic device. Geomagic is a company involved in developing haptic devices. Geomagic touch X simulates different resistance of kinds body tissues and bones. When I contacted them, they claim that it can simulate large amounts of forces like hammering impact, but they are much expensive. These virtual simulations are not perfect and time taking at the same time. It was a decided to stop exploring in this direction of virtual simulation and focus on mechanical setup.

Prototyping

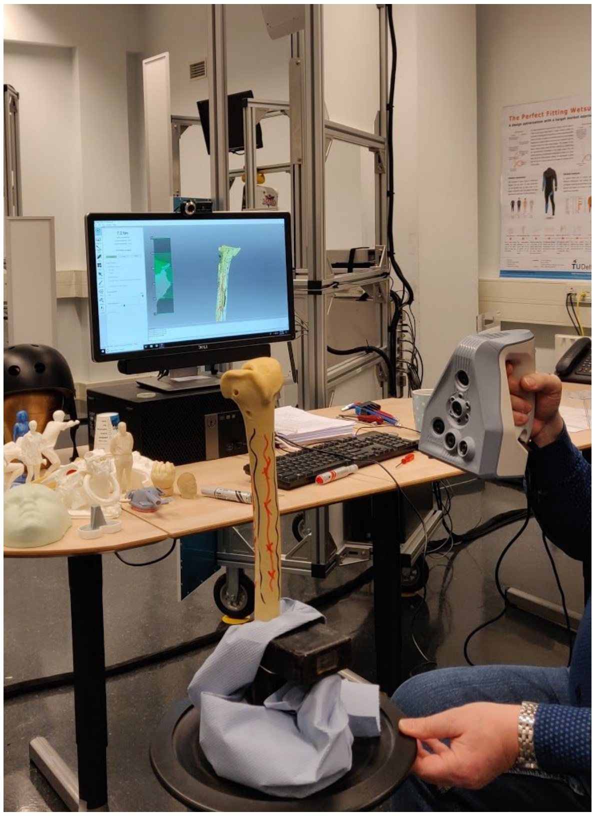
The idea is to make a test setup to position the sawbones in the device in a position of 120 flexion. The surgeons in the oxford training session insert the sawbones that they already worked into the device and do tibial insertion and impaction. The test setup will read the insertion part of the tibial component by tracing the inserter and also reads the total amount of impact given.

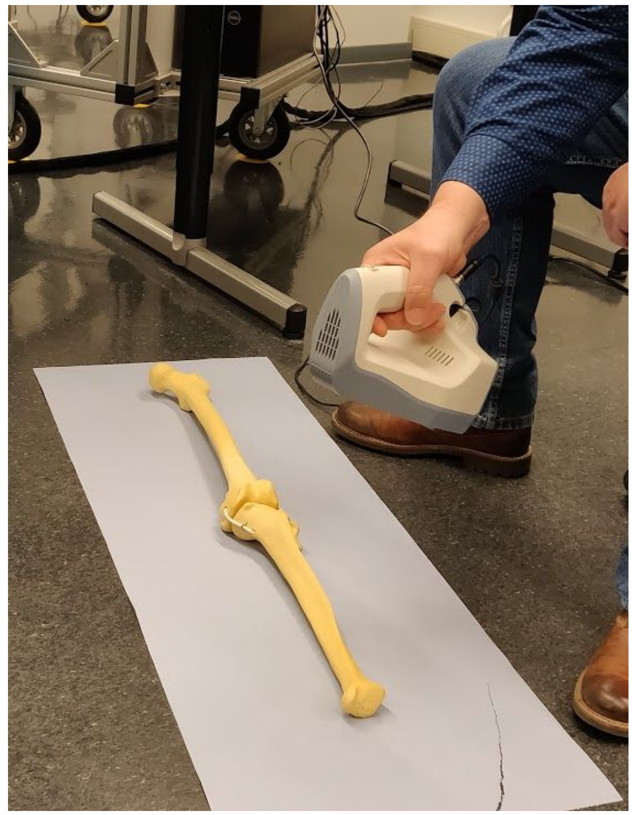
Approach

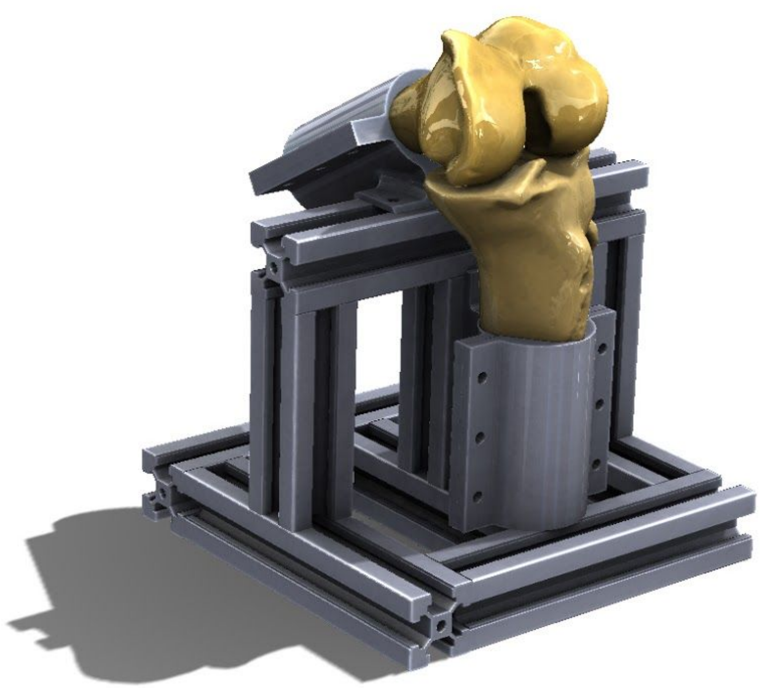
- Build a structural setup for placing the bones
- Build a cutting tool to cut the bones in the right size
- Make silicone simulations of soft tissue
- Attach the sensors to the setup to track position and impact
- Test with Oxford surgeons and new surgeons a the Oxford training

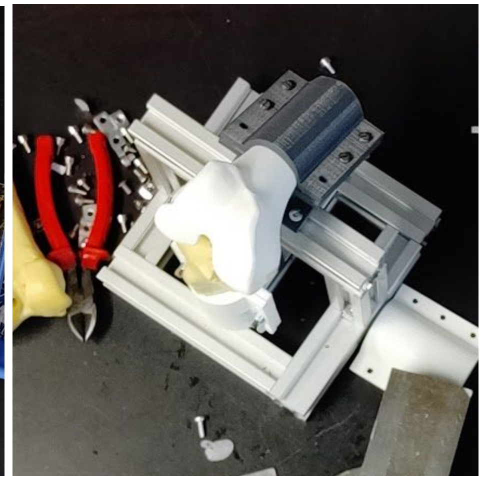
Progress

3D scanned the bones to design a structural setup to position them correctly.





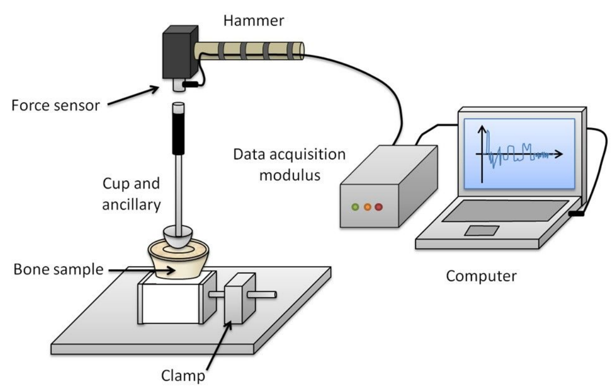




Next step is to make a silicon simulation of the soft tissue and place it around in a way to simulate the visual and functional constraints.

Measuring the parameters - Sensors

Impact



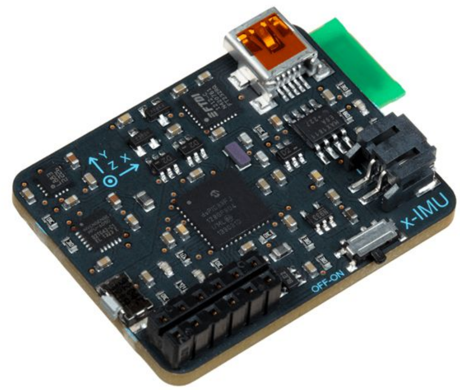
[1]

It was understood that piezo force sensors are the best to read impulses from hammer. Kistler B.V manufactures these sensors and also impulse hammer with built-in sensors. As the hammers are expensive, being priced at 3000 euros and sensors at 580 euros, thought its making the whole product expensive. Michael had a conversation with his boss and said that it's not a good idea to add such an expensive addition every product. Moreover, from the discussion with Oxford surgeons, impact wasn't a crucial thing to care for, so the idea of using the impulse hammer has been dropped off.

Other options that I'm planning for is to use a regular arduino based load-cell under the test setup bed or use an accelerometer in the hammer to read the force values.

Motion tracking

The initial idea is to place an accelerometer on inserter and track the position, but it turns out to be not that simple. 6 axis accelerometers can know the motion and tilt but cannot position the object in the 3 dimensional space. The other options that I am exploring currently are to use a camera based tracking, just like kinect sensor or use dedicated motion tracking chipset like x-IMU. This chipset is a combination of several sensors that can track the position of the board in 3 dimensional space. This is priced at 350 euros.



Next

Visit to UK has been finalised

There is an Oxford training happening at Oxford on 16th of April. The plan is to reach Oxford along with the test setup on 14th to assemble and prepare for the the trail test. Oxford surgeons can try implanting on the test setup. Later during the workshop the new surgeons can also place their sawbones and try implanting the implant. I will not be showing them any visual feedback but want to track the sensor value.

Silicon Simulation

Figured out the type of silicon to be used to mold the soft tissue. The next week I will be busy casting a knee(probably Michael's knee) or 3d scanning the knee to make a cast out of it and then making silicon tissue.

Motion tracking

Kinect seems to be good option to try first and if not x-IMU chipset would be the next option.

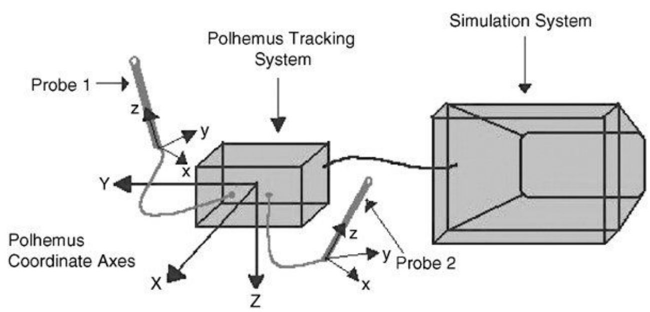
Weekly newsletter - week 5

Motion tracking for inserter

Using electromagnetic sensors

Continuing the last weeks' research, I looked into the electromagnetic trackers. These systems have a stationary transmitter that produces series of electromagnetic fields to know the position of a probe which is moving in a 3 dimensional space.

Polhemus tracking



Polhemus is an American company that produces such trackers. Most of the medical simulators use Polhemus tracking technology to track the movement of surgical tools. They have a product range with varied accuracy, tracking size and mobility. The company is widespread across the world and I almost find their products in every engineering precision company website. I spoke to a reseller of them from Germany and also one person from Polhemus Germany.

Liberty Patriot

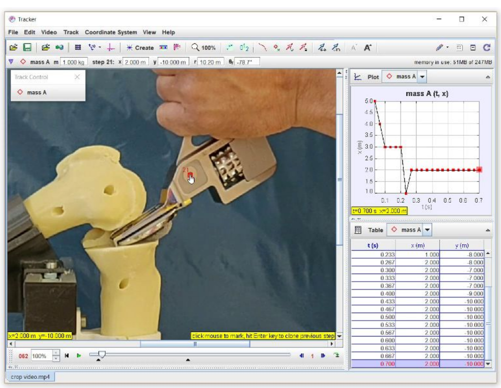
These two ugly looking tracking systems are the ones that they suggested for my setup. Liberty is more accurate, detecting up to 0.75mm. Patriot can detect upto 1.5mm. Patriot also has some low specs in terms of update rate but this is the basic/cheapest tracking sensor they have. They gave me a rough estimation over the phone call. Liberty system including all the accessories, costs 7000 euros and Patriot costs around 2500 euros. I really emphasized the hammering effect and got to know that they didn't come across any application of their product in a hammer impaction. They say it is upto me to filter out the noise that occurs during hammering and it should be fine. I conveyed them that it's an expensive option for me for an indefinite solution and I’m yet to confirm them something in the next week.

Using camera

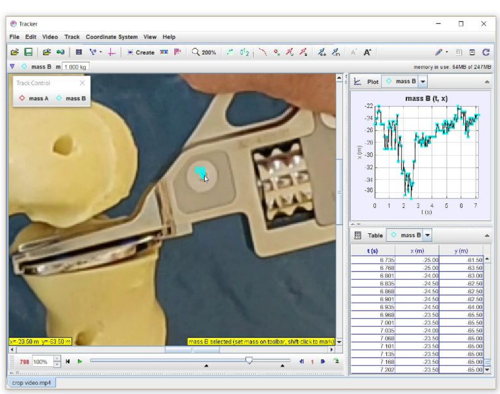
Motion tracker software

To track the motion visually, a camera with openCV algorithm is an obvious solution maybe, but I thought before I spend some time on coding, let me see what I’m going to extract from it. I found this amazing program from opensoursephysics called, Tracker. It is a video analysis and modeling tool built on the Open Source Physics (OSP) Java framework. This is used in physics education to create particle models based on Newton's laws.

Test 1



Test 2



Having shot a small video of me performing two procedures of insertion on sawbone, It allowed me to track the path of inserter and analyse the paths from two tests and compare how they differ. Once I make an analysis I have several fundamental values which can be used to calculate the physical parameters like force, momentum, angle of impact and so on. I looked into what useful parameter would be useful to calculate in this aspect. I listed out 7 parameters by myself, but could be even more:

1. Horizontal tilt of inserter
2. Vertical tilt of inserter
3. 2D path of implant
4. Change of slope of implant during the whole travel
5. Hammer impact
6. Hammer contact point
7. Angle of contact of hammer to know X and Y components of impact

I took the results to Richard and got some really nice directions to extract the useful parameters that I want from the video analysis. But then the question comes in that how are these values going to help me analyze the learning curve, or efficiency of a procedure. Then the first solution as richard suggested is to define the ideal parameters. Although these are hard to define, it seems sensible from the discussion that every parameter can have an acceptable range, which can be defined by analysing in the same way the procedures done by Oxford surgeons. When the video clips from each surgeon performing couple of times are analysed, there will a huge valuable data. Although, this data will be too extensive to feedback a new surgeon, it will help me to understand at least what kind of parameters are important measure. Then the level of measurement can be scaled down to may be one or two basic parameters like tilt or point of contact, which are comparatively easy to measure.

So I planned to fix a camera to the setup to record every procedure in 2D when Oxford surgeons can perform on it. Then use those movie clips to analyse after I get back. So for now, I could not figure out how the product will eventually track the motion eventually, but made a plan for testing if it is really worth of tracking or not.

Impact measurement

Hammer quotation

Subject:	Description	Quan-tity	Price per unit in €	Total in €
	Miniature Impulse Hammer			
086E80	Miniature Instrumented Impulse Hammer, 0 to 50 lbf	1	1,099	1,099

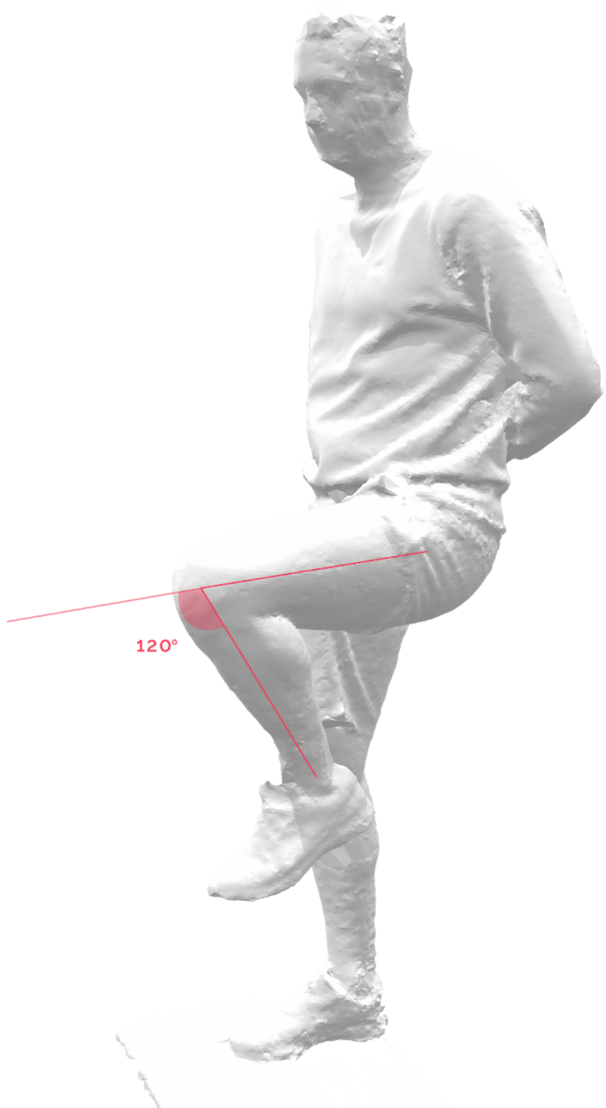
If the hammer will be used for educational purposes a discount of 15 % applies.

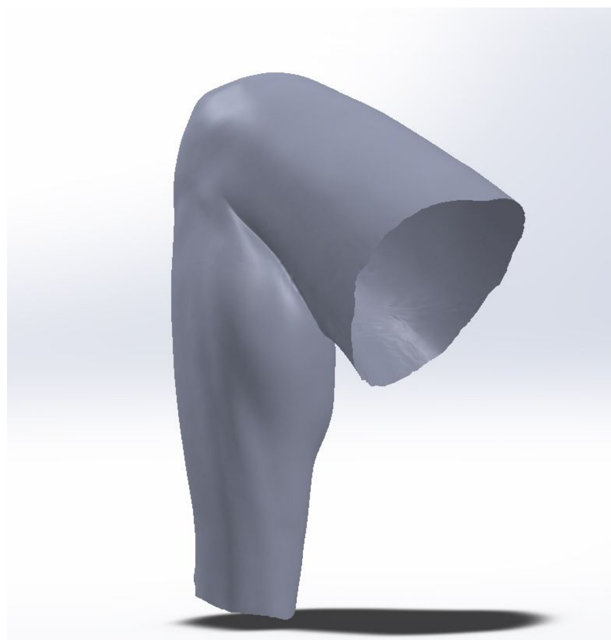
I received another quotation for hammer from pcb.com. Their hammer is a bit cheaper than the previous one, 1099 euros including accessories. Although it is an expensive sensor to put in the final product eventually, I think it will be useful to source it to at least evaluate the effectiveness of impact hammer in this case.

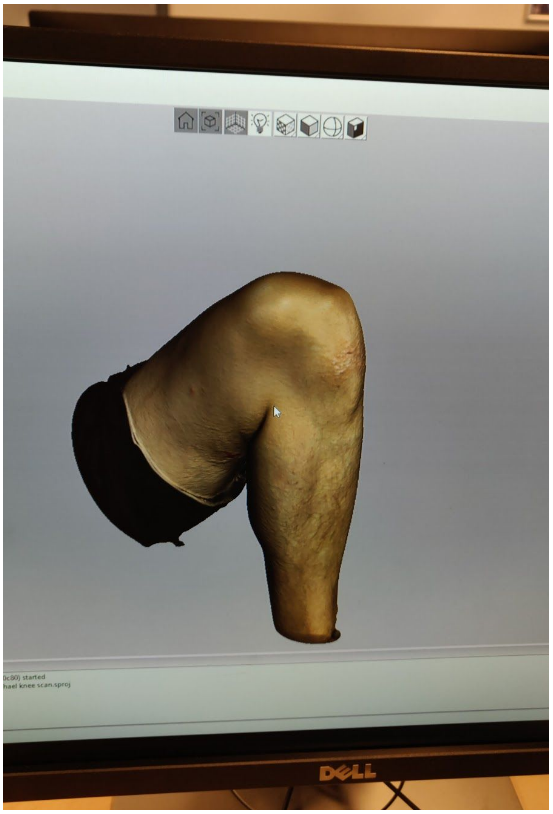
Soft tissue simulation

3D scanning

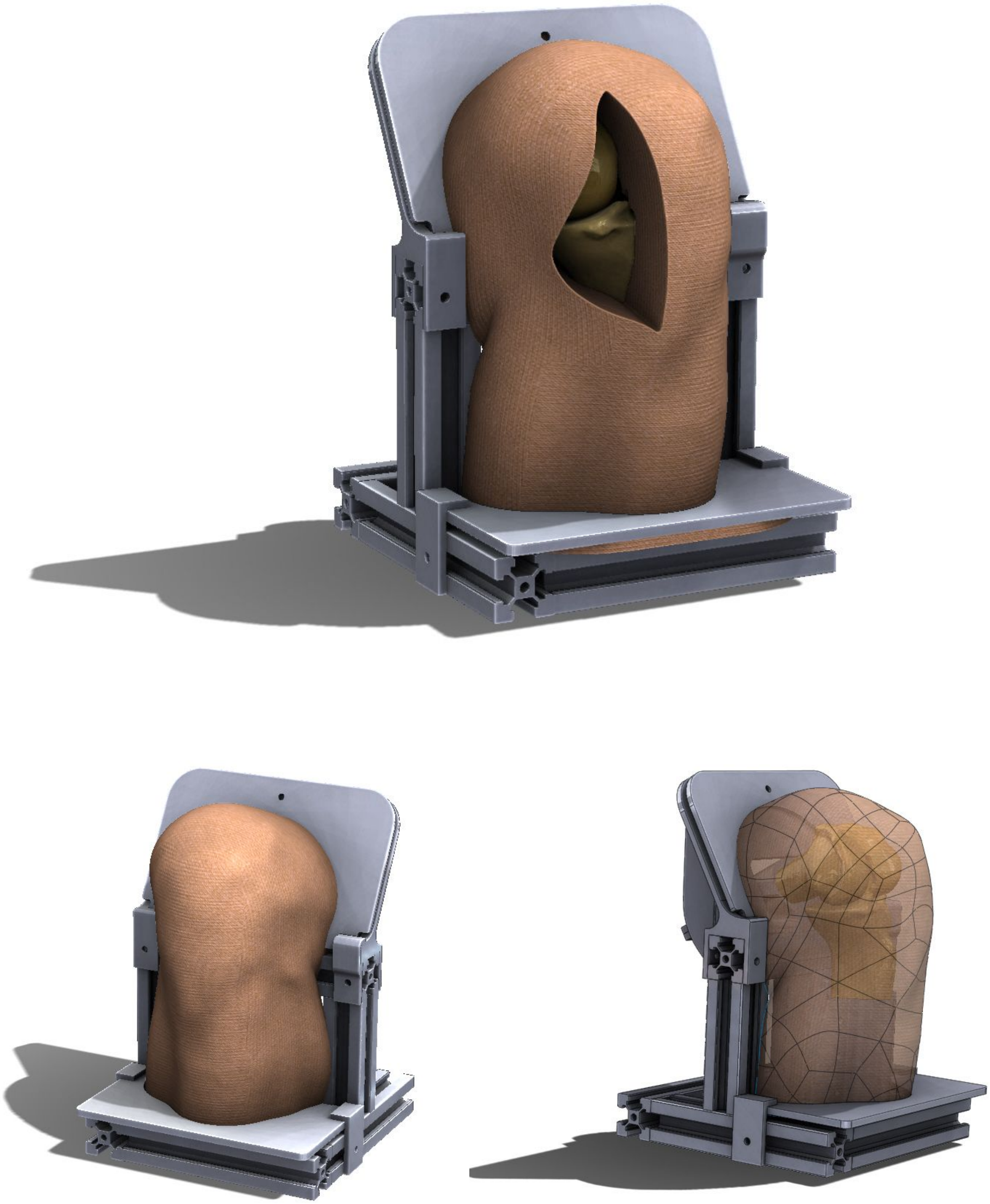
I 3d scanned Michael's knee at an angle of 120 degrees. Usually when the leg is left freely it is flexed to 110 during surgery. While implanting the tibial component, surgeons press the leg little more to increase the working space, so I counted it to 120 degrees for making a setup.



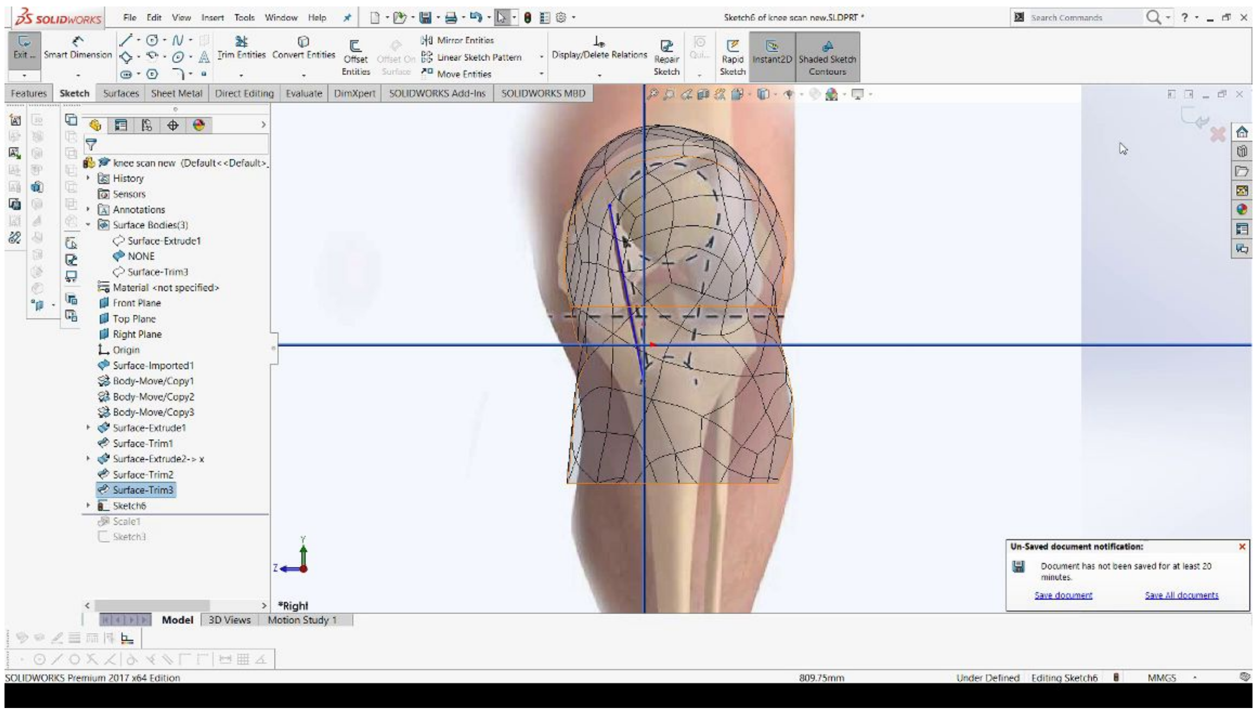




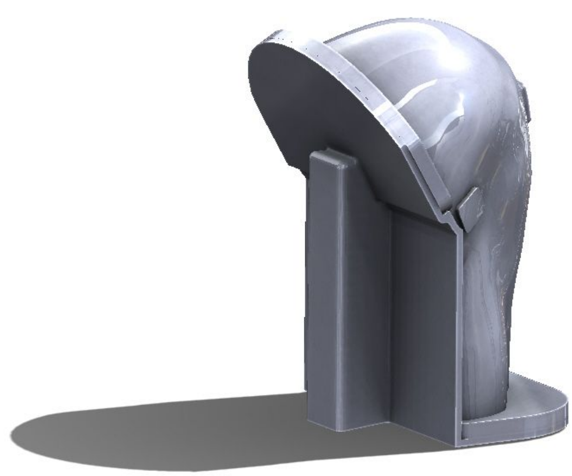
Soft tissue design



I adjusted in a way that the 3d scan of knee as a soft tissue covering the sawbone setup I created earlier. I used the picture from microplasty instrumentation as a reference to make the incision and developed it further taking the pictures from Hagaziekenhuis as a reference.

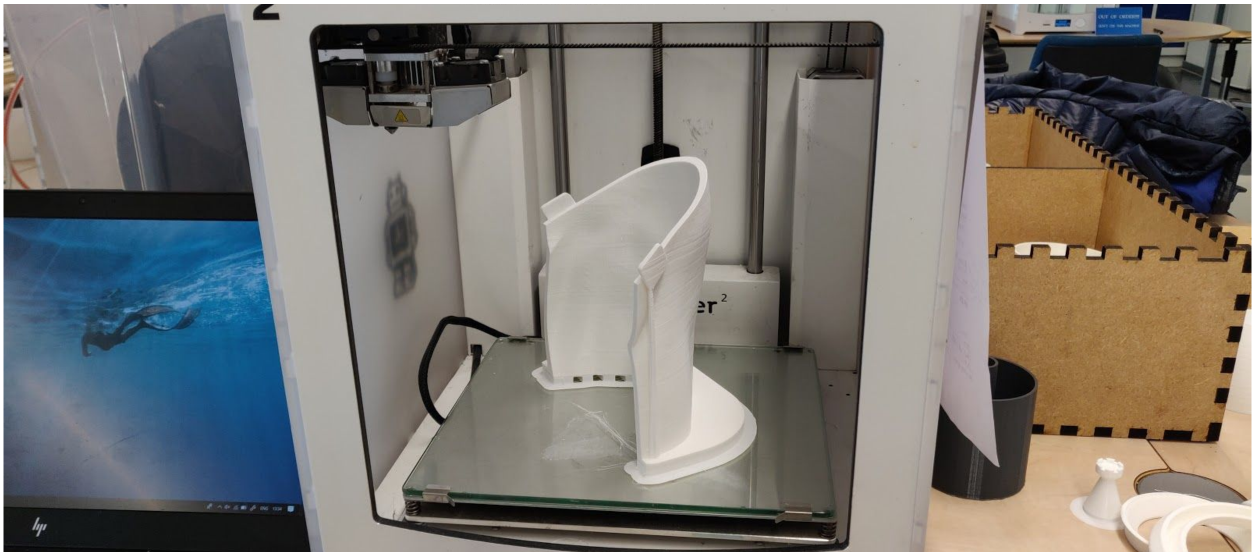


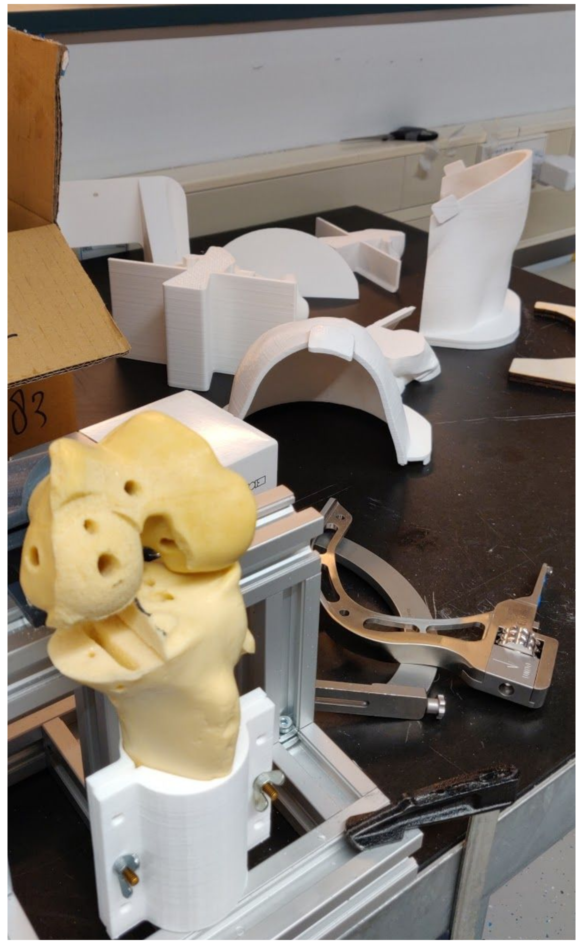
Mold design



To make this tissue in silicon, I created a mold around it to fill in the silicon and let it to cure.

Mold 3D print



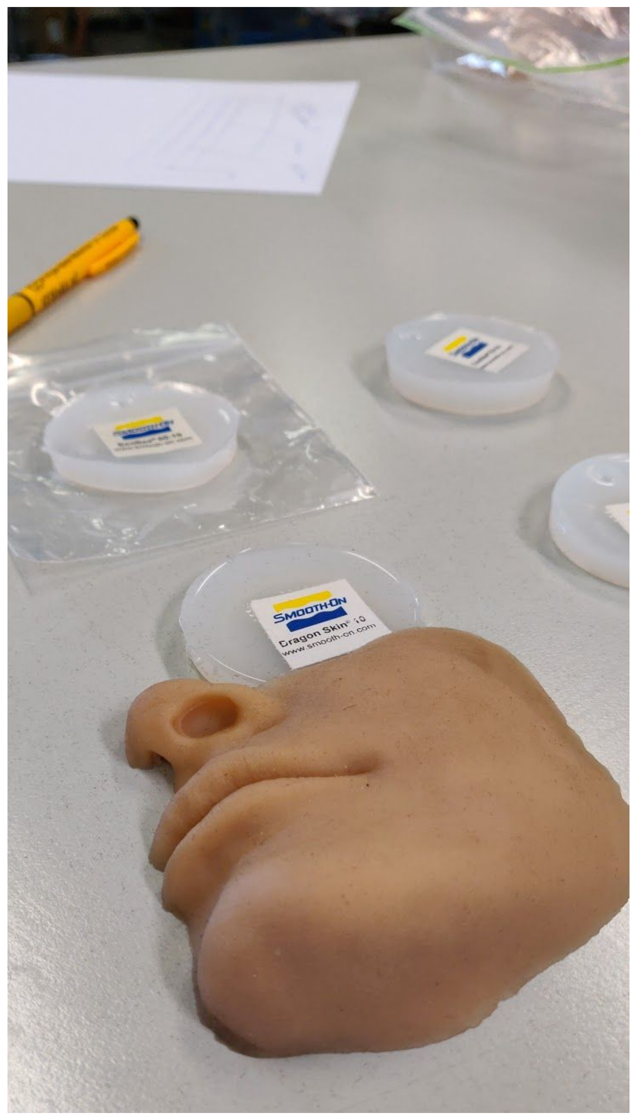


Silicon sourcing

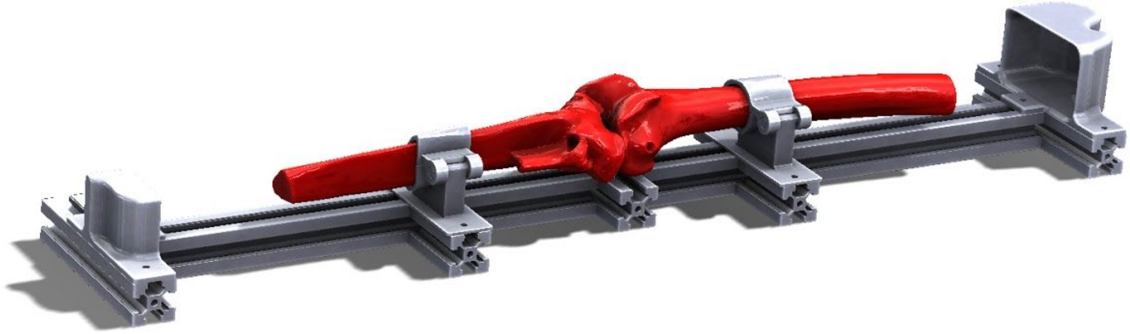
FormX Amsterdam visit

Form X is a company specialized in silicon prosthetic making. They supply silicons to world renowned artists in film making. They have a person specialised in medical simulation at their Amsterdam office. So payed a visit and had an inspiring discussion with him. He is Cawrence, been doing the silicone prosthetics for 15 years now, he owns a business other than working at Form X, which makes personalised prosthetics for medical simulators.

He suggested me to go for layering with different silicons to make it more realistic than using just one single silicone filing. He even shared some of his previous works and explained the way he built. He really liked my approach of 3d scanning and printing the mold than lifecasting a person. He is much interested in how the molding goes and would like to help me further to make some hyper realistic models.



Sawbone sizing



I started making a setup to cut the sawbones during Oxford training in the right size

User Research

I was able to meet Dr. Wouter Eilander who is working as a fellow with Dr. S. Spruijt at Hagaziekenhuis in The Hague. He was performing certain steps himself when I visited the hospital to see the Oxford partial knee procedure in February. Besides asking him several questions, I even involved him into a short brainstorming on analysing the insertion and impaction. I have the whole discussion documented here with key points highlighted in red.

Discussion

What is different in cementless fixation

When Dr. Wouter Eilander was asked about the differences that he personally see in cementless fixation from cemented, he said that Cemented procedure is usually stressful as surgeons have little time after they put the cement to place the component as the cement dries. In cementless procedure surgeons have enough time to ensure they are in the correct angle and the component is fixed properly in place. Lastly the feedback that they receive during hammering is quite different both cemented and cementless fixation. Personally Dr. Wouter relies on three things during impaction, Visual cues that the component is touching the bone correctly, haptic feedback from the inserter and sound from the impaction.

Post complications and what are the reasons

There were studies reporting the revisions of cementless fixation and a lot of discussion going on if it is caused intra-operatively or not. Wouter thinks that it has something to do with extended vertical cuts of tibia may be. Especially when you are switching from total knee to cementless partial, the tibial cuts are quite challenging than femur cuts.

Most challenging parts of the procedure
Hammering the tibial component softly to ensure it is in the right place. The soft tissue blocking the visuals makes it difficult to estimate if the component is fully though or not. Aligning the ankle piece which is crucial for tibial cuts. Vertical and horizontal cuts are very challenging because there is no visibility and it is hard to understand if the cut is too deep or shallow. Using feeler gauge to decide the flexion gap. Wouter emphasised couple of times on the starting of tibial cut, which is making sure that the ankle piece is in right position and placing the g clamps to proceed with horizontal and vertical cuts.

Why don't they have insertion and impaction steps in Oxford training?
Wouter finds it interesting as well that why is it not included in the training. The first time he did the procedure in OR he found it quite difficult during this step. The soft tissue around the bone and limited visual of the working area due to fat tissue. The first time anyone does its difficult to know where exactly to hammer and he thinks it is really important to train those steps.

Most common mistakes by novice surgeons
They might not give much time to ensure if the component is in good position. When there is little gap between implant and bone due to irregular cut, they need to leave it but some try hammering more and more.

What is different in real surgery from the Oxford training?
It is always different from training he says. The soft tissue blocks the visuals and they need to be careful about cruciate ligaments in real surgery which is not the case in sawbones. Flexion and extension gaps are different in real patient and sawbones. So the course gives a good basis and best way to learn is to see several times and do it. The fellows usually do one step in every surgery and once they finish all the steps after a number of surgeries, they do it all by themselves.

Does a product like my prototype can add some value in reducing learning curve?
Wouter thinks that a product like that would be very useful for him to practice on in real life just the day before a surgery.

What he expects from such a product?
He would like the product to be able to let him practice all the steps from the beginning to the end with all the cuts including implanting the prosthesis. May be using real implant is good if possible. It should help them to practice all the steps one by one to remember the whole procedure. Unlike my prototypes, he likes to have a setup with full lower leg as well that allows this to do the flexion and extension

Analysing the insertion and impaction
I explained my approach of analysing using a video analysis. I showed the insertion path from two tests that I performed earlier but there was no ideal path or rightful way of doing it. Here, Wouter gave me really nice idea, he said in medicine it is hard to define what is the right way, so

we look for what is not the right way or not acceptable way. Finding the wrong way of doing is more important than finding what is ideal way of doing. He suggest few things like making sure that surgeons never hit horizontally when the implant is completely flat.
He says, if at all possible, may be it is good to have sensors to track the position of implant continuously. Then I raised a doubt about the necessity and effectiveness of tracking and feedbacking on their insertion path that if at all such a feedbacking is achieved in the product, is it going to be really helpful for the surgeon. Wouter says may be a little bit but not much because off course the fat tissue and bone density changes from patient to patient but the movement will be similar. So such a product might help to practice couple of times but it is difficult to feedback what is good and what is not.
Further he agrees with just feedbacking on the vertical tilt of inserter and making sure it does not exceed certain limit. Adding to this he thinks it is may be nice to show them what is the right position on the inserter to hit. He say orthopaedic surgeons always try to keep the instructional part simple. Just a brief instruction in 3 steps of where to hit and that's it.

Ending the discussion, Wouter suggested that it is good to focus first on providing the most accurate model and then the simulation of movement would only be a nice addition to it.
Meeting with Wouter

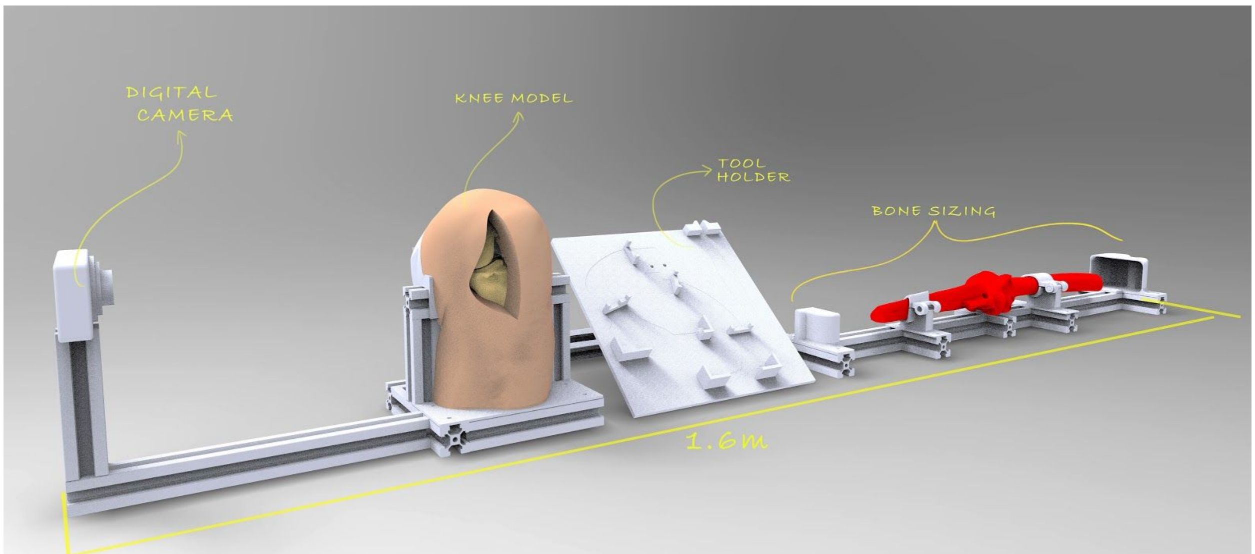
Next steps

Finishing up the bone cutter assembly
Silicon molding
Oxford test plan during the course
Making two setups ready for testing in Oxford
Transport plan

Weekly newsletter - week 6

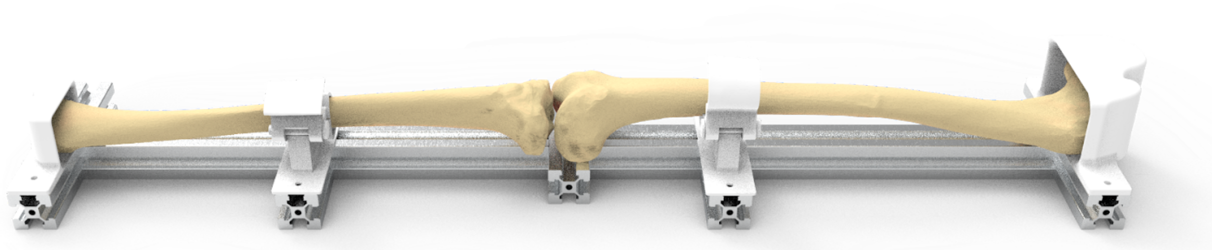
Prototyping

I had the whole set of items planned for Oxford test. A camera is attached to the knee model in certain distance to record the insertion patterns. Then I have the tool holder holding all the 3 tools that are necessary for implanting on the bones. Lastly I have the bone sizing to reduce the bone length to be able to put in the knee model.



Bone cutter assembly

For the same reason that I want the setup to be compact, I planned to cut the tibia and femur to lengths of 150. To make it easier to cut it during the Oxford workshop, I prepared this template. I place the full length bone and cut it to the pre-calibrated length that can fit exactly in the knee model.



Oxford test plan

Oxford training workshop is taking place on the coming Monday and Tuesday. I planned to occupy a table somewhere at the end of the hall. I'm going to stand there with two setups. When the surgeons finish all the procedures that are taught by faculty surgeons, they come to my table with their sawbones. I'm going to first size the bone to calibrated length and insert in the knee model. Then the surgeon will continue with implanting the real implant on their sawbones.

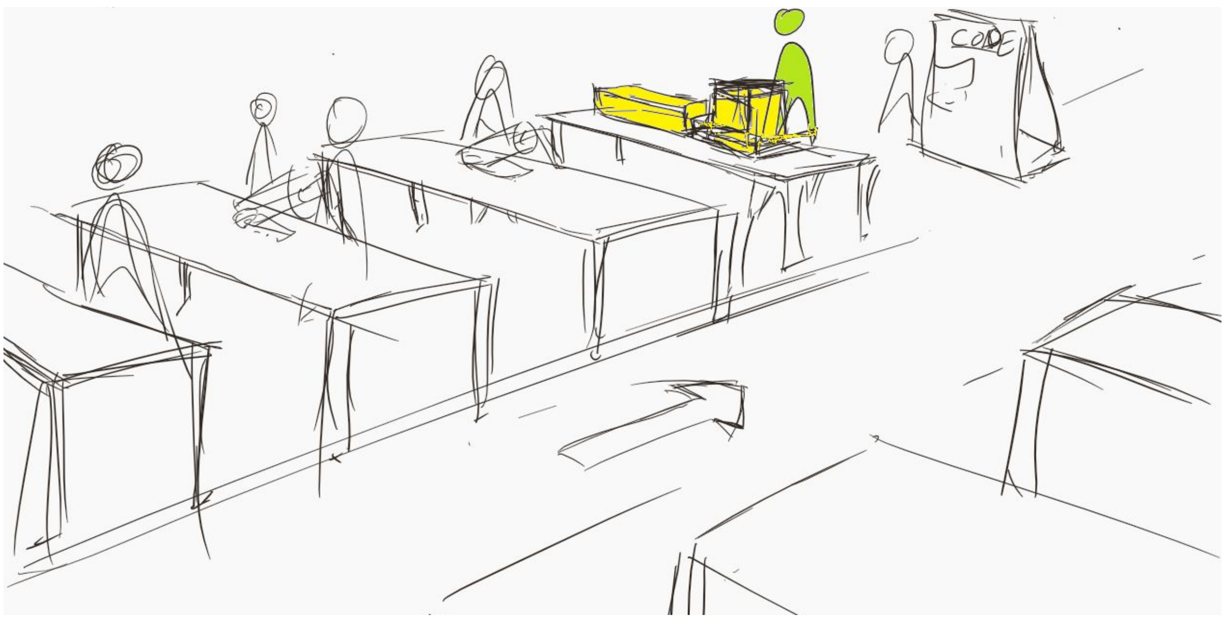
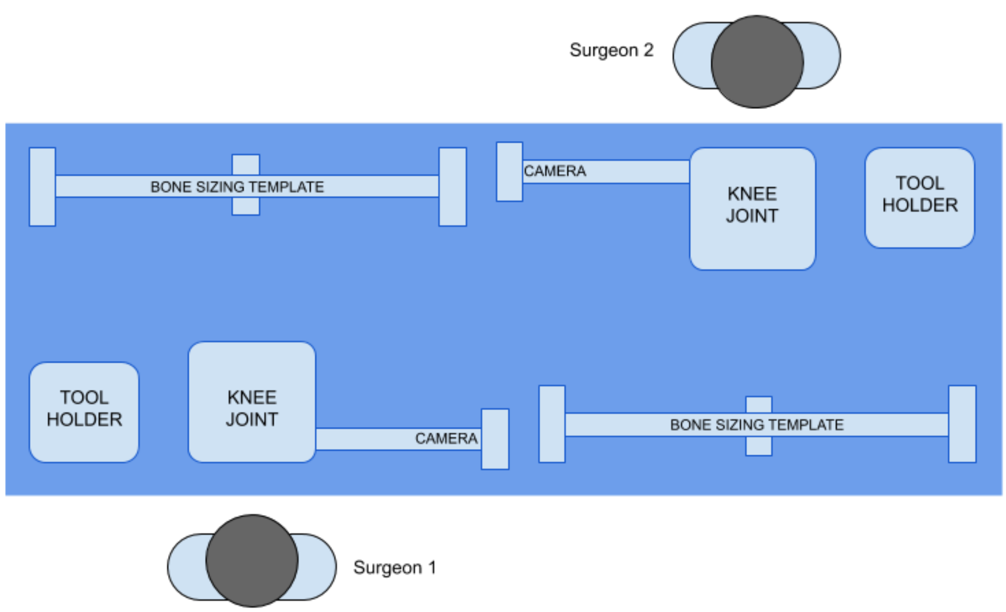
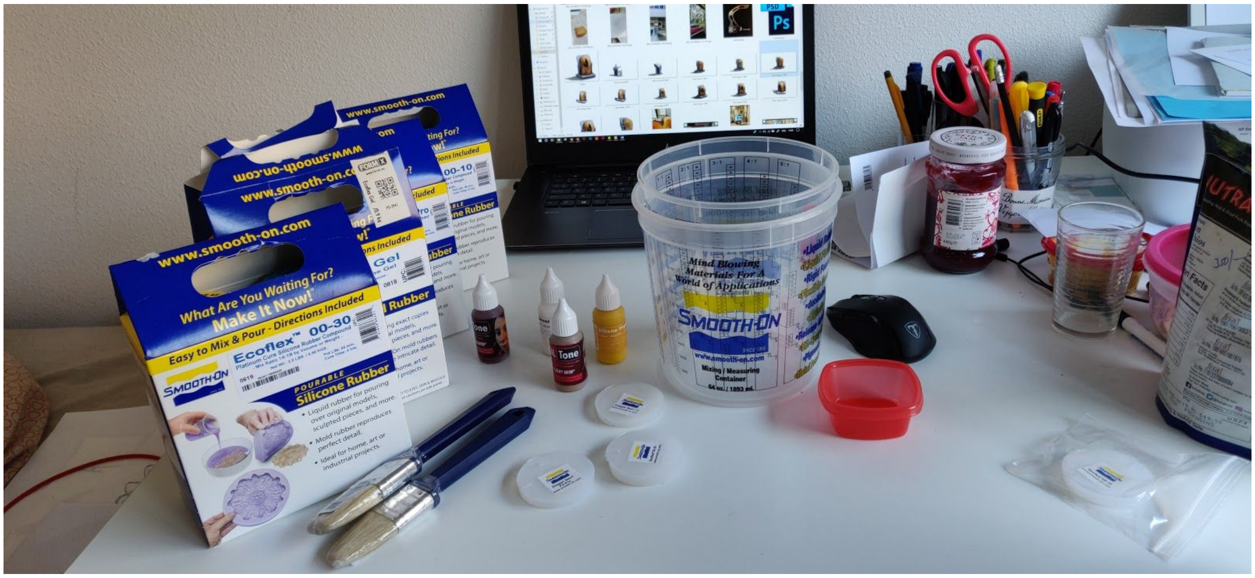


Table layout



Silicon molding

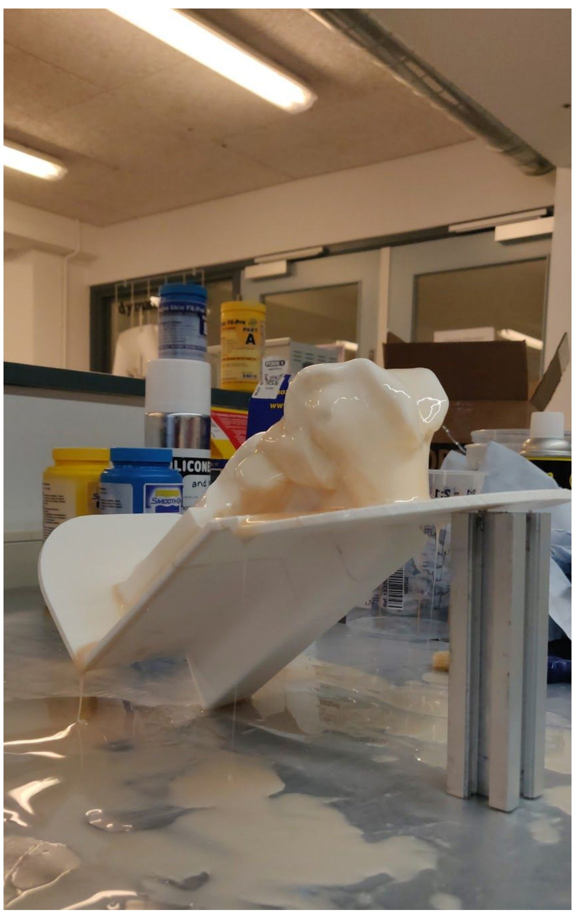


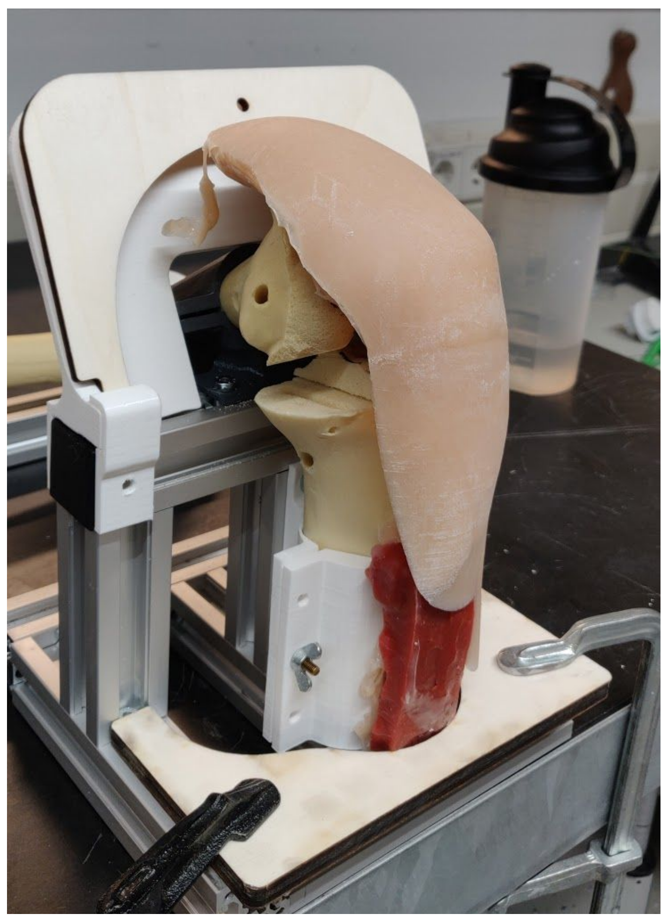
These are the three types of silicons that I used, one for dermis layer, one for far layer and the other for muscles. I used three colors, ‘light skin’ for dermis layer, ‘yellow’ for fat and ‘fresh blood’ muscles.

I casted the muscles first into a random block and the then cut them into four quadriceps muscles and one left tibialis muscle.

Trial molding

The first attempt wasn't really great, The dermis layer got too thick before it flows all around inside the mold so I couldn't inject the fat ayer in it. So it ended up as a half knee.



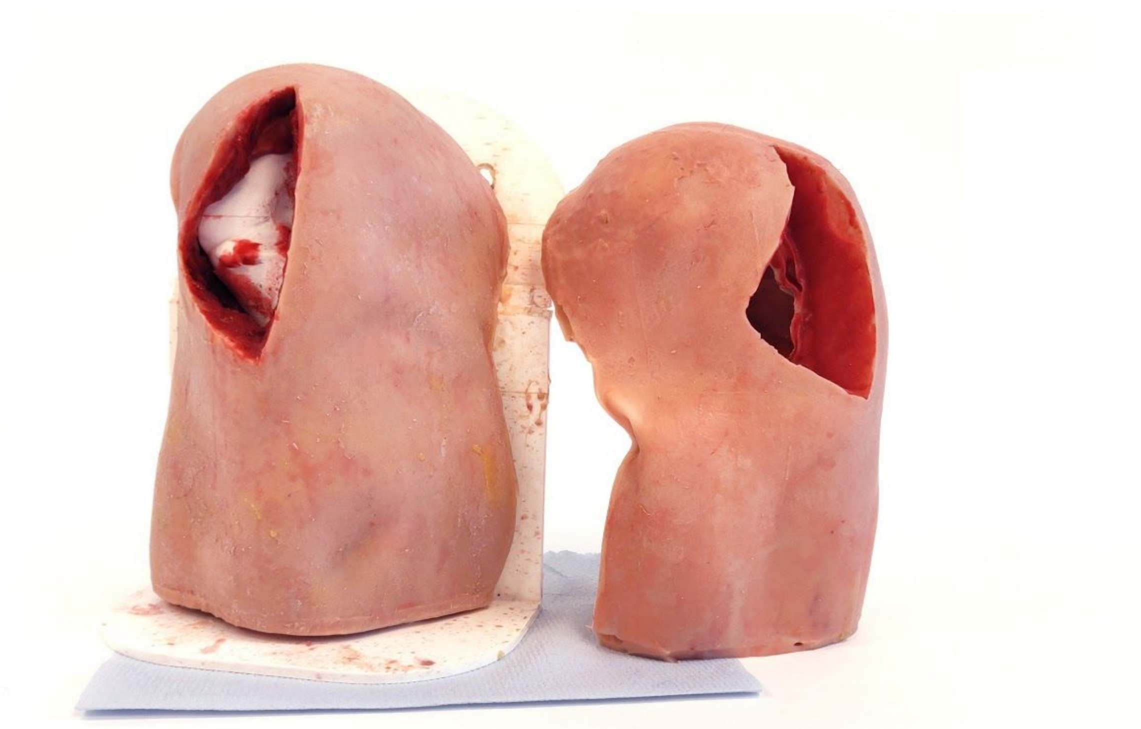


Second attempt


Ecoflex GEL
Ecoflex
PLATINUM SILICONE
www.smooth-on.com
Make It Now!
9:1
8:1
7:1


Ecoflex GEL
Ecoflex
PLATINUM SILICONE
www.smooth-on.com
8:1
7:1
3:1
2:1
12:1
10:1

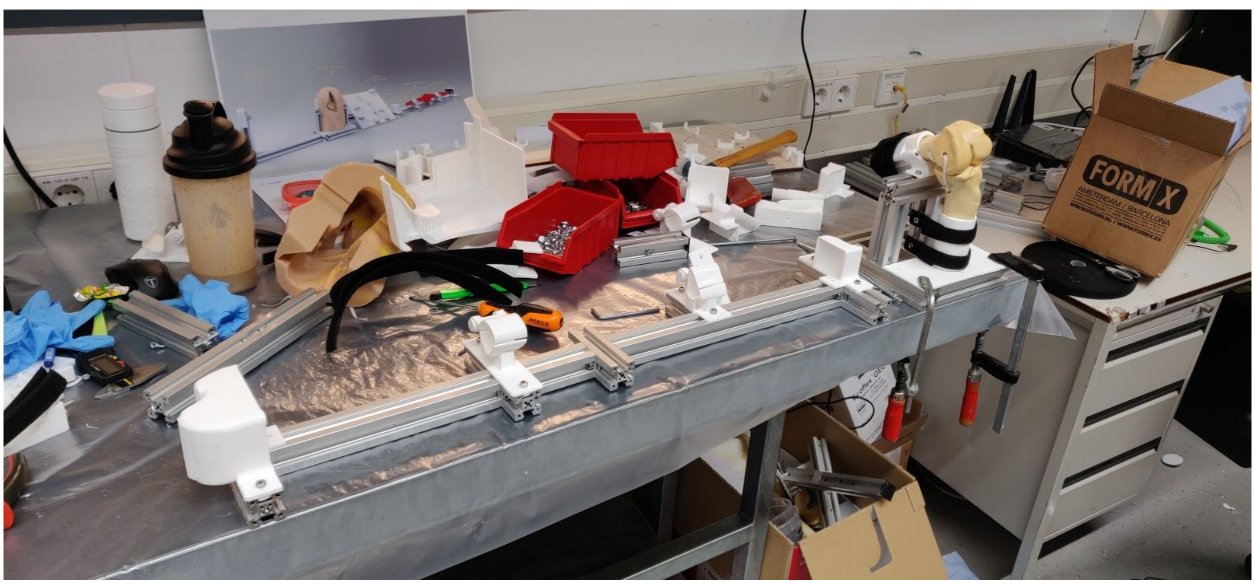

Make It Now!
GEL



Eventually I was able to make two soft tissue simulations with some skin texture. One of them has got a very sticky surface due to my errors in molding. There were few tricks to make skin better which I understood later after making these two models. Hopefully next attempt would be better.

Test setup assembly

I have all the 3d printed parts and aluminum frames ready for assembly. Although assembly took quite longer than I expected due to the the metal frames.



Pack n go

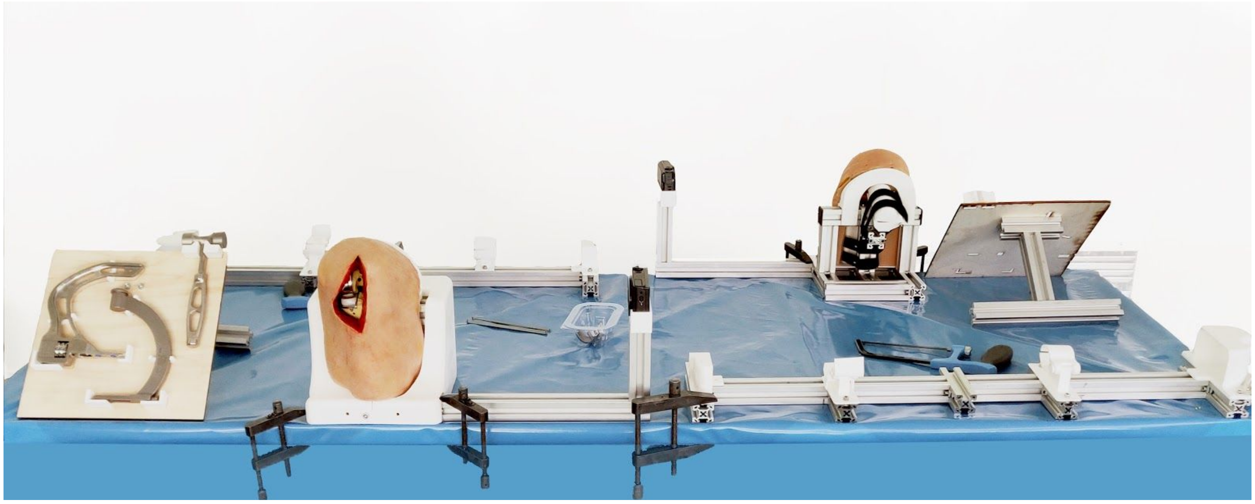
We started after the noon on Sunday and arrived at Keble College in Oxford.

Weekly newsletter - week 7

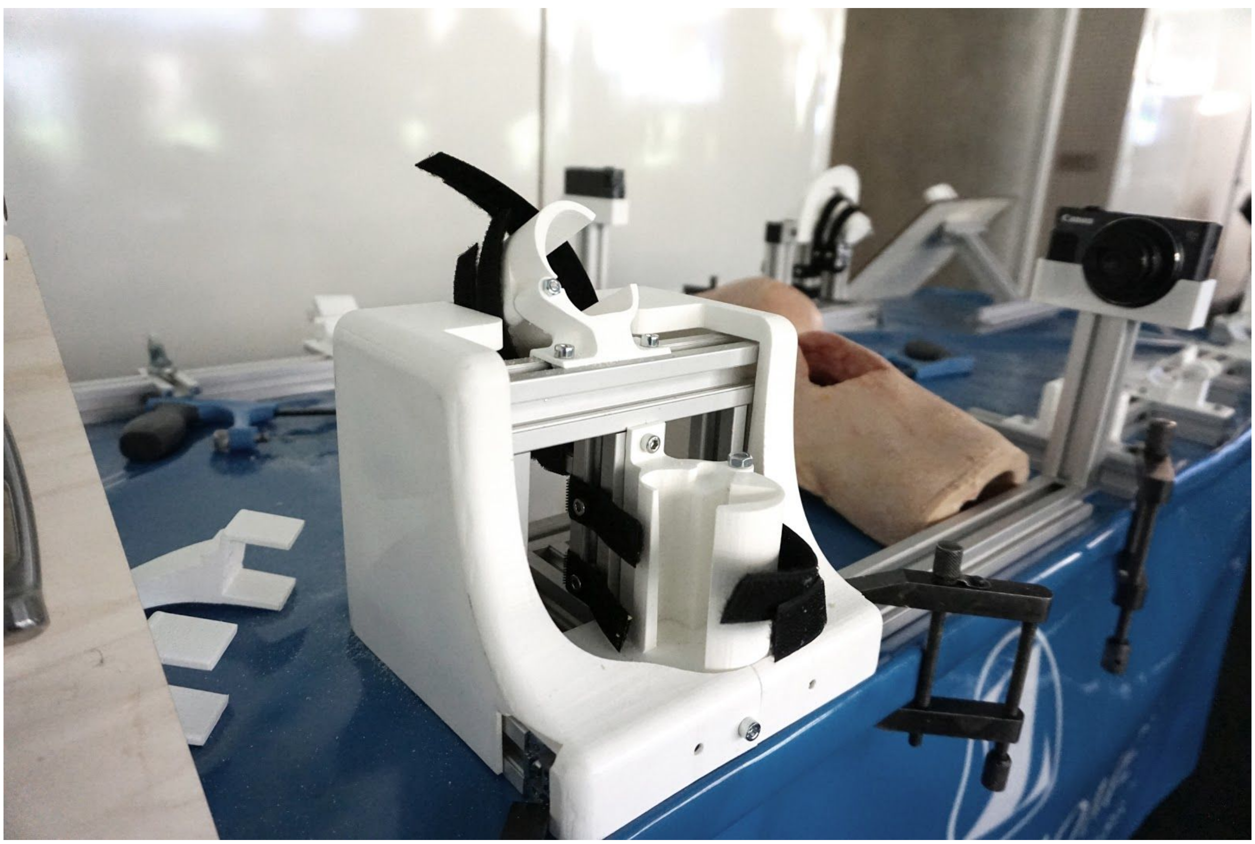
Oxford visit - Keble College

Oxford training workshop setup

The training setup was already ready and I got a table at the end of the hall to setup my model.



I was able to set it up as planned, but it’s just that the table wasn’t sturdy enough. The lighting and the table are few things that I need to take care of in the next visit. But I had enough place to set up the cameras the way I wanted and it was ready for the surgeons to try on.



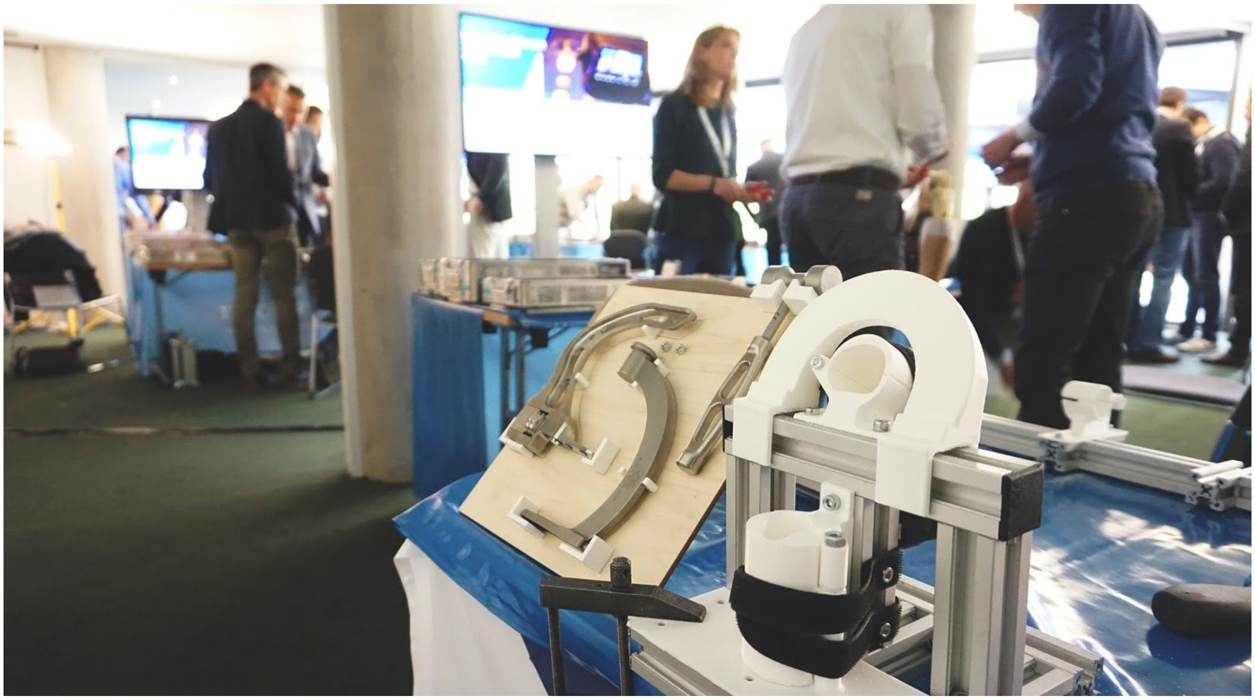
David murray visit

Prof. David Murray and his team made a quick visit before the workshop begins to see what we’ve got. We explained him our plan that surgeons can try on the setup after they are done with sawbone procedure during the workshop. David said the setup looks very realistic and agreed for letting the surgeons to try on it during workshop. I received some quick feedback on the structural design. They said the model is a good advancement from the current model they have in the training workshop. They liked the idea that surgeons could bring their own bone to work on this setup so that they cannot blame the tibial cuts.

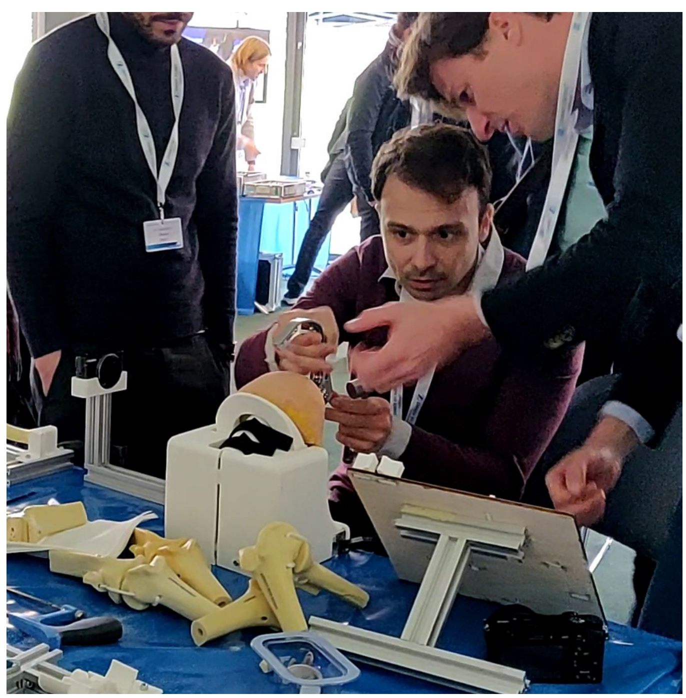
John O’Connor visit

It was an honor that John O’Connor, the Inventor of Oxford partial knee visited the workshop to see the prototype. He wanted to understand the added value of this setup to the existing workshop. He believes it would be advantageous but wanted to see it in action when the surgeons are working on it during workshop.

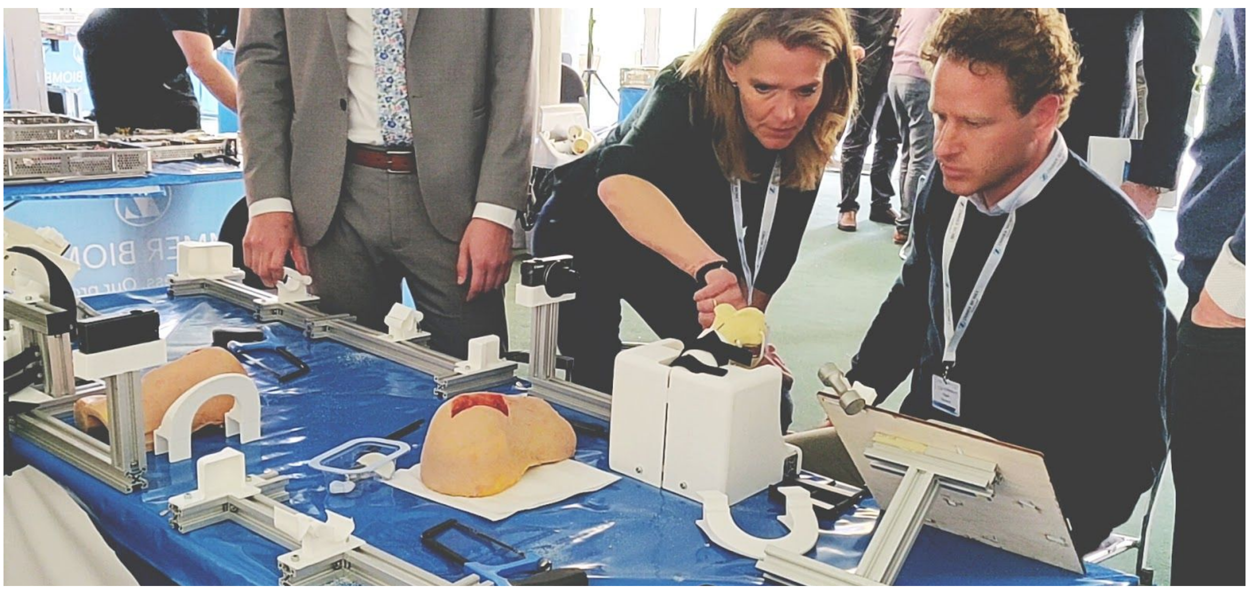
Sawbones workshop session 1



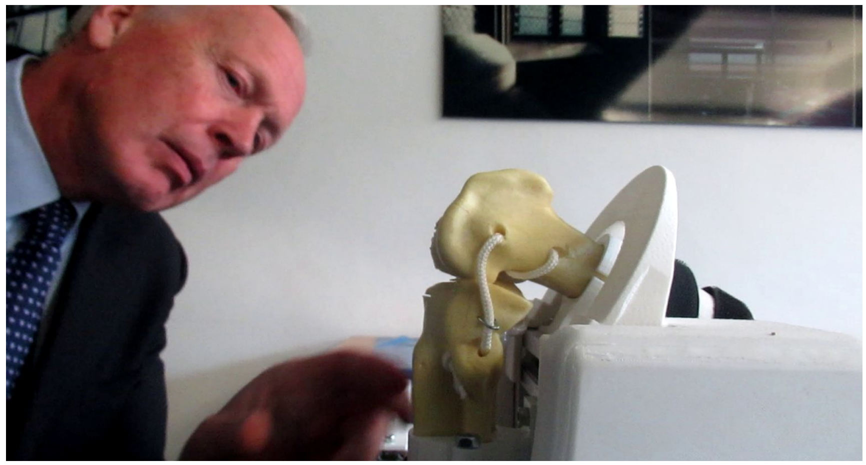
There two groups of surgeons training in workshop. Blue group started first. As soon as they finished the tibial preparation, Prof. David encouraged the surgeons to visit my table to try insertion procedure.We had three surgeons visiting us at the table wanted to try the procedure. Two of them were doing on one side of the table and the other surgeon was doing on the second setup on the other side of the table.



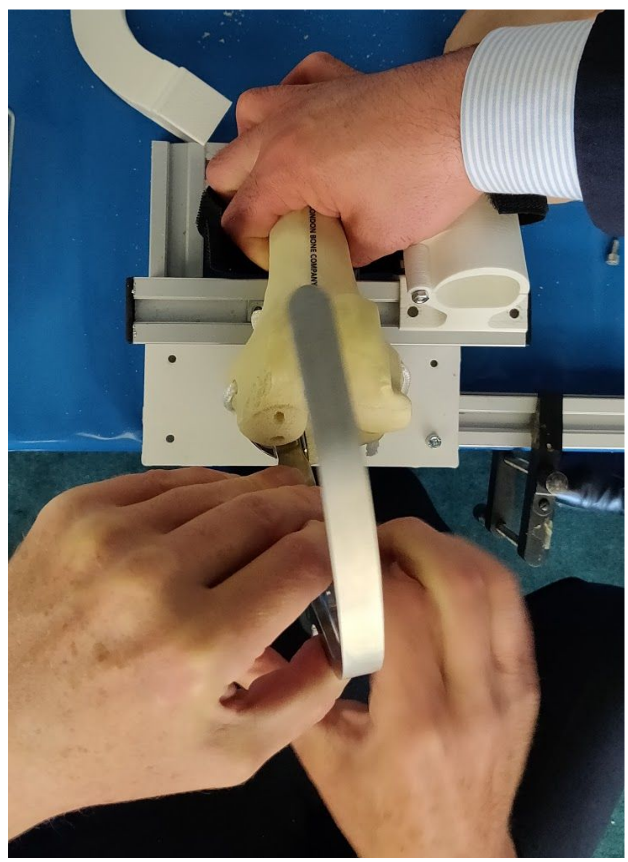
Sawbones workshop session 2



David Murray’s test



Prof. David Murray was able to test the prototype at the end of the day. He tried to get hands on the prototype and thought that he would need little freedom to move the bones.He said that although it’s good to have the tibia fixed, there needs to be a little freedom to fix it wherever the surgeons wants. So he removed the sawbones from the setup and put it over to show me the valgus deformation that they would do to to increase the joint gap during tibial insertion.

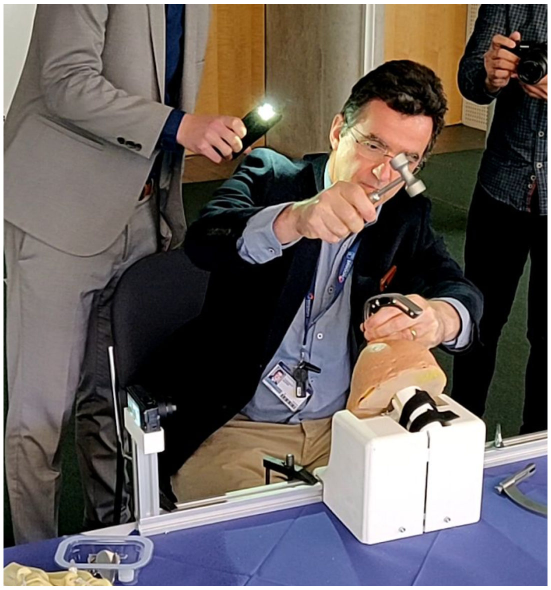


Abtin Alvand’s test

Dr. Abtin Alvand had few thoughts on the fixture design as well. He said the femur is not straight generally, there would be some inclination when we look from top. Prof. David helped him removing the femur from fixture and held it in a desired position.

Andrew Price test

Prof. Price was able to test the device on the second day. Here I fixed cameras on both the sides as I had only one setup. One of the first things he pointed was the lack of retractor to clear off the soft tissue. He was also missing a black chisel that they use it to flush the tibial component to the bone. He says the model was already able to solve most of the purpose, tracking the values and feedbacking would only be an additional benefit.



Summary & keypoints

Demo kit with uncut & pre-cut sawbones

Tim, product manager for Europe likes the idea of sending a demo kit to hospitals, but he says surgeons don't want to do the tibial cuts again. So it's good to have an option to order demo kit with precut sawbones. But then Dr. Hemant Pandit says, there should also be an uncut/regular sawbone in the demo kit where they can perform the whole surgical procedure on it.

Bone sizing needs to be simplified or eliminated

Cutting the bone to smaller length to fit in the product has got a lot of negative feedback. Dr. Hemant says if it is not the part of real procedure, it better not to make surgeons do it. I even cut my finger while cutting one of the bones myself. Michael see it as unsafe and may be better not to have it in the final product.

Adjustable height

The table I have been using at applied labs is much higher and I completely ignored about the training table height. So I let the surgeons sit on a chair for the procedure. But an adjustable height seems to be an important thing to consider for the next iteration.

Silicon soft tissue is anatomically incorrect

It was CAD error that I placed the bones slightly away from the skin. I didn't had a reference to place them together in 3D space. This resulted in a very thick fat layer on the anterior side.

Tibia need to be free and fixed at the sametime

Besides, Prof. David Murray mentioning, Dr. Hardeman's from Belgium also emphasised on having the fixed and at the same time having some freedom to move the tibia or femur to adjust the right position. usually they adjust this to make sure they have enough gap for tibial insertion.

Structural design first

As soon as the Oxford surgeons try the insertion procedure on the prototype, I brought up the question about level of analysis required. I asked them if analysing the insertion and impact patterns will be useful in feedbacking and if I even make it happen, what kind of value does it add. They say that the physical prototype already solves the purpose to some extent. All I have to consider is the ease of using the product and freedom to move the tibial components. The soft tissue already adds little value in simulating the visual constraints. There could only be a minimal use of sensors something like in the hammer just to track the impact force and make sure they do not exceed certain limit. But it was still unsure that feedbacking these values would be helpful to the surgeons or not.

Retractor for soft tissue

Retractor is generally not used in the training. I made sure that the incision is wide enough to do the procedure, but they still wanted a retractor to push the soft tissue away and a black chisel to flush the tibial component to the bone.

Tracking Insertion patterns

Prof. Price mentioned that I was almost close to what is required. he thinks tracking few parameters like impact patterns on inserter would be helpful. Tracking number of impacts on the side and the top of inserter, finding if they're exceeding a certain angle in the beginning would be useful.

The lighting isn't good

Prof. finds it too dark in the incision area. It could be the reason that I changed the setup position for the second day. But like he mentioned, they usually have a very bright lamp in the OR which is missing in this case.

Bone density is not similar

Prof. David Murray and Dr. Abtin Alvand said the current sawbone is not very good simulation fo the real bone. When I am trying to make realistic simulation of procedure, it would be good to use the realistic bone simulation as well. They suggested to get the composite bones from Sawbone company.

Weekly newsletter - week 8

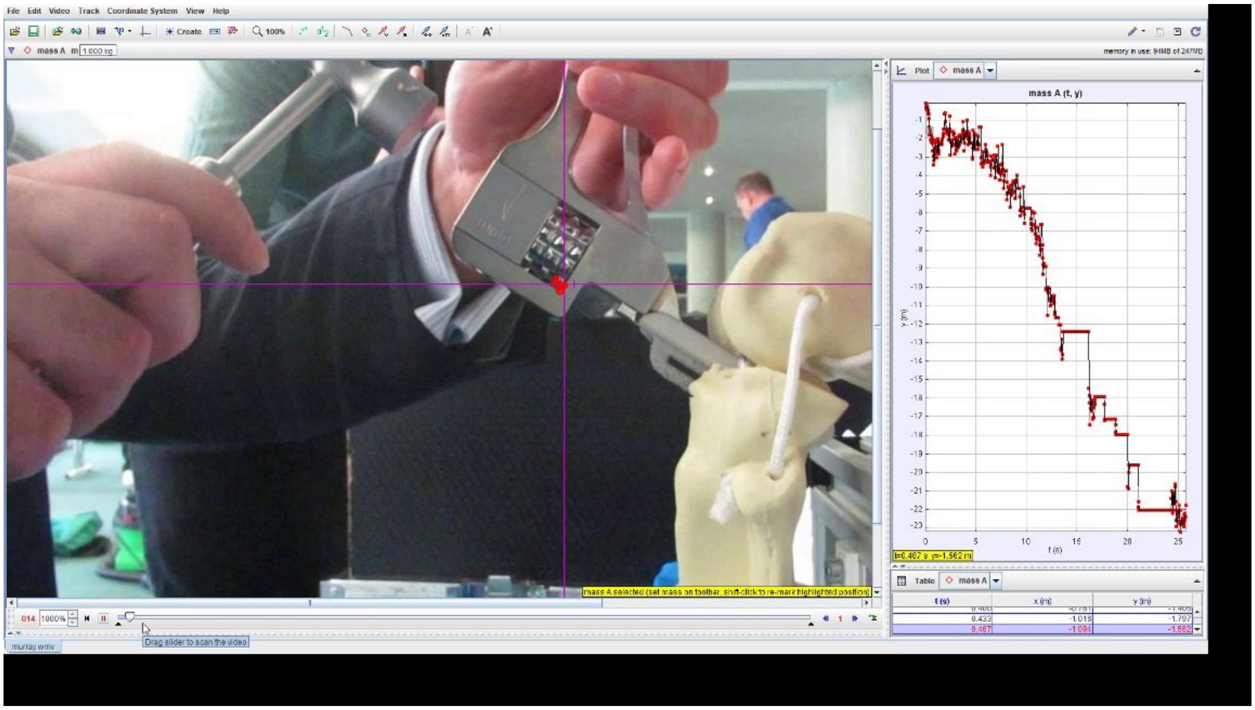
Midterm presentation

Key points

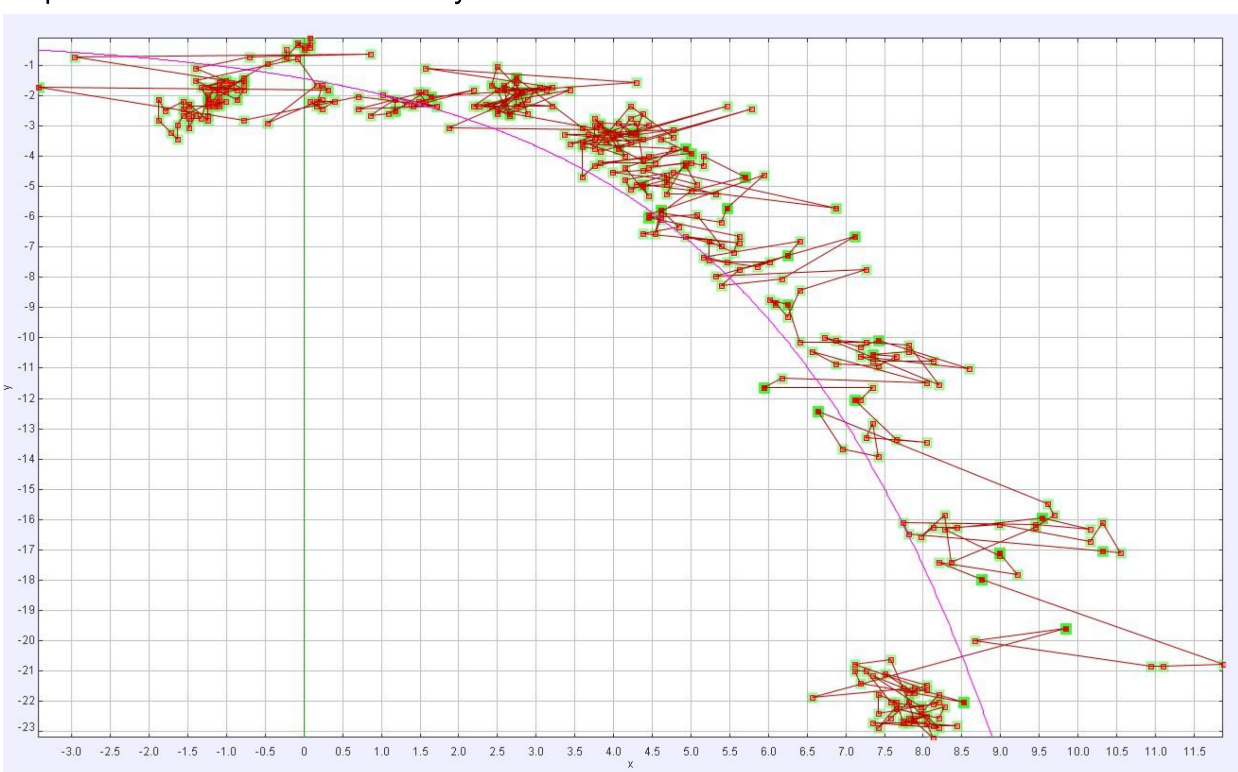
Its okay that evaluation of learning curve is very subjective. So the evaluation of the product can be on different levels. Look and feel comparing to a real surgery can be the first level of evaluation. Secondly, the opinion of surgeons and lastly a long term observation of patient outcomes over the a duration of 2, 4, 6 and 12 months.

When the composite bones are expensive to be used in the sawbone training, there could be alternatives like 3D printing. Since we only need the bone-implant interference, 3d printed bones with right infill density could be used to replicate it. Sawbones company uses the. When we have pre-cut bones with keel slot, surgeons could directly try the inserting the implant.

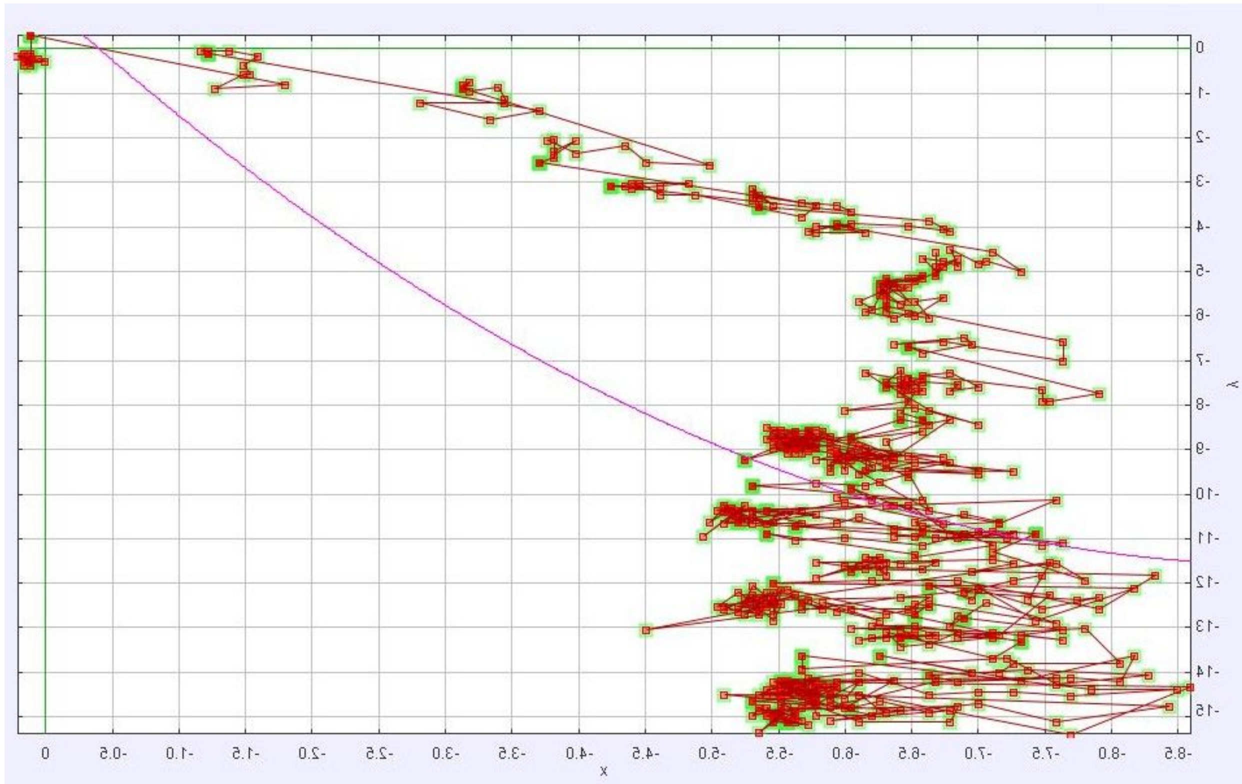
Analysis



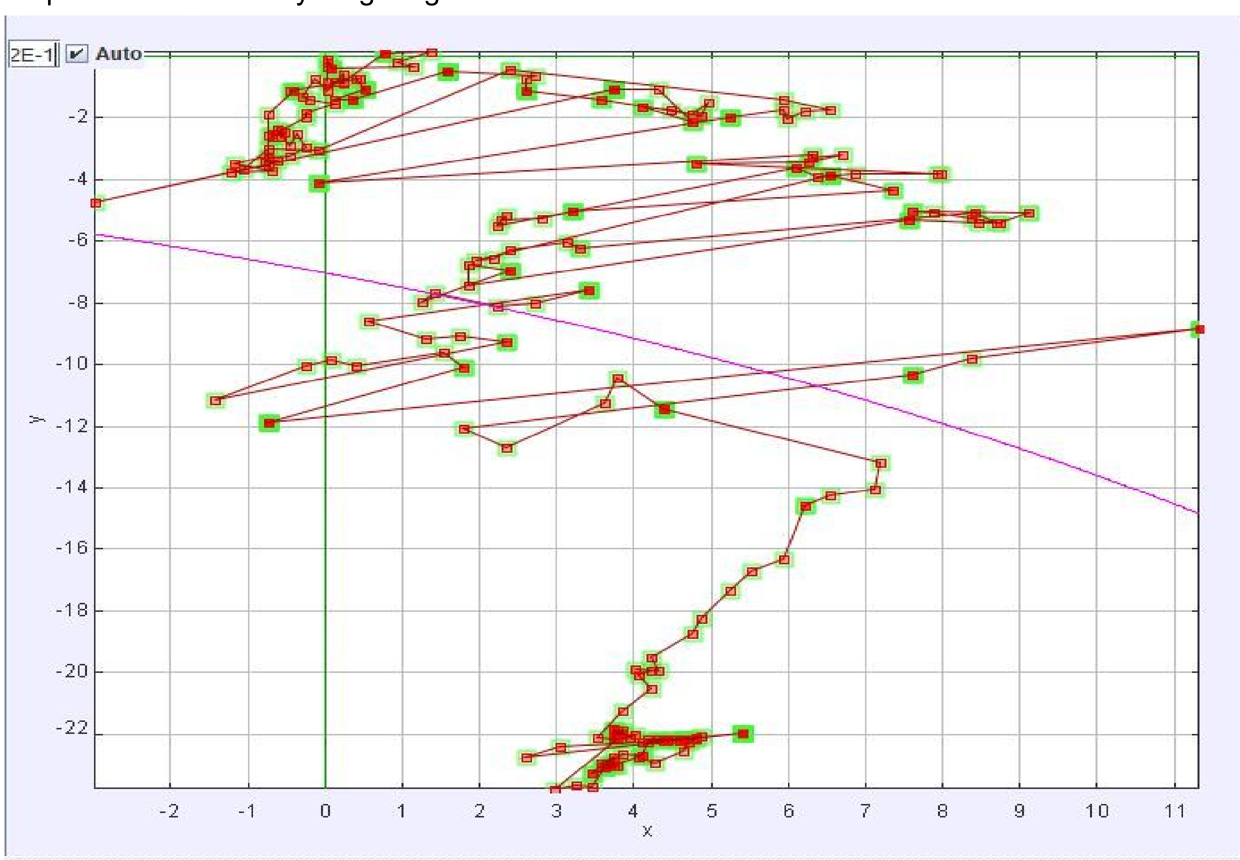
2D path of insertion of David Murray



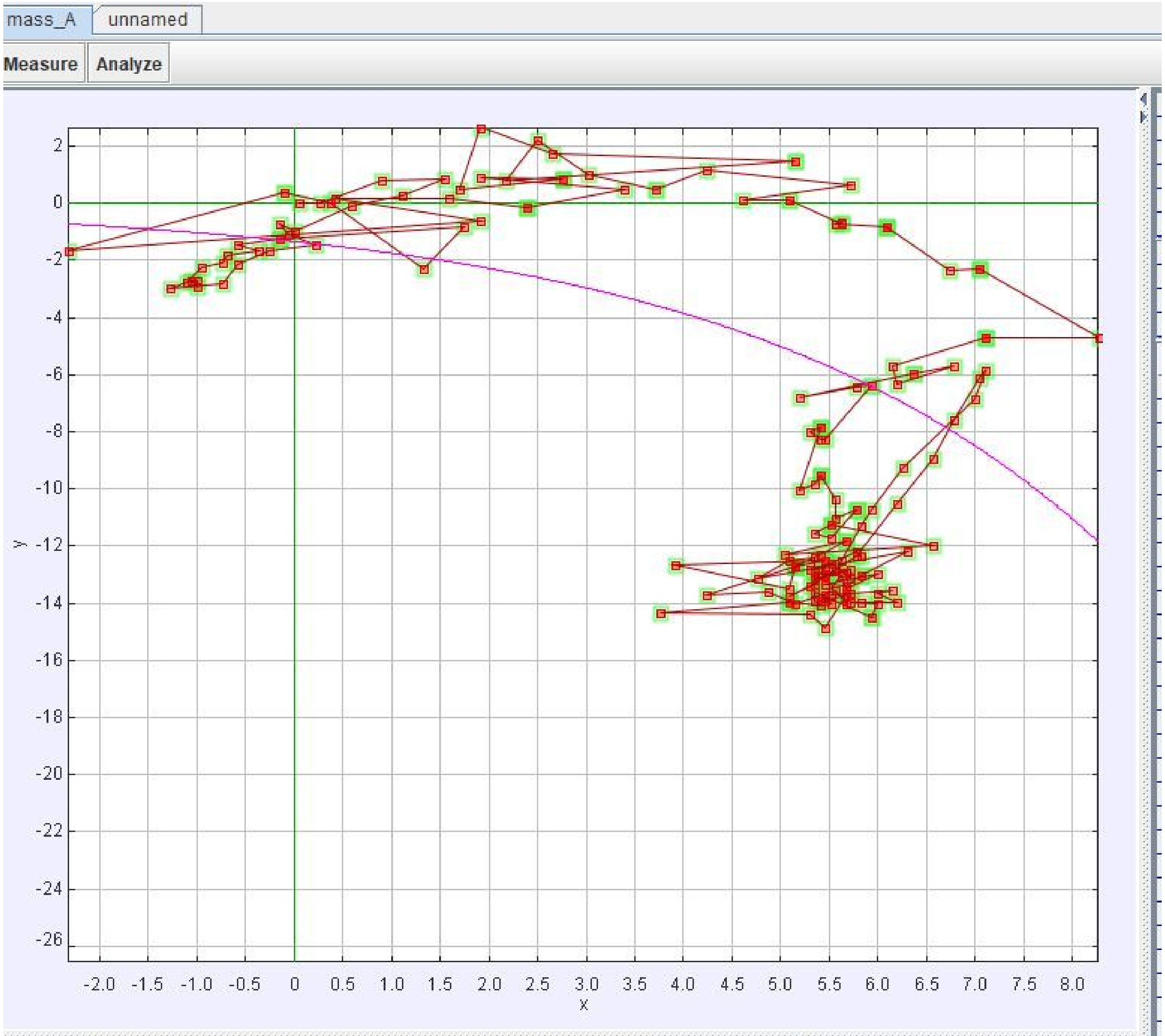
2D path of insertion by Andrew Price (flipped because it was captured in an opposite camera)



2D path of insertion of young surgeons in session 1



2D path of insertion of young surgeons in session 2



Conclusion

2 dimensional path are plots of literal movement of inserter at a specific point. This allows only a brief comparison of the movement of inserter of young surgeons with that of Oxford surgeons. But there are more parameters that can be extracted from the analysis. It need some more time to be spent in evaluating those parameters before drawing some conclusions out of them.

Sawbone testing

I tried making the keel slots on the sawbone PCF20 which is a close simulation of actual bone density. I made the keel slits of width 2.8mm (As said by Duncan from Swindon office). I had to really hit with greater impacts compared to what i have been doing on the normal sawbones that are used in workshop. Since I have never done any insertions on cadavers or any other real bones, it was a completely new feel of impaction. I wasn't sure if that is exactly how it feels on areal bone. If that is so, there is definitely a lot of difference between implating on the sawbones that are used in workshop and impacting on a real bone in surgery.

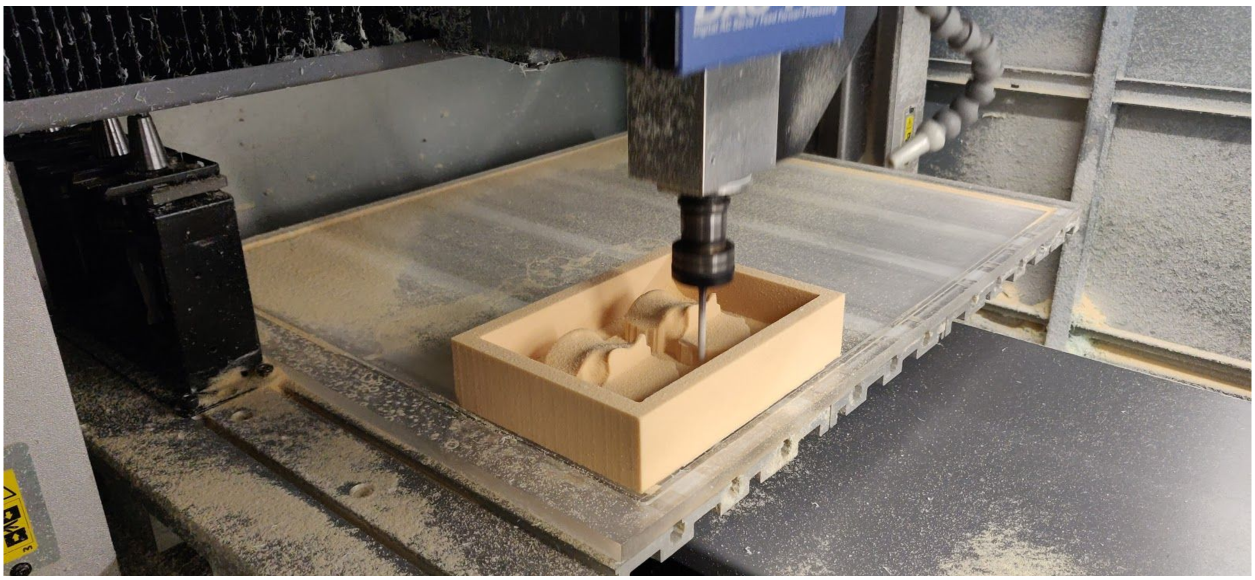
Next steps

More user testing and analysis
During the next week, I wanted to invite some young surgeons to the faculty and let them do the procedure in controlled conditions.

Weekly newsletter - week 9, 10 & 11

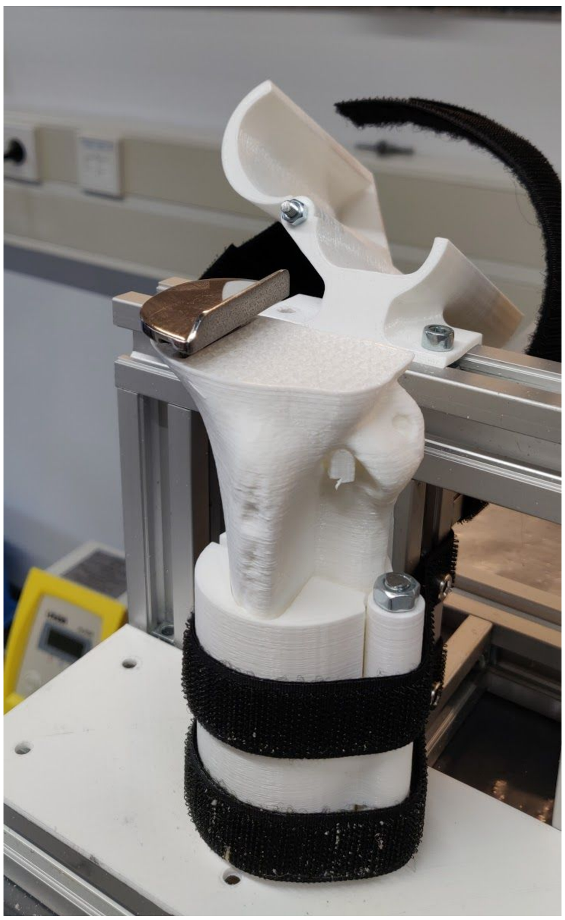
Sawbone preparation #pcf20

I iterated a bit more with polyurethane to make a tibia that is closer to an actual bone. The current sawbones that are used in the training workshop are great for the the tibial preparation and trial implantation. But when it comes to implanting the actual implant the sawbone is too soft to provide enough resistance. As suggested by Duncan, Zimmer Biomet engineer at Swindon, I got the PCF20 sawbone block which was approved by FDA that it has similar density to actual bone. I milled the block in the shape of tibial condyle and fixed it to a tibia step.



3D printed bones

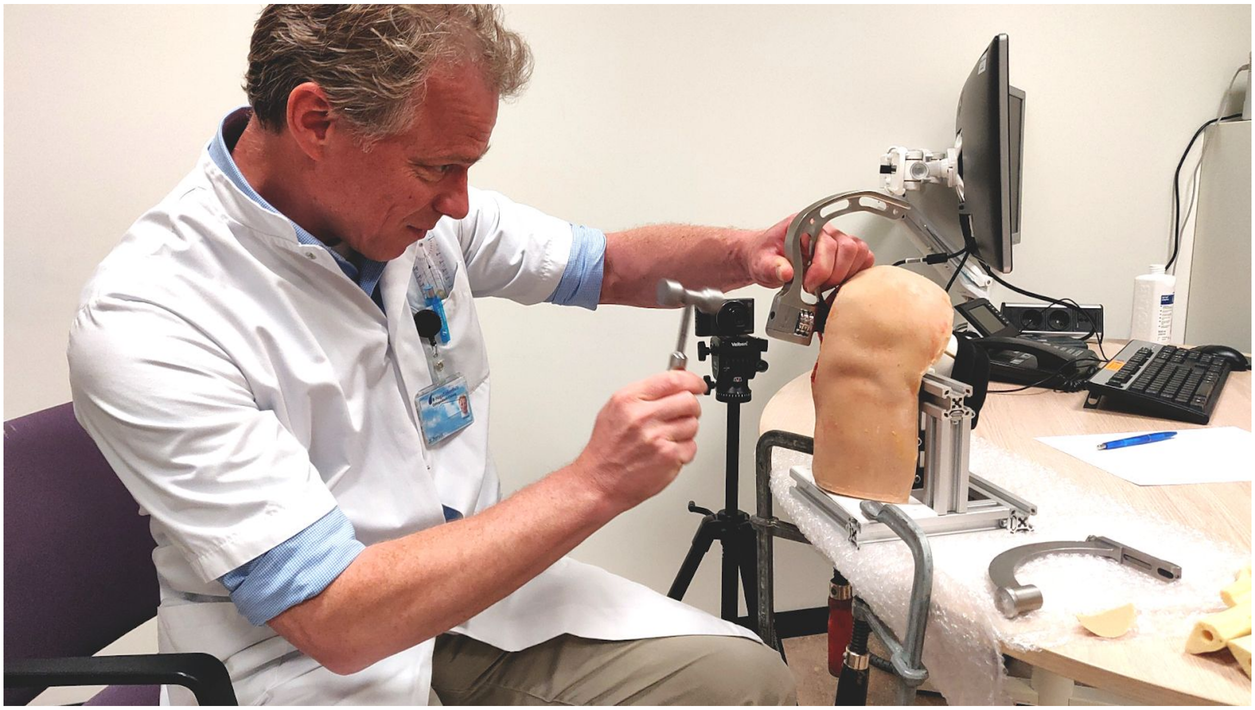
Besides the thicker bone, I also prepared some 3d printed bones with 20% infill and with a wider keel cut. In the first i tried implanting myself with the same keel cut width and it was so hard for me to implant on it. I almost had to fracture them to the implant in. Then I changed the width couple of times to make the something closest to pcf20. The plan was to approach a surgeon with this 3d printed bone, pcf2 bone and a normal bone to test which of these bones are more similar to an actual bone.



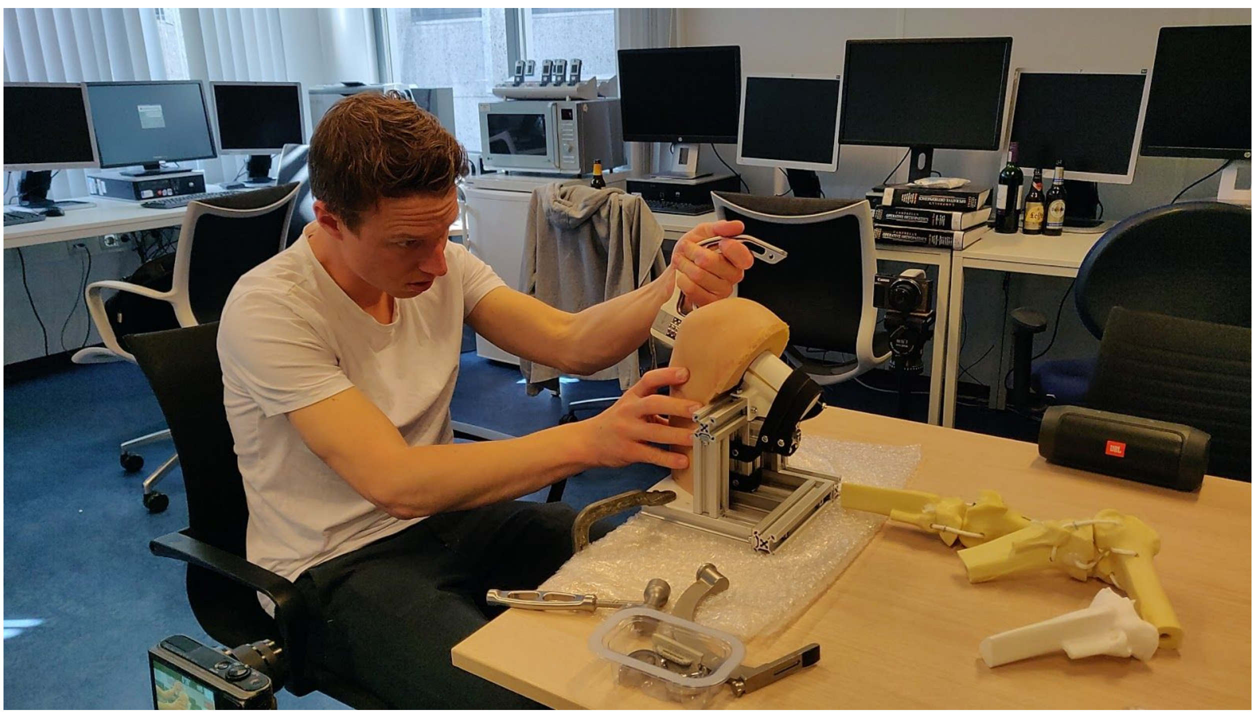
Haga Visit

Test with Dr. Spruijt

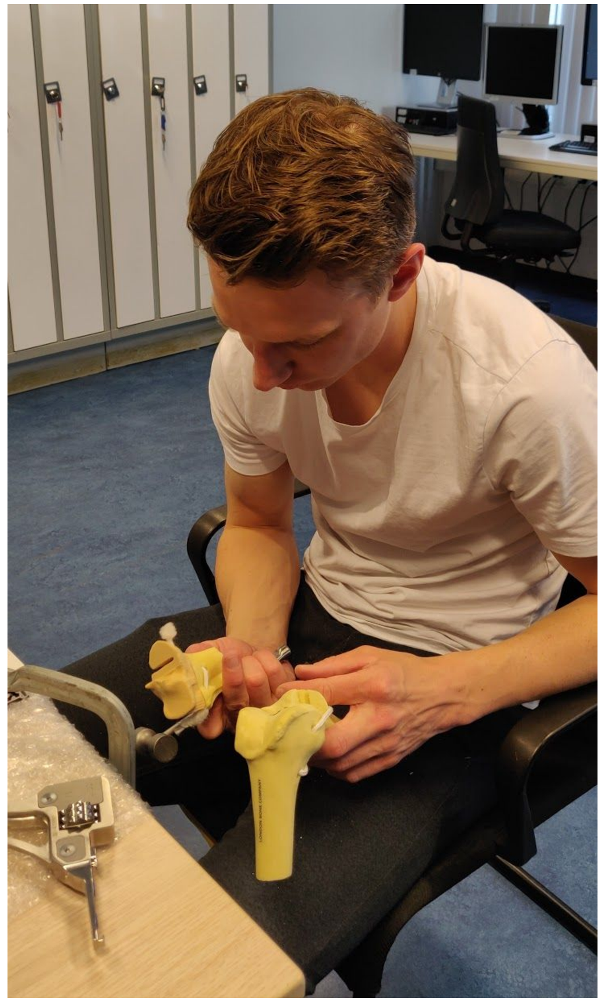
Michael arranged a meeting with Dr. Spruijt and we took the prototype to Hagaziekenhuis in The Hague. Dr. Spruijt agreed to test the the prototype. He thinks the soft tissue looks realistic and setup is useful for young surgeons to practice. He said the sawbone is too soft for implantation and that was the point I gave him the pcf20 bone and 3d printed bones. Pcf20 bone was little better than the normal sawbone, but the condly got broke when impacting. He thinks this is because the whole bone is not made in one material. The tibial condyle which is is pcf20 is not able to transmit the forces to stem which is glues to a normal sawbone. Lastly, he tried with a 3d printed bone and says that it is what harder than a real bone. If it is being this difficult to implant on a real bone, he would be worried and go back to check the tibial preparation.



Test with Wouter Eilander

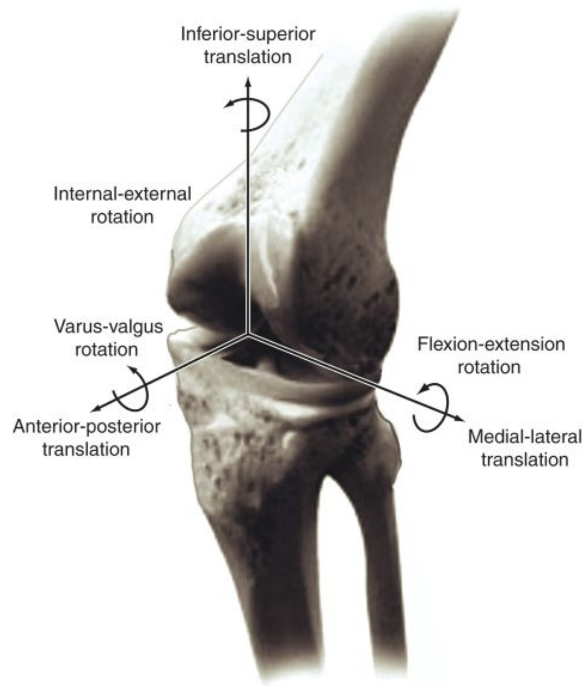


During the same visit I was also able to test with Wouter, who worked as an assistant for Dr. Spruit. This test was quite useful as he belongs to the actual user group that is going to use the product eventually. He was quite excited to see and try implanting on the bones. I asked him few questions about his expectations out of such a device that they can use regularly to practice the procedure. He says it is quite useful for them to have such a device accessible in the hospital so they could practice before a surgery or try something different they wanted to try after a surgery.

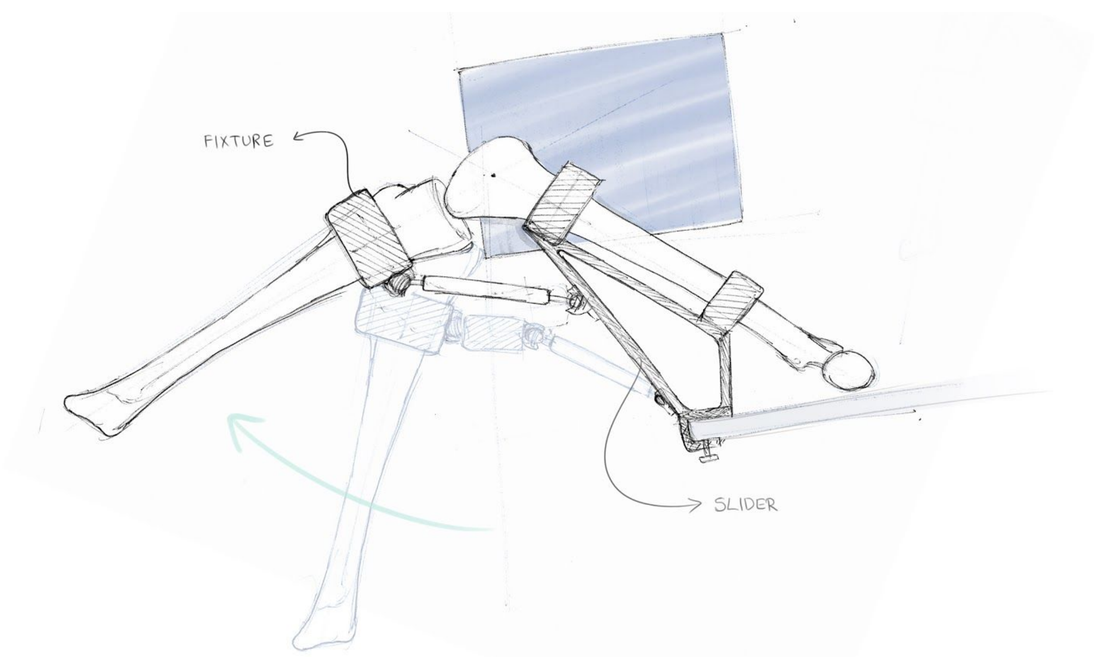


Fixture poc

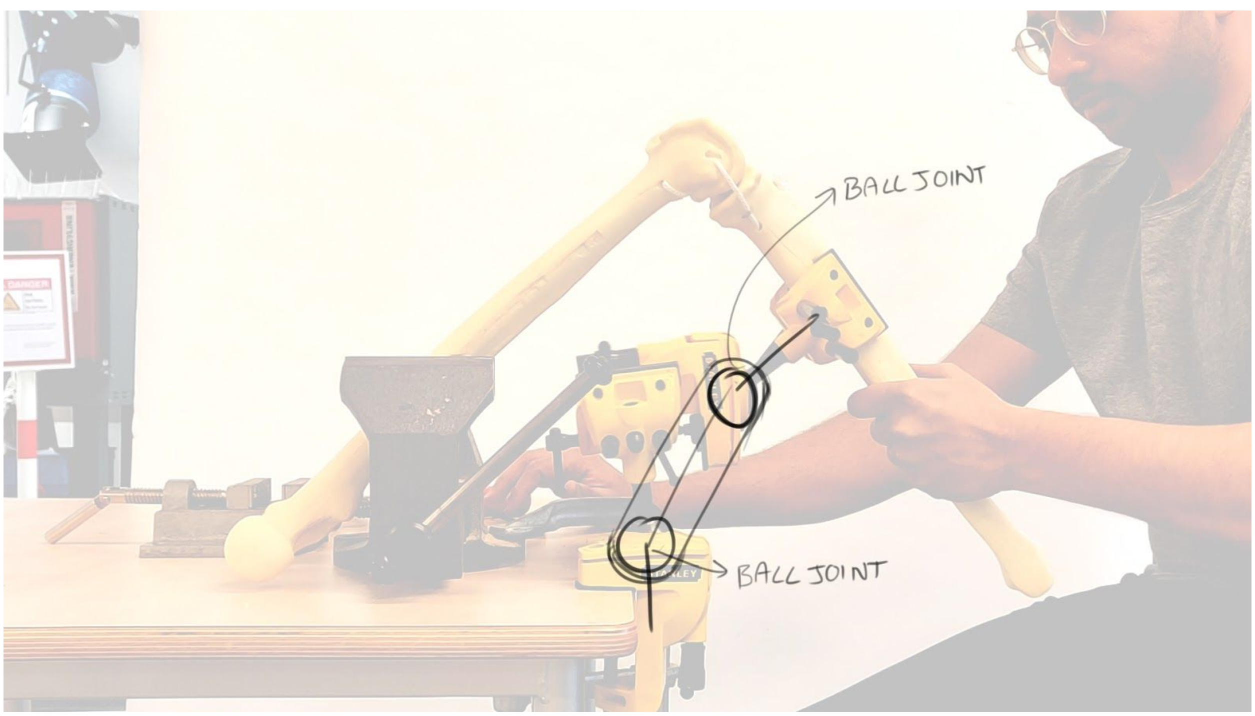
Looking back into the feedback from Prof. David Murray that they wanted to have the leg free to move and also fixed at certain point they want. So I looked into few fixtures that allow a desired movement of the leg and also can be locked wherever necessary. A Human knee joint has 6 degrees of freedom which is characterised as 3 types of rotations (a. Flexion and extension, b. Internal and external rotation and c. valgus and varus angulation). Flexion and extension ranges from 0 to 160°. Valgus and varus angulation in a normal knee ranges between 6-8°. An internal and external rotation 25-30° is possible. Besides these rotations, a knee joint also exhibits some translation of 1-10mm in different planes.



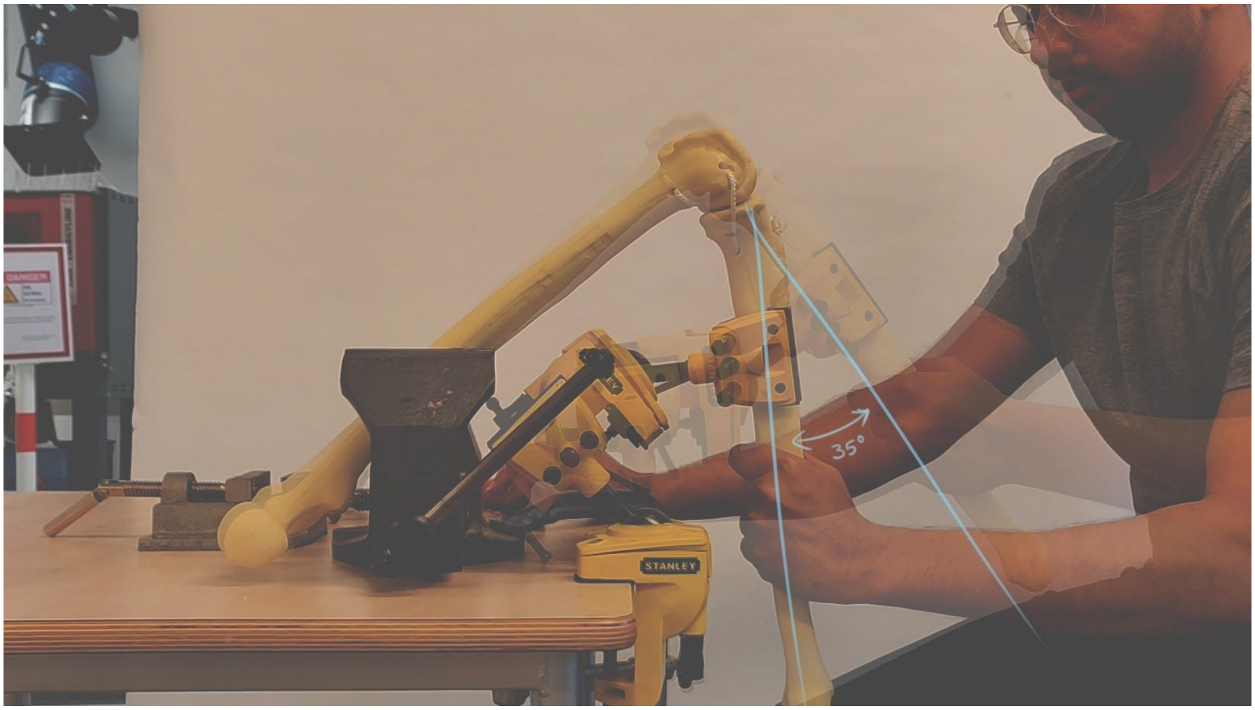
For the current model I am neglecting the translations. This is because if I have a fixture holding the bone far away from joint, the elastic nature of sawbone already poses some translation at the joint. So I only considered the rotational degrees of freedom to design a fixture. During a surgery when an incision is made and the bones are prepared with the cuts, the valgus and varus angulation is much larger than usual. Also the internal external rotations exceed the actual values.



The above idea seem to promising but having a double ball joint and slider bearing needs a lot of time to lock and unlock the fixture. I was trying to minimise the fixation time as it is not the part of real procedure in an operating room. During the insertion and impaction of the implant the surgeons usually use the leg in complete flexion and don't really extend except when they want to check the tightness of joint after implantation. So I do not require provide a fixture in the extended position. That eliminated the need of having a slider bearing. I tested the double ball joint with a small proof of concept(POC) without any slider.

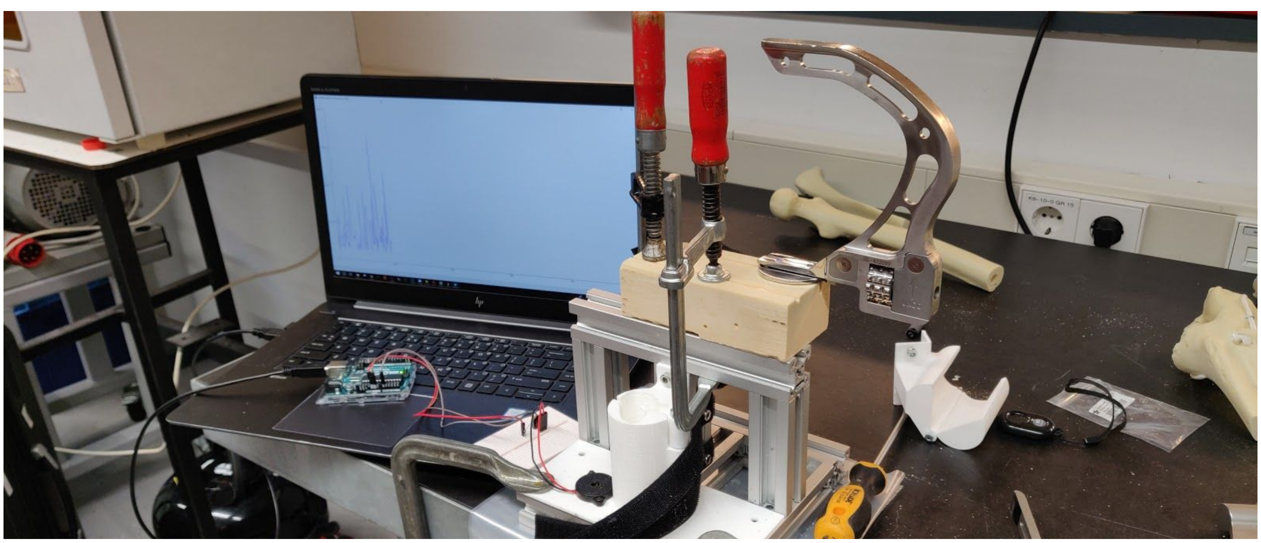


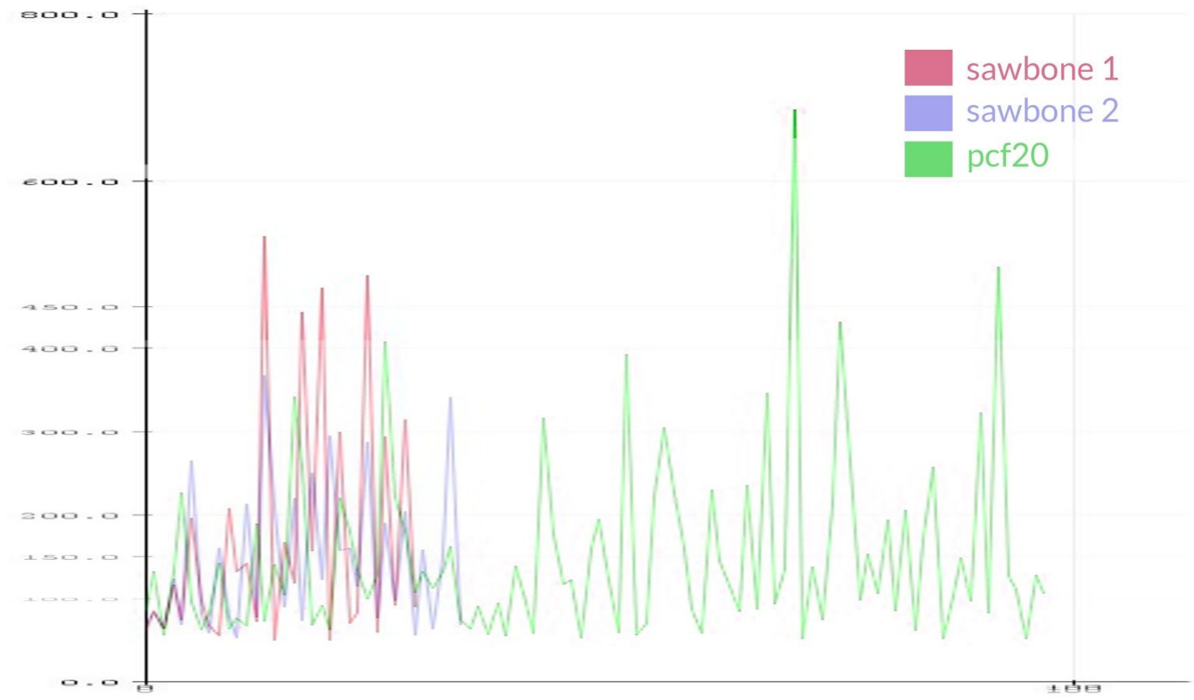
With this POC, I was able to achieve 35° of flexion and extension range, 20° valgus and 20° varus angulation. But couldn't achieve an internal and external rotation. This POC gave me a direction to conceptualise few concepts on tibial fixtures.



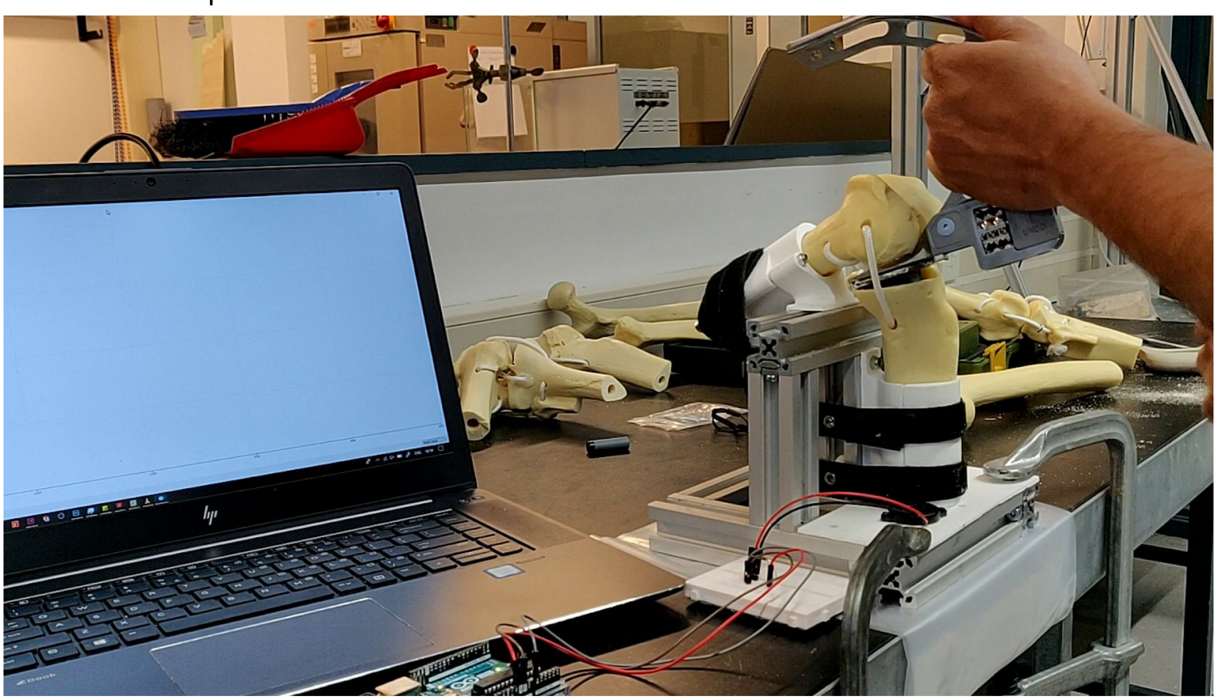
Electromechanical prototype

I have integrated a piezo sensor on the base of the prototype to analyse the impact forces. First I compared two tests on regular sawbone to make sure the values are matching. Then I compared those values with an another test with solid foam pcf20 block.





X axis is the timeline, and y axis shows the impact values on a scale of 0 to 1023. The values clearly showed the the impact force was while implanting on higher in pcf20 foam. Although it compares will the values are not very accurate. I am planning to make a more reliable sensor system that can get accurate values, compare them with an acceptable impact force and alerts the user if an impact exceeds that limit.



List of requirements

Before I jump into the concepts, I drafted the list of requirements and ranked them to Michael's preferences. (1= most important & 10= least important).

1. Product should be able to simulate a more reliable surgical process (Trial and final implantation).
2. The product should be reusable.
3. Soft tissue enclosure should be removable when necessary.
4. Soft tissue should be reusable and bones should be replaceable.
5. Full flexion and Extension should be possible.
6. One surgeons alone should be able to do the procedure.
7. Surgeon should be able to operate conveniently in any posture.
8. Should have height adjustability.
9. Should be able to fit to most to the tables.
10. Should be portable.

The 'good to have's (no ranking)

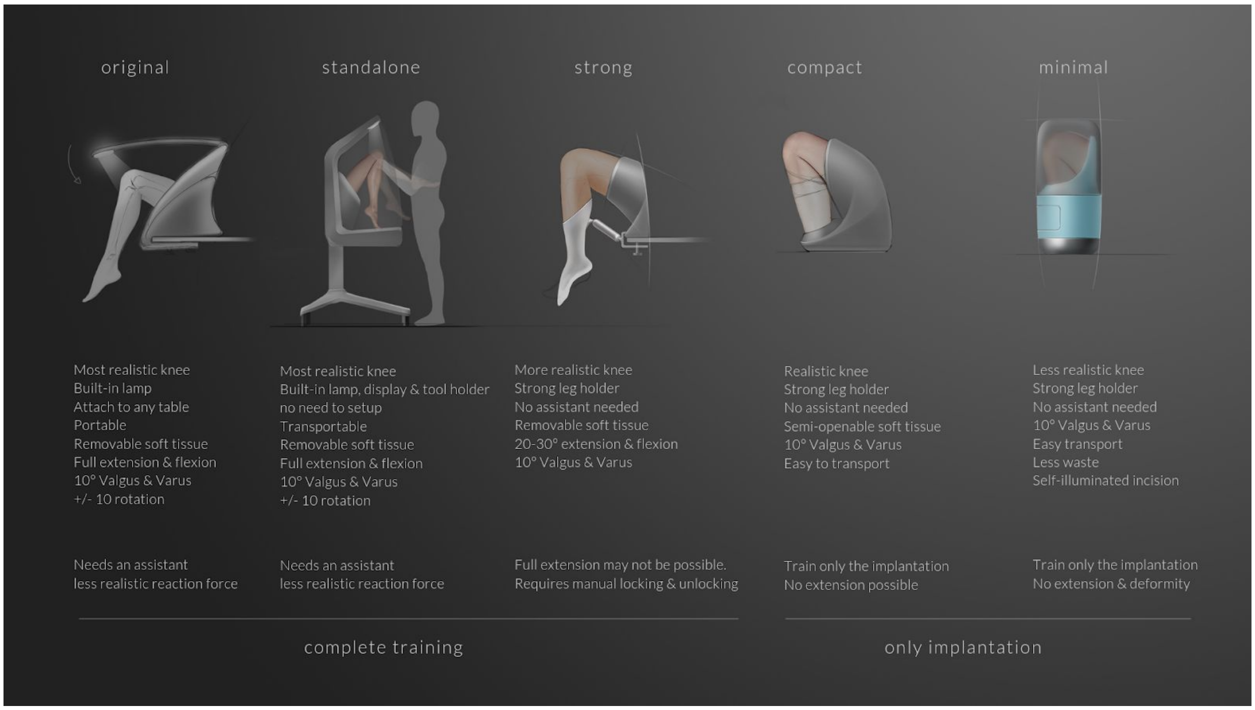
1. Product should provide feedback on impact force & insertion procedure.
2. A good simulation of light is necessary.
3. Clamping the bones should be as simple as a click of button.
4. Soft tissue sleeve should be easy to put on and off.

Concepts(in a separate document) :

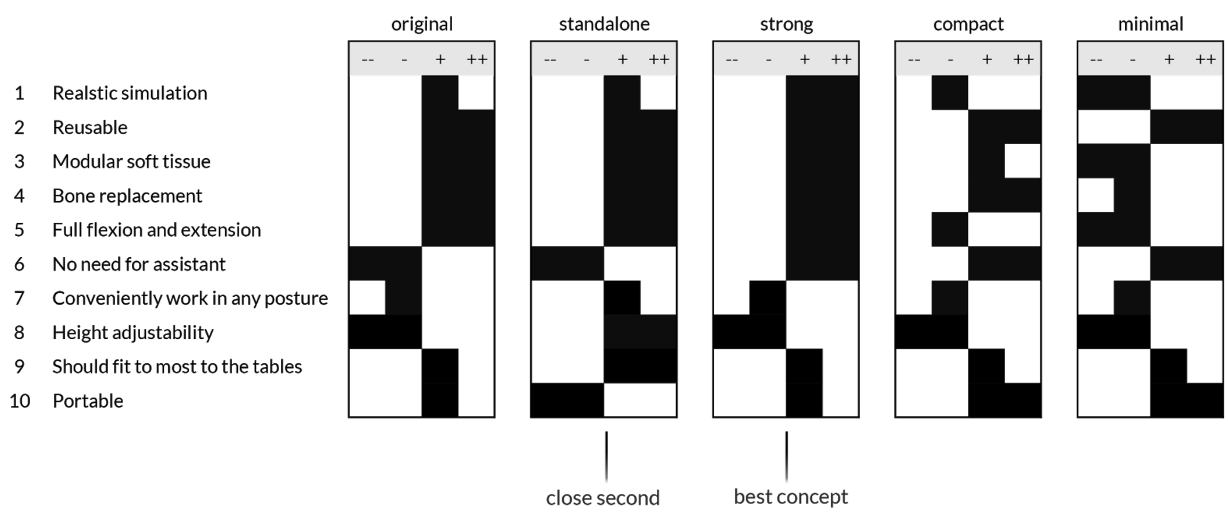
https://www.dropbox.com/s/bmuj66rrfzh34hi/code%20concept%20presentation.pdf?dl=0

Weekly newsletter - week 12, 13 & 14

Concept selection & development



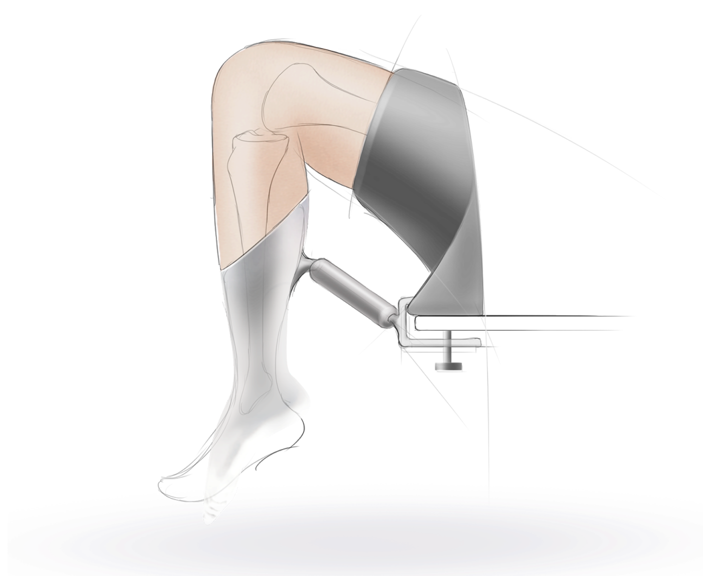
From the discussions with mentors and observations the Oxford demonstration and feedback from the surgeons, a list of requirements is made and ranked in order of most important to least important. This is implemented in a harris profile to evaluate the concepts.



In a Harris profile, the main design requirements are ranked in order of importance with the most important one on top. An even number of possible scores are used to prevent neutral scoring. This way of evaluating is helpful when ideas and designs are still conceptual and not worked out in detail: imagine the black squares are the building blocks of a tower. By viewing 'which way the tower of blocks would fall', a choice can be made.

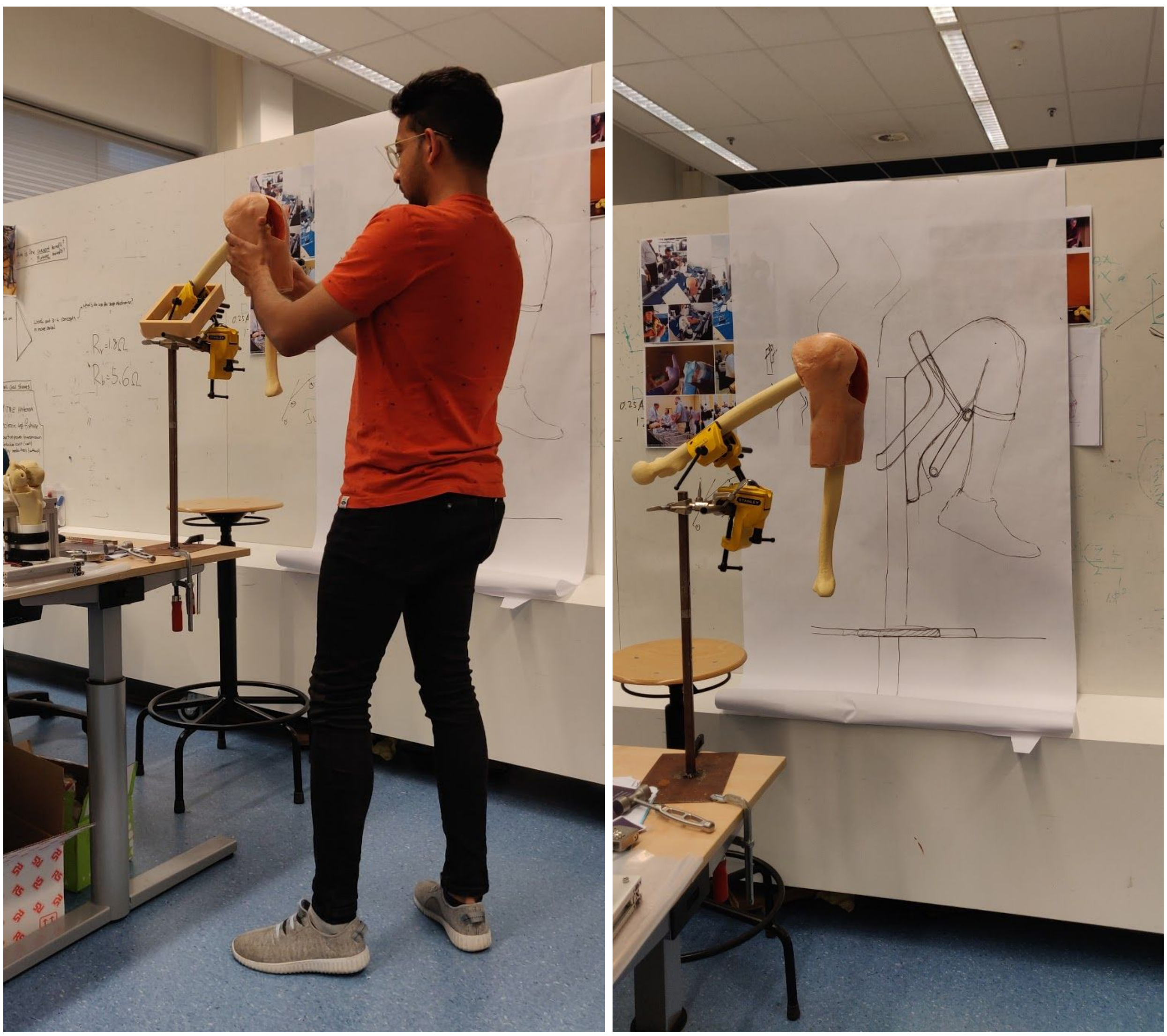
From the above evaluation, the block profile of concept 'strong' seems falling to the right compared to others. Besides this evaluation, the same concept has also been chosen based on discussions with the mentors. From the discussions, it was evident that leg fixture is necessary for surgeons to be able to work alone. A leg fixture that can allow full valgus and varus angulation and some flexion and extension is necessary so that surgeons can position it as per convenience.

Looking back at the harris profile, this concept is missing few of requirements like height adjustability and ergonomics of working. The next iteration of the design are made considering incorporating these elements into the design. So keeping the core idea of the concept which is a leg fixture, the other elements of design are iterated further. There were different design decision taken in detailing concept further. Some of them include:



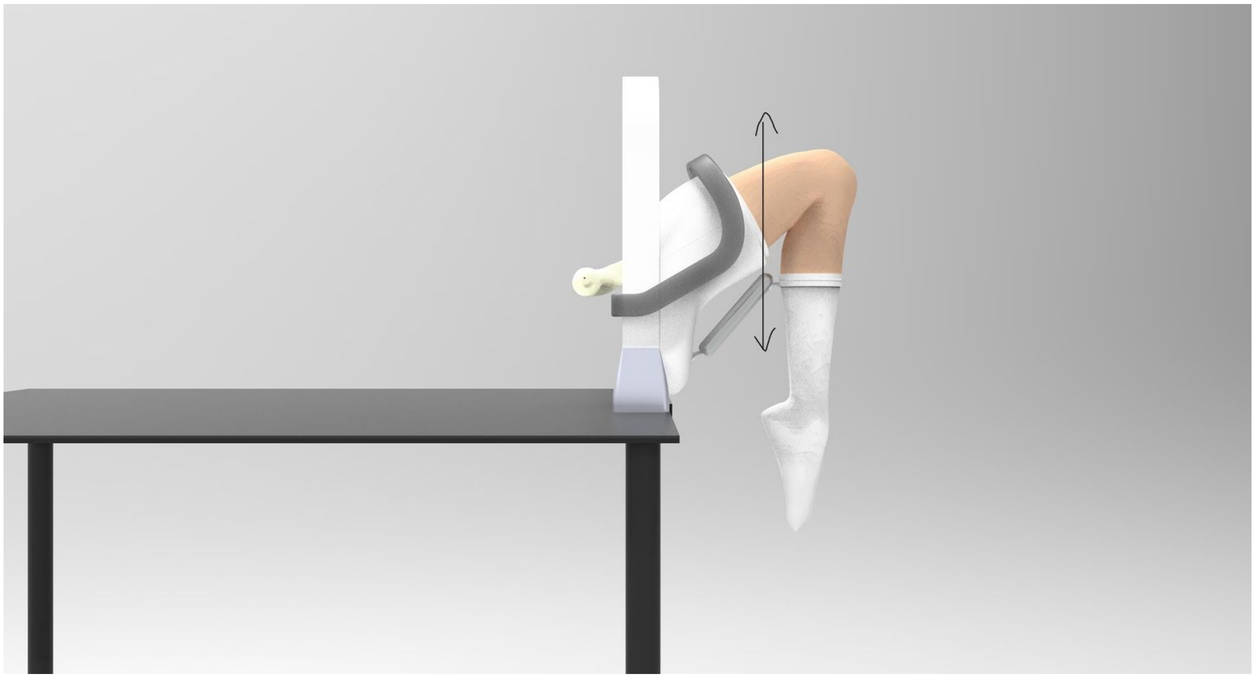
- Locking the leg fixture can be simplified by using a double ball socket arm.
- A handle is necessary to adjust the height.
- A counter weight inside the frame to make it easier to adjust the height.
- Soft tissue is limited to only some part of the leg and the rest is going to be rigid plastic structure.
- The visual feedback will be in the form of an LED lining along the handle to indicate the amount of impact for every hit.
- Lamp is not attached to the product by default but it can be an additional fixation to the table or to the product.

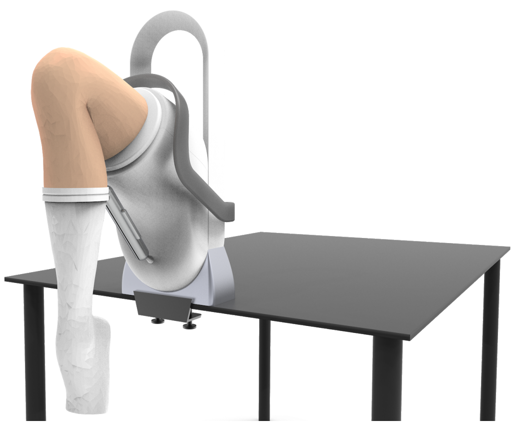
Feasibility POC

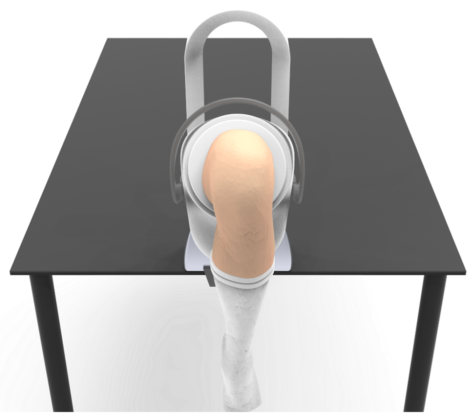


A feasibility proof of concept is made to understand the height adjustability mechanism, working height in different postures and visibility angles. The height

Initial ideas







DISCUSSION POINTS

CHAIR- MENTOR MEETING

Structural analysis is necessary for the frame.

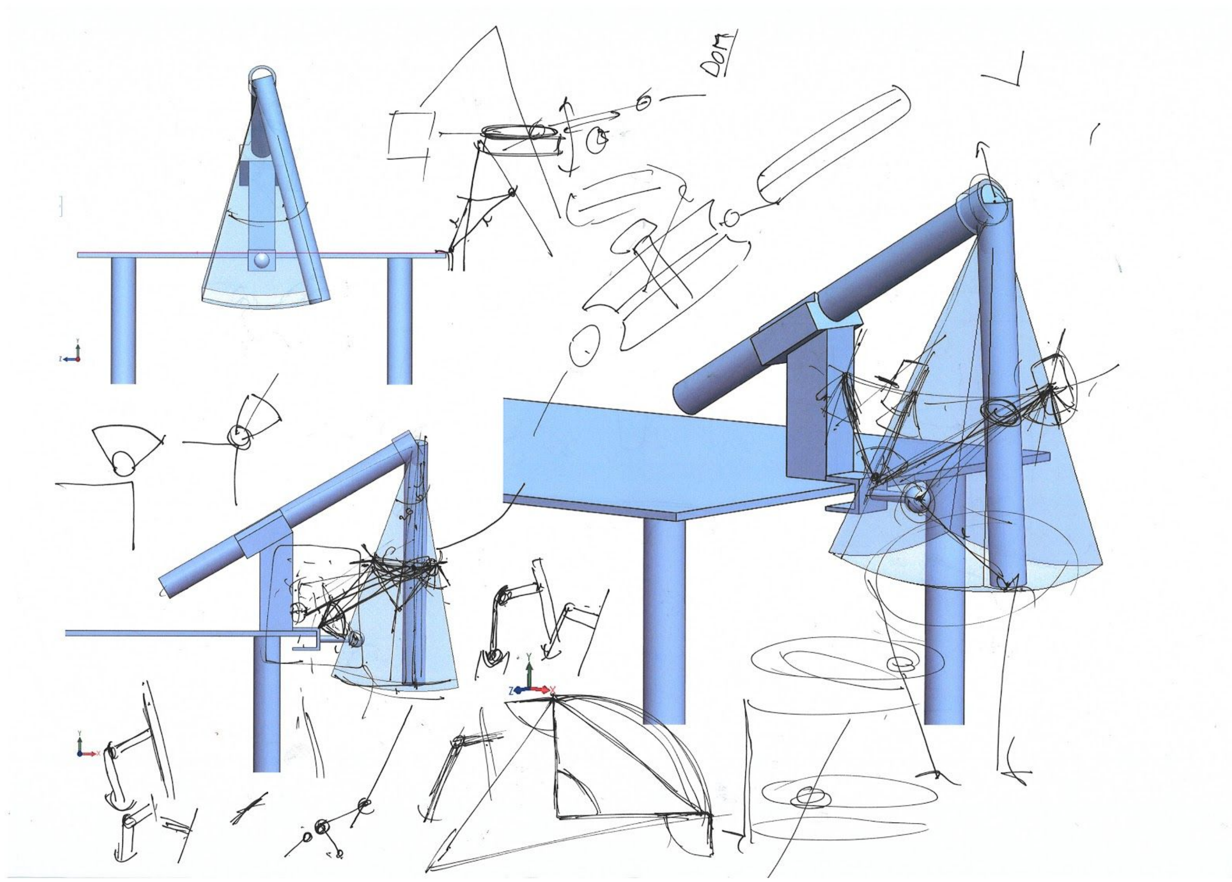
Evaluate the frictional force required for product stability.

It is better to test small components like ball socket arm before finalizing the design.

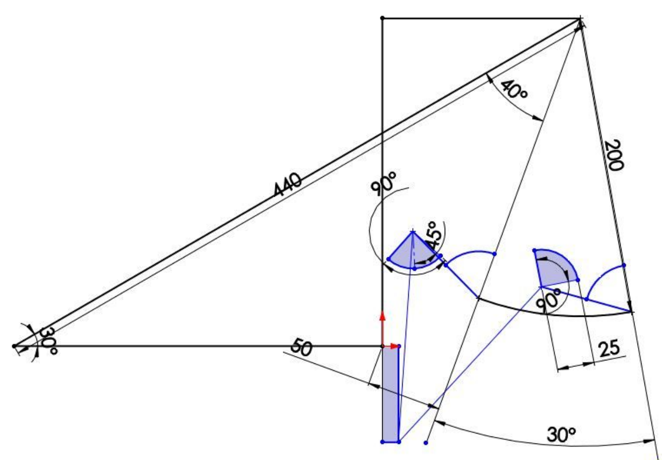
Locking and unlocking the ball socket arm need some attention as the hand might not reach in full flexion.

More ideas can be explored for easy setup of table fixture.

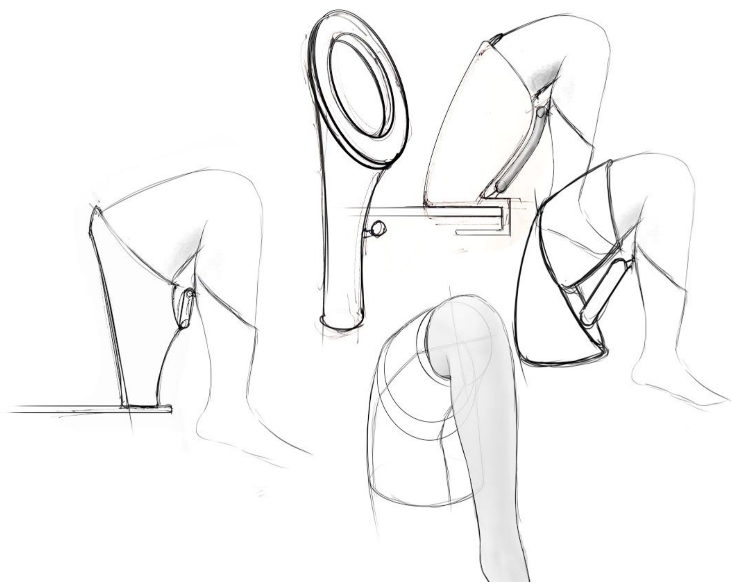
Double ball swivel arm

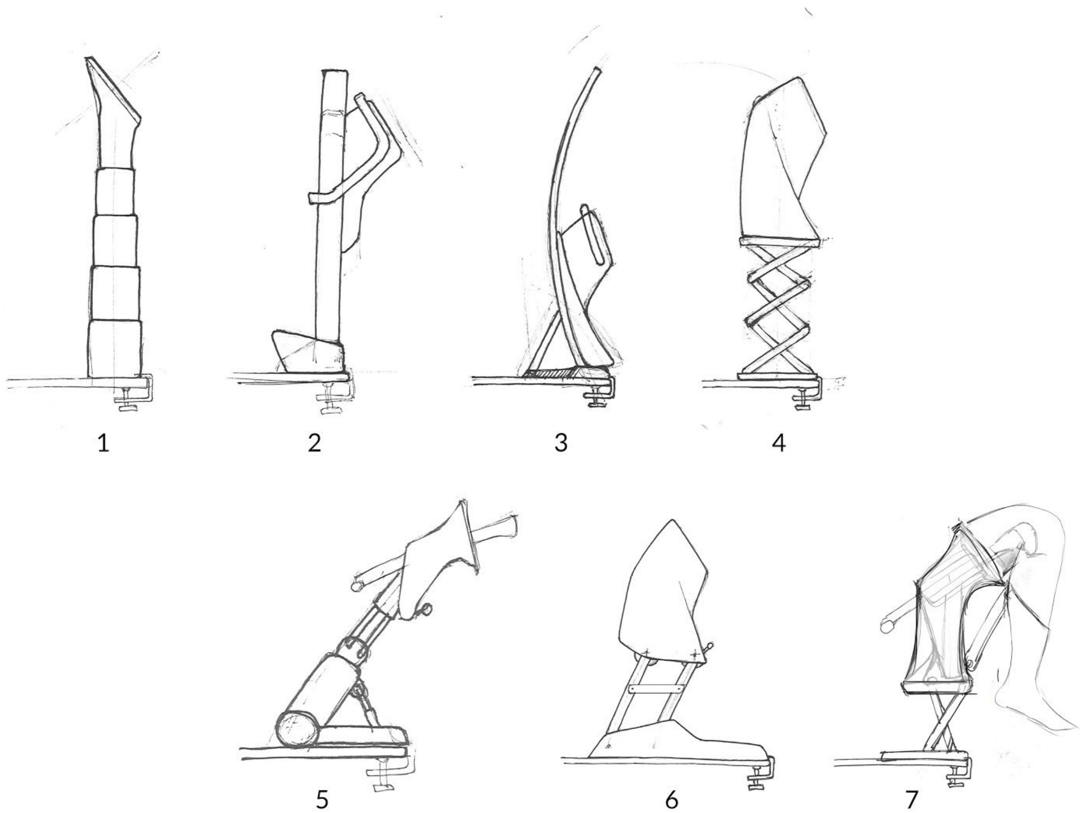


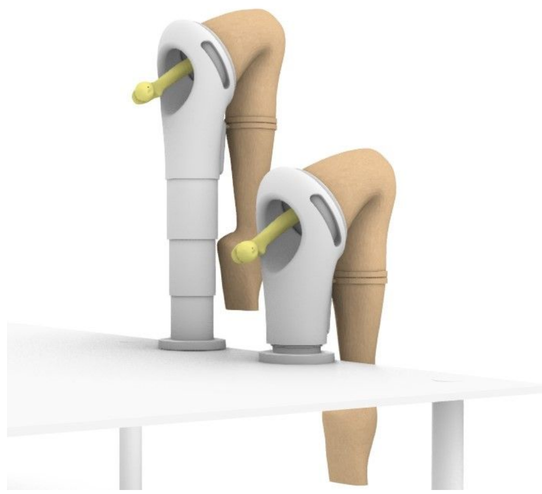
I was able to calculate the most suitable length of the swivel arm and degrees of freedom at both the ball joints. This swivel arm will be able to let the surgeons lock the bottom limb at any position within 30 degrees of flexion/ extension and 15 degrees of varus and valgus angulations. To extend beyond the 30 degrees the swivel arm will be detached with latch.



More ideas



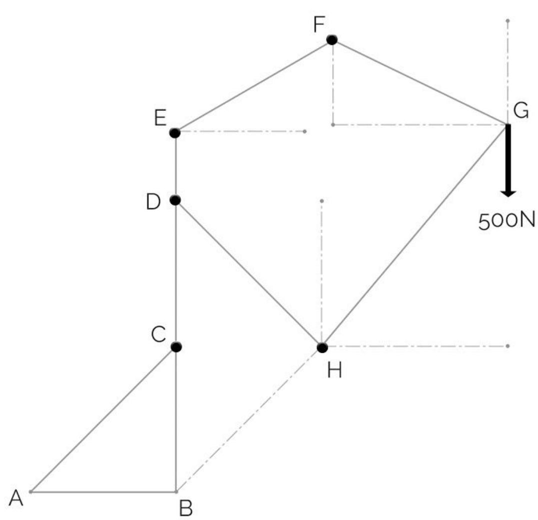




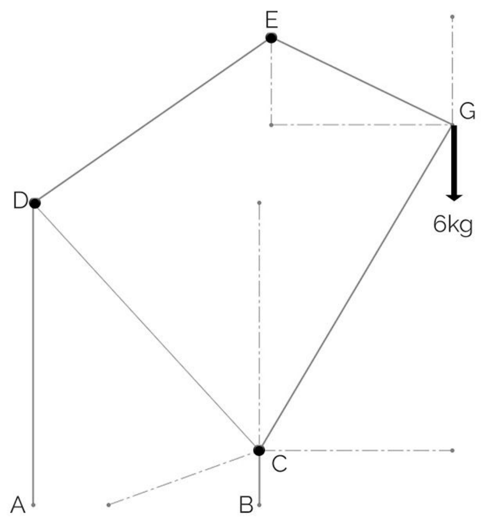
This type of static base seem to be more promising than the previous slider mechanism in terms of structural stability. Here the chassis is connected to the table right at the point where most of the product weight is acting. To be sure, I made some structural calculations. For this, I converted both the designs into simple frame to find the equilibrium and internal forces of the member.

These are the following frames that I considered for evaluation:

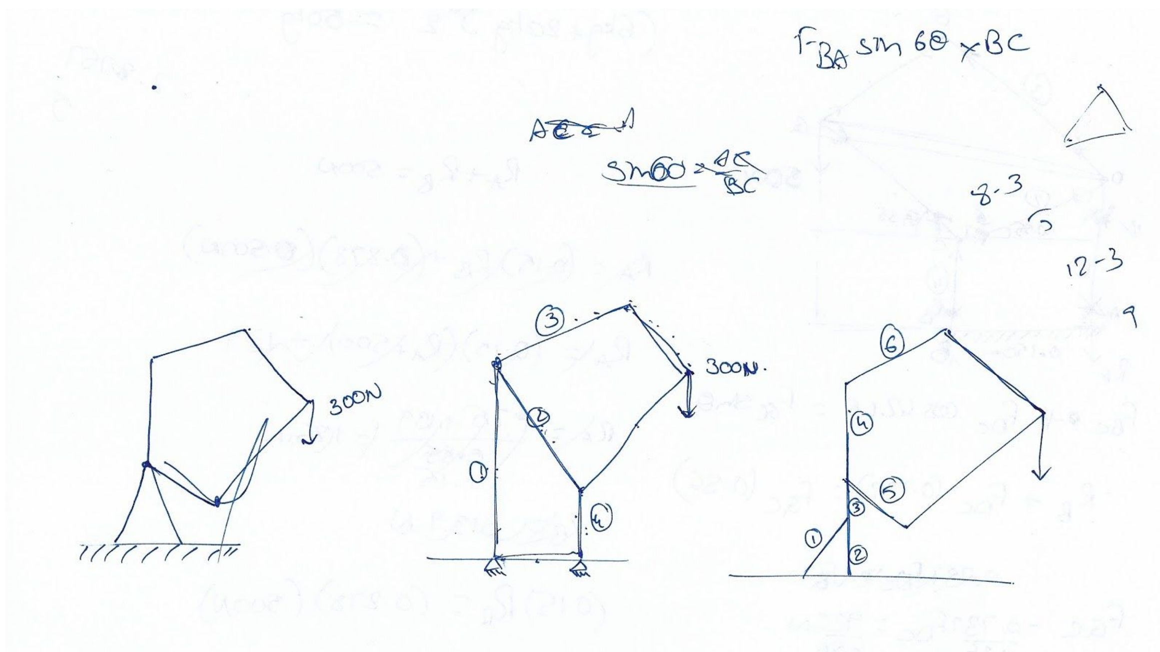
Frame 1



Frame 2

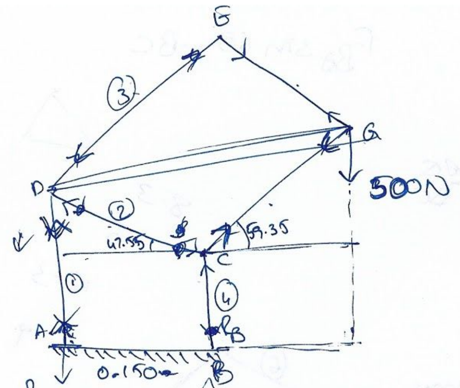


The leg weighs about 6kg and the hammer impact is observed to be 20 kg from a test using force transducer. Taking the factor of safety of 2, I considered the weight at the point G to 500N to do the calculations.



$(6kg + 20kg) \times 2 \approx 50kg$

2.875



$R_A + R_B = 500N$

~~$R_A = (0.15) R_B + (0.278)(500N)$~~

~~$R_A = (0.15)(R_A + 500) + 139$~~

~~$R_A = \frac{75 + 139}{1.15} = 186N$~~

~~$R_B = 313.9 N$~~

$(0.15) R_B = (0.278)(500N)$

$R_B = 926N$

$R_A = -426N$

Joint C

$F_{BC} + F_{DC} \cos 42.45 = F_{GC} \sin\theta$

$R_B + F_{DC}(0.737) = F_{GC}(0.86)$

~~$0.737 F_{DC} + F_{GC}$~~

$F_{GC} - \frac{0.737}{0.86} F_{DC} = \frac{926N}{0.86}$

$F_{DC}(0.678) = F_{CG}(0.509)$

G $\quad 500 + F_{CG}(0.86) = F_{EG}(0.9)$

$F_{EG} = 5030$ (Tensile)

D $\quad R_A + F_{DC}(0.737) = F_{DE}(0.627) + R_A$

~~$F_{DE} = \frac{426 + (3970)(0.737)}{0.627} = 3354.89N = 5345N$ (Comp~~

$F_{DE} = \frac{3970(0.737) - 42}{0.627}$

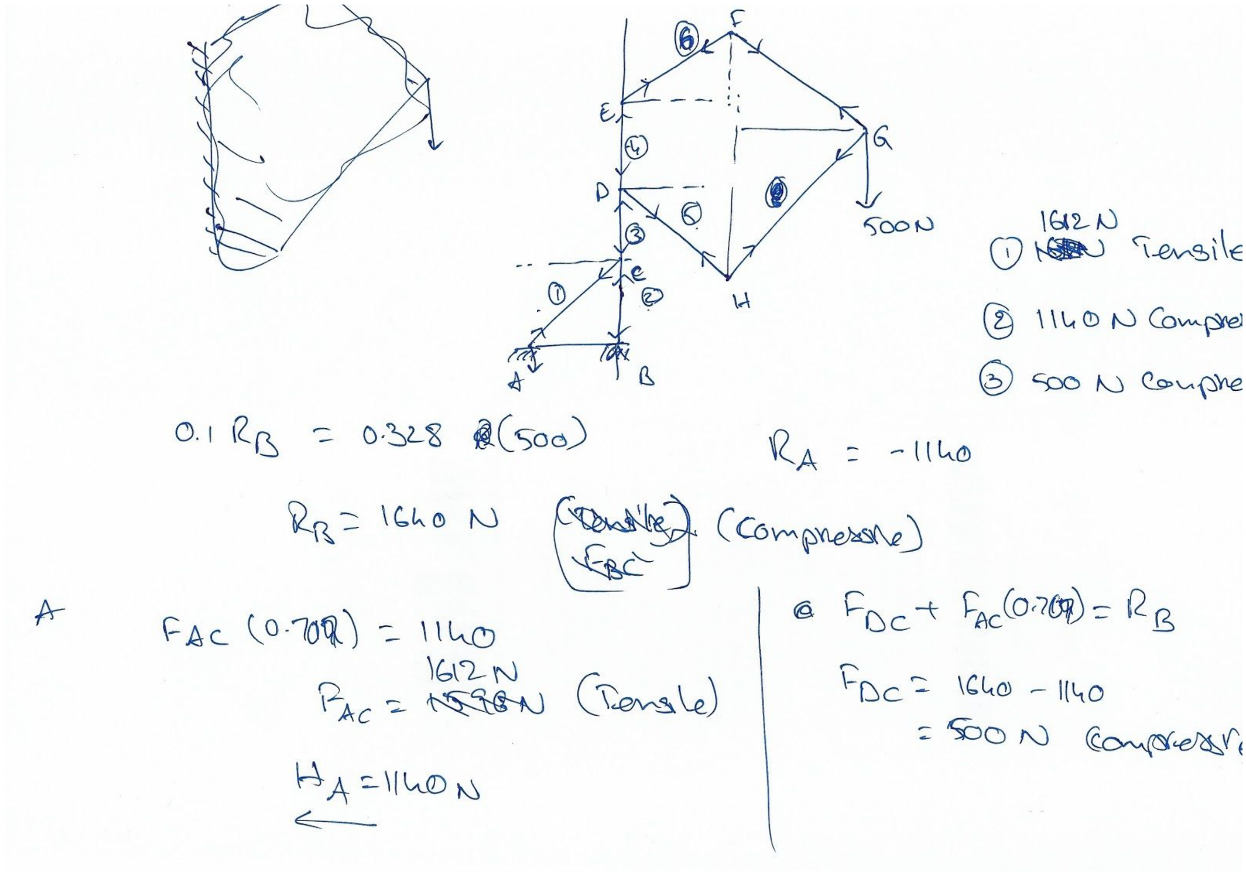
$= 3987$ Compres

① 426 Tensile

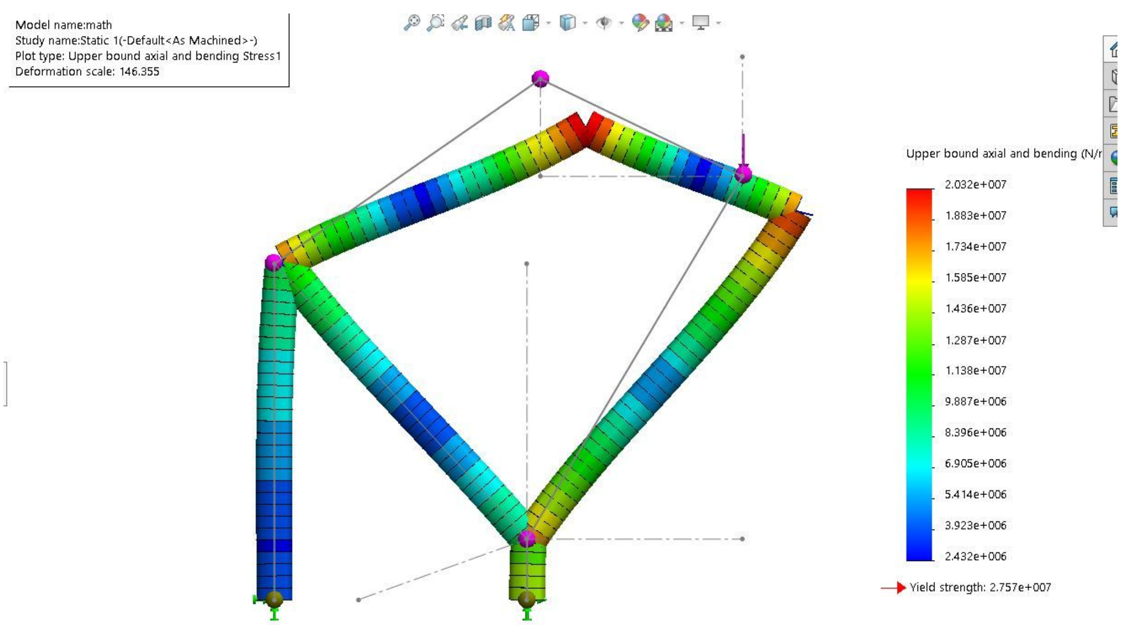
② 3970 Compressive
3987

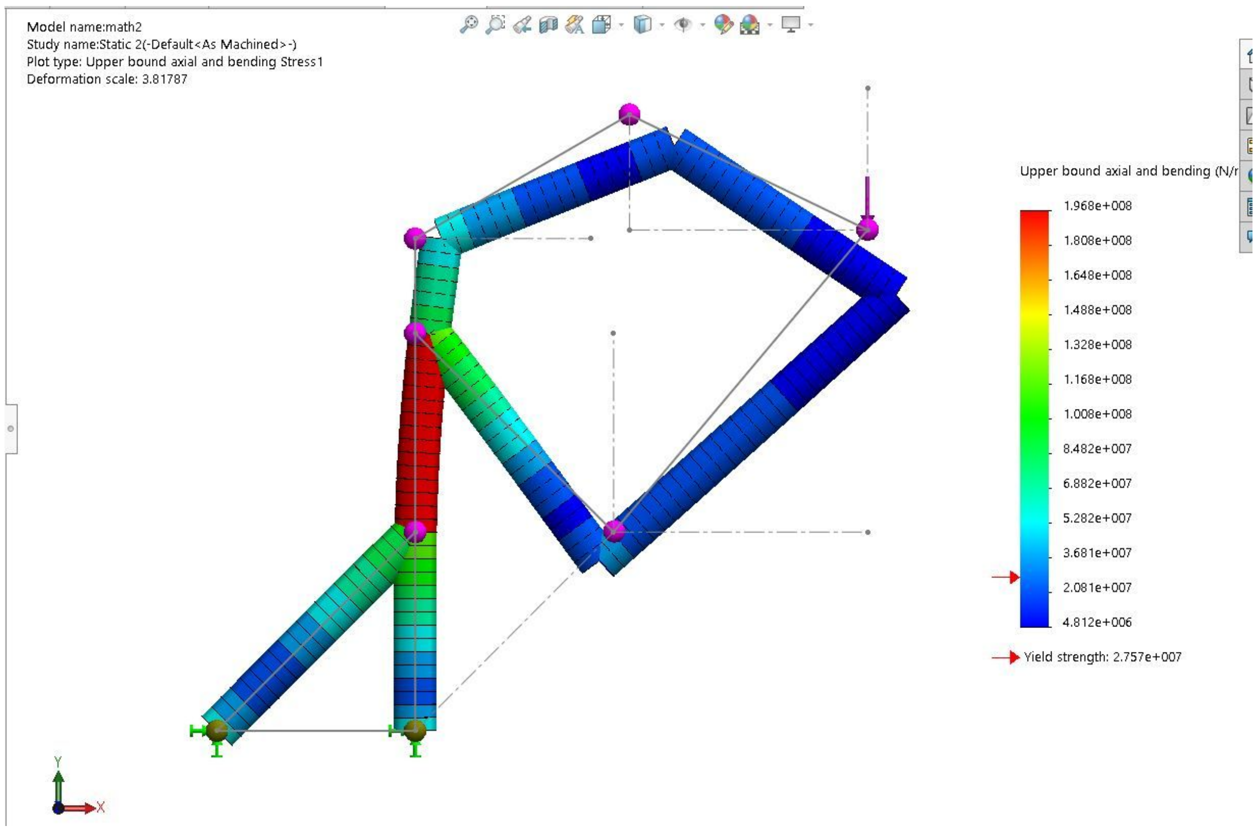
③ 5345 compressive

④ 926 compressive

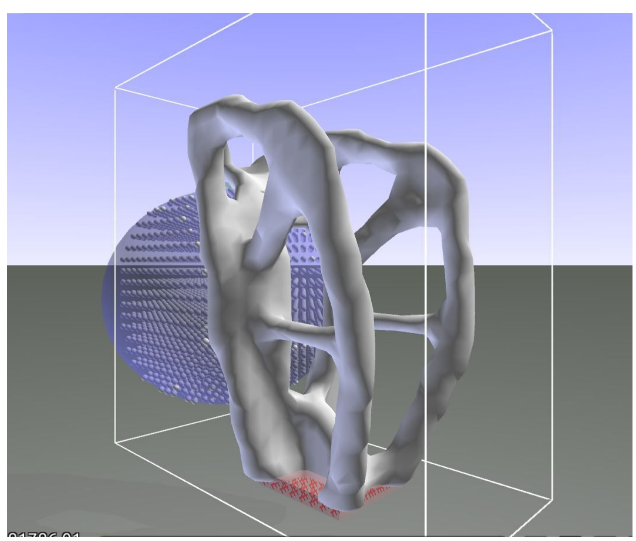


It was evident that the members at the base are subjected to higher loads in the second frame than the first. Secondly, the frame 2 is not in equilibrium as there are some unbalanced horizontal loads. To verify the results I simulated a simple frame of weldments with the given load.

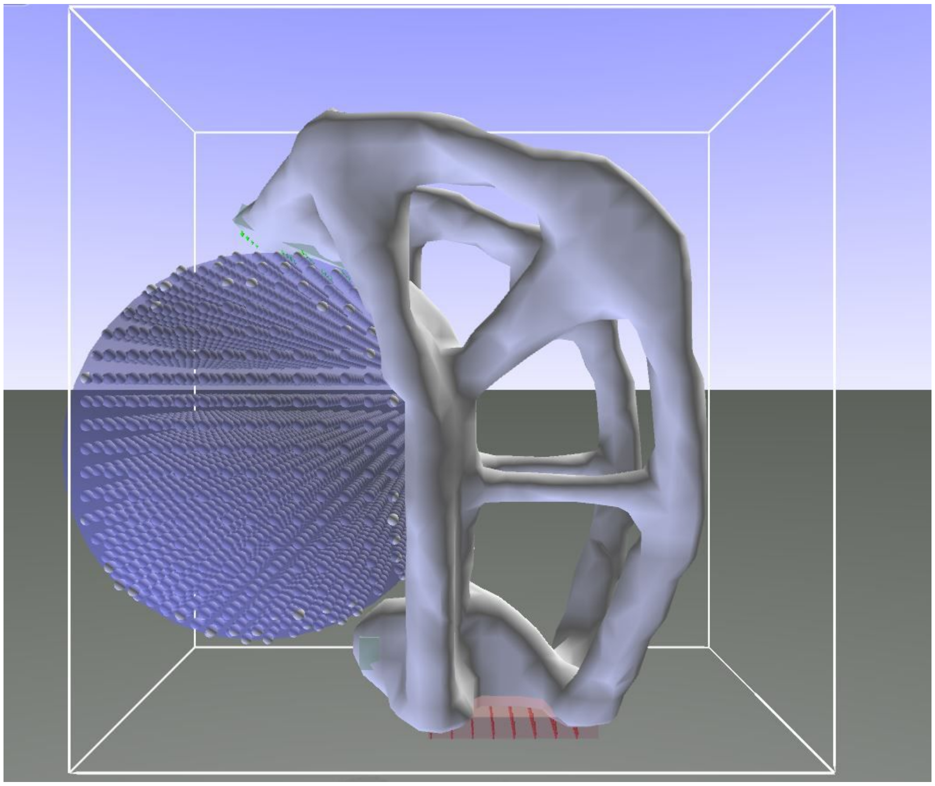




The profile is an aluminium 1060 alloy pipe. The frame 2 exhibited a breaking stress at the supporting member. Whereas the frame 1 stands stable with highest stress(20MPa) being below the yield strength (28MPA). So I wanted to move ahead with the frame 1 but improving the frame in way that highest stress satisfied at a factor of safety of 2. I extended this study to a



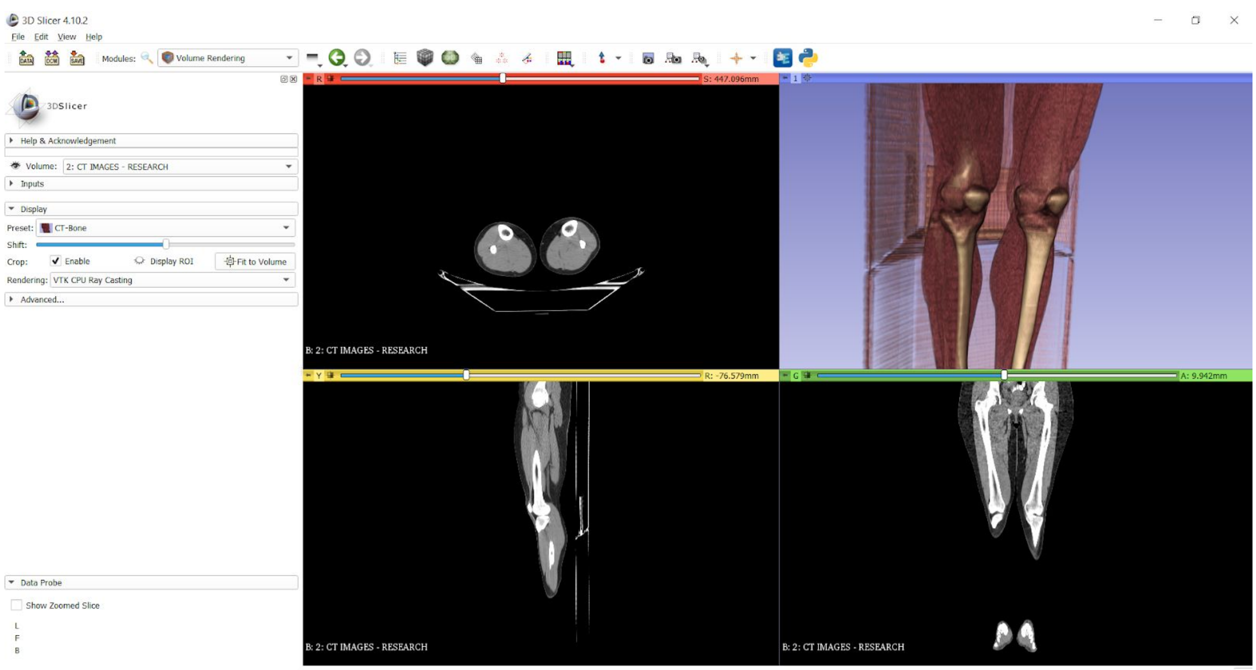
I extended the study to a topology optimization tool to see what will be an ideal case for the given loads and fixtures. From the known parameters, I placed the core components in the required position to understand the structural mechanics. It is known that the fixed support is at the bottom position where the product touches the table and the force acts on two different points on the product. One is at the femur clamp and the other are the swivel arm ball joint. The result gave me an idea of how the chassis could look to ensure maximum stability.



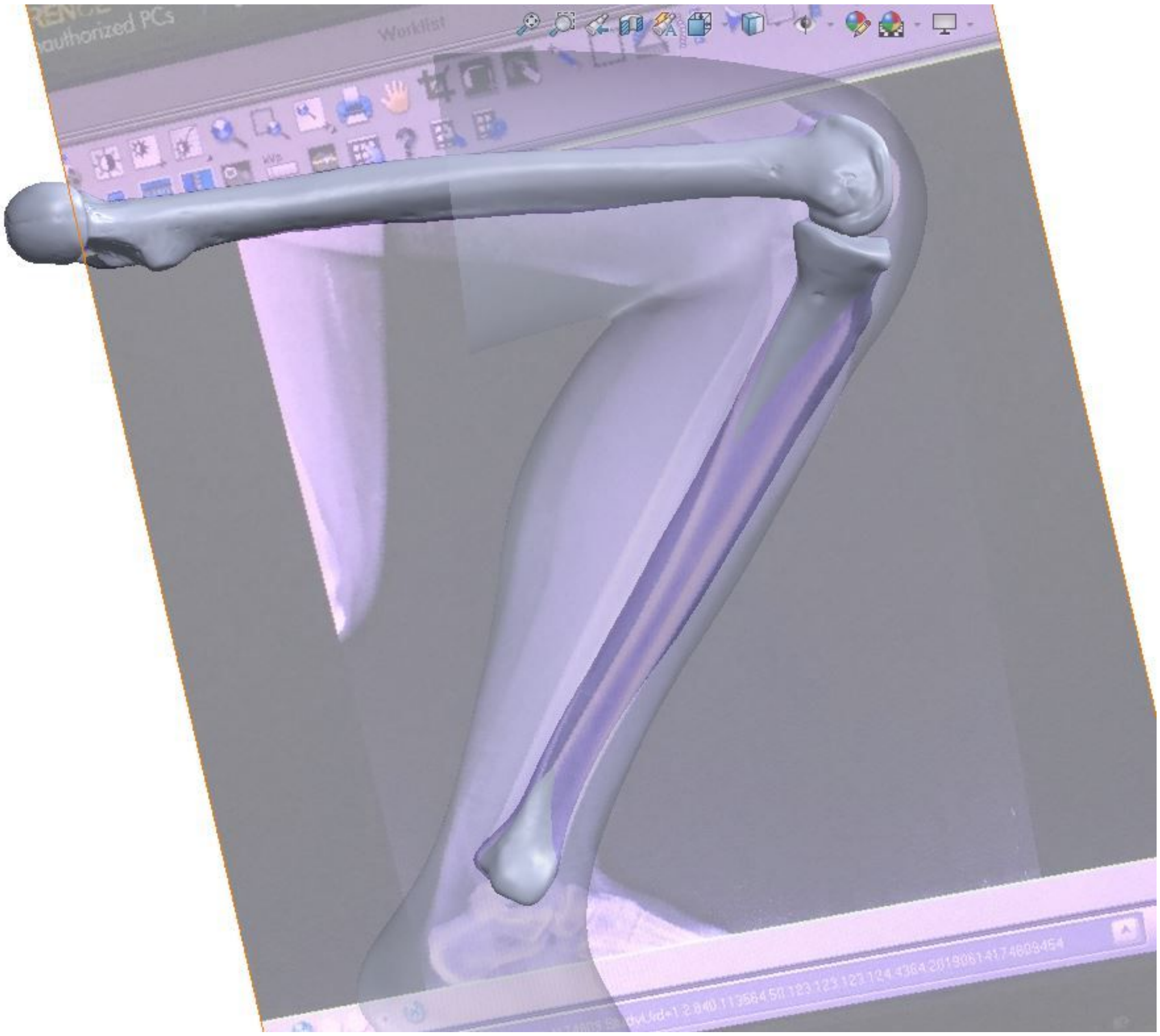
Making anatomically accurate model

3d scanning the skin

CT scan model

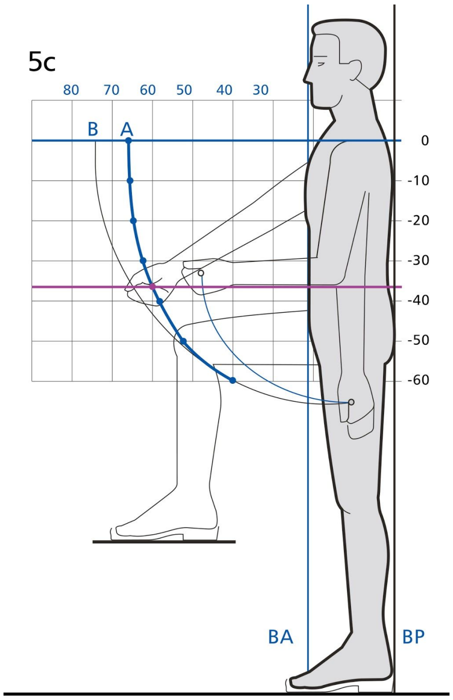


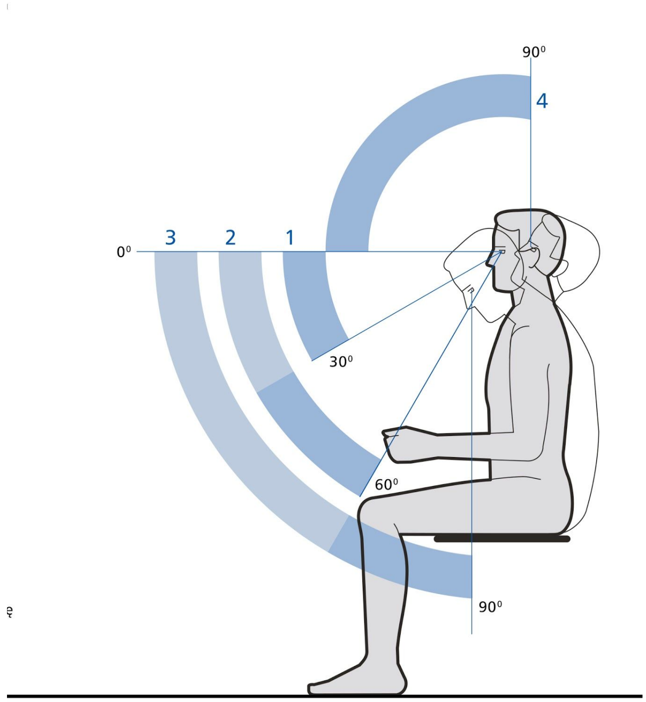
X- ray Alignment



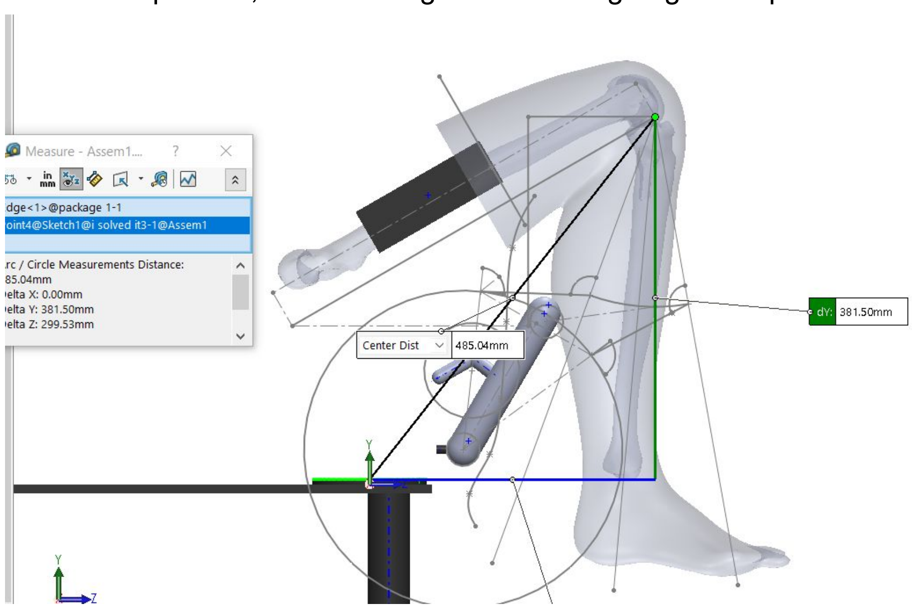
It was close to impossible to get a CT scan of leg in flex position. To get such a scan, the knee has to enter the detector ring first following the rest of the leg. The scanner bed has not bed designed for this and none of the CT scan operators agree to do this as they are not supposed to do. Then I had to use a ct scan of a subject's knee in a regular posture with full extension and make 3 x-rays of the same subject in front side and top views in the flex position that I need. Overlapping both of the sources, I was able to align the bones inside the 3d scanned soft tissue.

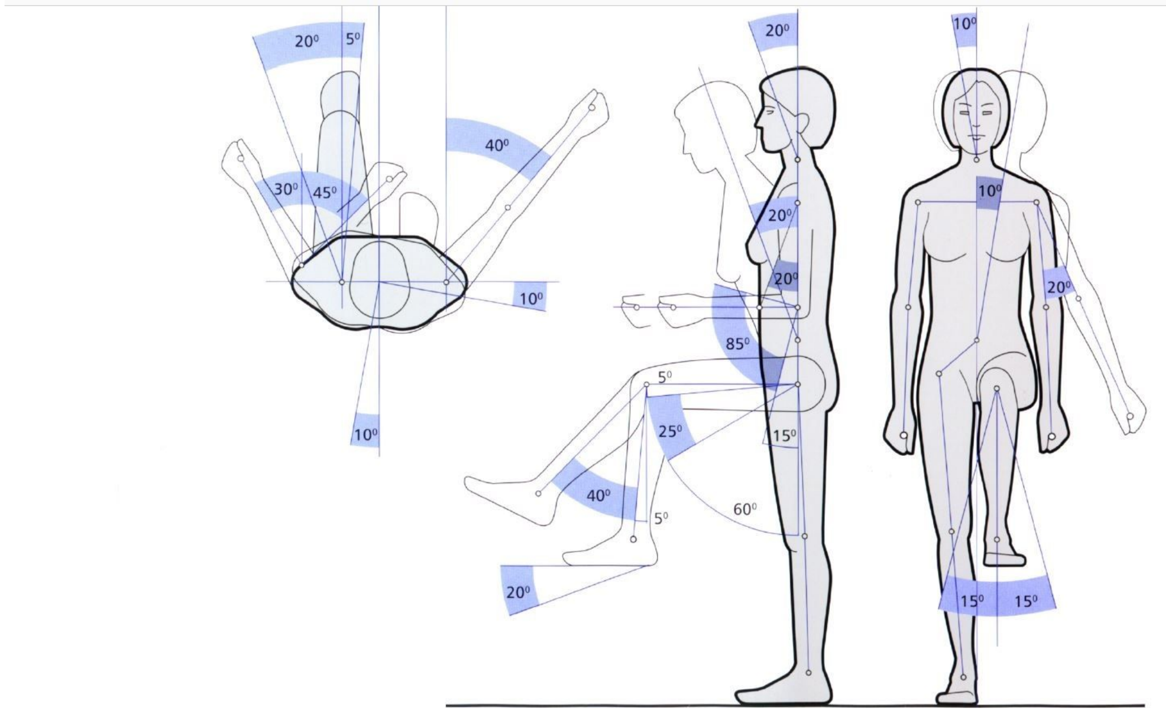
Ergonomics



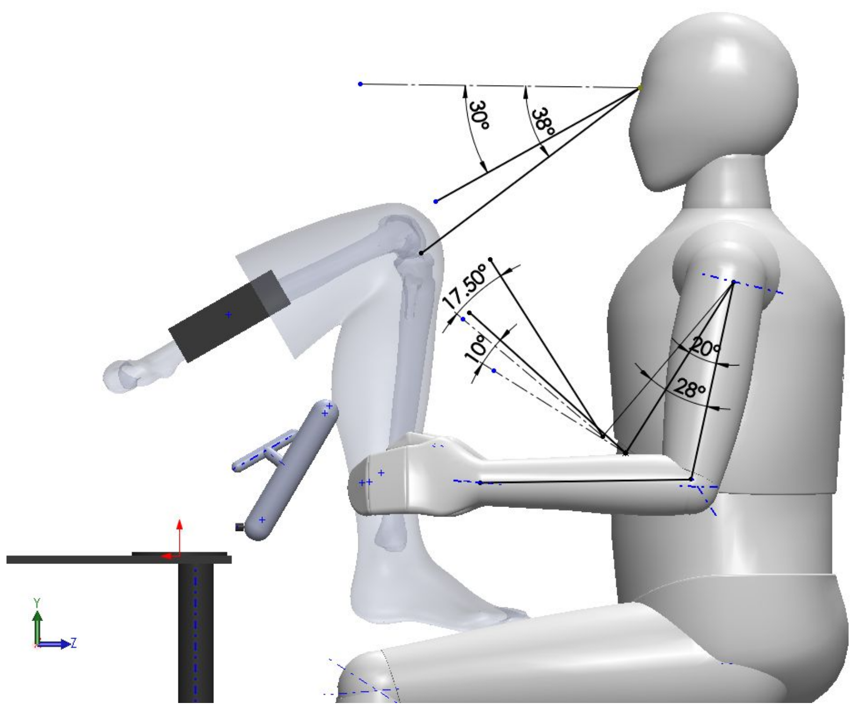


Now that I finalised the shape, I considered some ergonomic references to finalise the size of the product. The core requirement of the height is the possibility of locking the leg using swivel arm. This requires the height of the incision to be at least 380mm. To make sure it is convenient for a person to use the product, I was looking at the viewing angle and posture comfort.

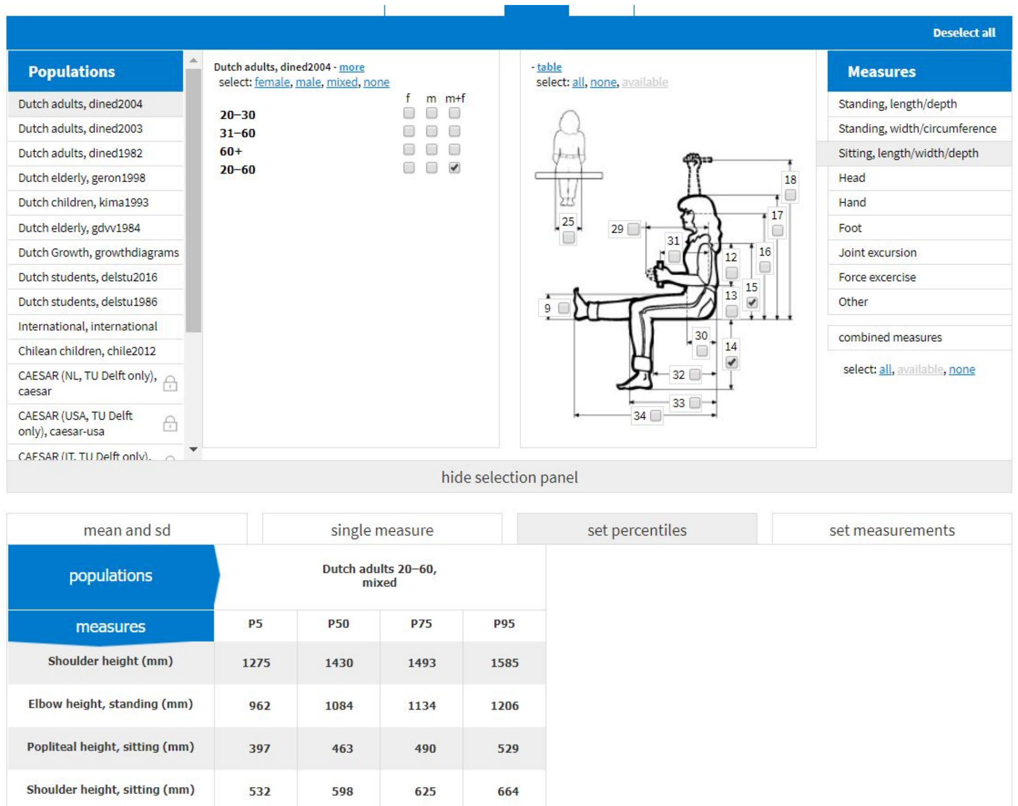




From the above reference , a comfortable viewing angle is upto 30 degrees below the horizon of eye. Besides the view the hand position needs to be in a comfortable position. The comfortable hand angle from the references is 20 degrees at the arm and 10 degrees at elbow.. But the hand needs to hold the tool at the incision. This cannot be possible without compromising the view angle. So both of them are adjusted to a compromised angles of 38, 28 and 17.5 degrees.



All the measurements are taken from the dined database of Dutch adults, male and female of age 20 60 years. From the above finalised angles, the hand angles can be even eased out by increasing the stool height. The above dimensioned are based on stool height equal to the 75th percentile of popliteal height. An ideal stool height is something close to percentile 5 so that even the softest person could easily rest the feet. But in this case P75 has been chosen to provide an optimal hand and eye angles.



measures	P5	P50	P75	P95
Shoulder height (mm)	1275	1430	1493	1585
Elbow height, standing (mm)	962	1084	1134	1206
Popliteal height, sitting (mm)	397	463	490	529
Shoulder height, sitting (mm)	532	598	625	664