Internship report

Validation of a measurement system used for quality control of one-way reflective targets

Eva van Duin, s1088793

Master Mechanical Engineering, CTW
Faculty of Bio Mechanical Engineering
University of Twente

November 26, 2014

Atesos medical AG (Aarau, Switzerland)
Supervisor: Walter Moser

Period: July 15, 2014 – November 14, 2014

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Eva van Duin, s1088793
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Faculty of Bio Mechanical Engineering
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Internship Company
Atesos Medical AG
Schachenallee 29
CH-500 Aarau
Switzerland

Guidance
Internal

Dr. Ing. Walter Moser
CEO

Dipl. Ing. Peter Wehrli
Head of development

External

Dr. Ir. Dorien van de Belt
University of Twente

Internship period
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2. Preface

For my master`s degree in mechanical engineering at the University of Twente (Enschede, the Netherlands), I had to do an internship in the second year. It appealed to me to go abroad for my internship, since this way I could discover a new country, learn another language and develop a broader perspective and understanding. Atesos is a company that appealed to me by their products but more due to the good communication I had with the company. My supervisors within this company were Walter Moser and Peter Wehrli. The main assignment found in this report is about a quality control measurement system for optical reflective targets. This measurement system had to be validated so that it could replace the current measurement system.

I would like to thank Atesos with its employees for the opportunity they have given me. I have had a good time and I have learned a lot.

3. Table of symbols and definitions

Ceramic-on-ceramic	COC

Single measurement	A measurement with the CamBar system, only consisting of a measurement of the plate with targets from one side
Full measurement	A full measurement consists of four single measurements. For every single measurement, the plate is turned a quarter. This way all four sides of the targets will be measured.
Camera measuring bandwidth	The difference between measurements done with the same target without it being touched or moved.
Total measuring bandwidth	The difference between measurements done when performing a full measurement, thus consisting of four sub-measurements.
Limit value	When targets get a value above this limit value, targets should be labelled as inadequate and when having a value below it, they should be labelled as adequate.

4. Summary

The internship was carried out at Medical Atesos AG, a Swiss company, making mainly conventional hip implants but also developing in short stem hip implants, knee implants, optical reflective targets, tooth implants and a special anti-infection coating.

The main assignment to be carried out was to validate a new optical tracking measurement system for quality control of optical reflective targets. This was done by using another already in use optical tracking measurement system. The key parts of these systems are the camera and the reference system. After measuring a significant amount of targets, it was concluded that a correlation could be found between the values found by both measurement systems. A limit value could be set at 2.70 (unfortunately, this new measurement system does not give values in millimetre as the current measurement system does). The camera measuring bandwidth was found to be good enough. Though, the system appeared to have a too big total measuring bandwidth. Also, measurements done under 50° appeared to have a mirroring effect of which it is not known how much effect it has on the measurements and values obtained for the targets measured. Recommendations consist of adjusting the measurement system in such manner that the reference system is totally fixed to where the targets should be placed, to put the camera under an angle of 50°, so that the targets can be horizontal and to have more distance between the targets measured since then the mirroring should definitely not have any effect on the measurements.

Another project done was literature research for a short stem hip implant. The age with which people need a hip implant is declining. The main problems with this declining age of patients are the short lifetime of a hip implant and the higher activeness of these younger patients. A solution for these problems is a short stem hip implant which Atesos is planning to produce in the future and therefore literature had to be found.

Another project was running to test a new anti-infection coating. To test this new coating hip implants for rats will be implanted in the rats at the University of Munich. For these implants, a holder was needed, by which the implant would be protected. Work has been done in the tool shop of Atesos to make these holders. The result can be found in figure 20.

Calculations were done and a design was made of an instrument for tooth implants. The conventional implants consist of two parts. This makes it more sensitive to infections. Therefore, Atesos together with a couple of other companies are developing a tooth implant consisting of only one part which has to be able to being bend, but which also has to be able to endure all normal forces when placed into a mouth. Calculations have been done on the bending force of this implant. An instrument has been designed to bend the implant for when the implant is already placed into a patient’s mouth for quite some time. Main results were that the implant is able to handle the bending force and the instrument can be found in figure 25.

5. Introduction

The company

Atesos medical AG is a small company in Aarau, Switzerland. Atesos stands for **A**dvanced **Te**chnical **So**lution**s** and the company focuses on technology for orthopaedic surgery. The main focus of today`s firm is on the design and production of implants and instruments for total hip replacement surgeries. At the moment a project is ongoing on the development of a short stem implant. The production of hip implants with the conventional longer stem is still running. Though, the company is also working on the design and production of knee implants, tooth implants, and a special anti-infection coating. Another emphasis is placed on optically active elements used for image guided surgery, which is the subject of my main internship assignment. Next to this main assignment, (smaller) projects in the other subjects have also been done which can all be found in chapter 10.

Internship assignment

The original description of my internship assignment is as follows:
Assisting in the development of surgical instruments and devices. Subtasks in the definition and validation of the production of implant and instrument components. Performing mechanical tests. Literature work, development of devices for production steps of optically active elements.

Translated into reality this means that my main assignment is the development and validation of a measurement system for optical active elements. Other tasks will have the subject of the other projects of the firm.

Goals of the internship

For me, the goal of this internship was to get to learn as much as possible; about the company Atesos, implants, design, production, technical drawings, etc., but also about the country Switzerland and to improve my German. At the company I hoped to learn more about how to make a good technical drawing including the ‘‘non-written’’ and practical design rules and how to apply tolerances. I assumed I would learn about optical active elements and how they are measured. An important part is off course to get to know a firm`s atmosphere, instead of the well-known university atmosphere. How will things be handled here?

In the end, I think all of these goals have been completed. Moreover, I have learned more about statistics, working with excel and NX CAD software. Also it appeared that the firm had projects running other than on hip implants by which I learned about knee implants, shoulder operations, anti-infection coating and tooth implants. Also I have learned a bit more about FEM analyses.

Structure of this report

In this report, first my main assignment will be discussed. The problem will be explained and results of literature research will be shown. Then, the work plan will be explained after which the results and an analysis of these results will be shown. A conclusion will be drawn and a discussion will follow. At last, recommendations will be given. After this part of the report, also other (smaller) projects I have done during my internship will be discussed, though a lot more briefly than the main assignment.

6. Main assignment: Image guided surgery, quality control

Introduction

High-precision optical 3D tracking and positioning systems are nowadays used in image guided surgery [2]. Retro reflective spherical targets are used in these systems in medical applications [1]. The targets enable surgeons to wirelessly track the position and orientation of any device from a frame of reference [3]. It is very important that these targets are very precise, can handle moisture (for example water or blood) and are supplied sterile [1]. The current limitations of some of the products on the market are that they cannot handle well with liquids, tissue and touch of hands since they soil the targets. The dome around the targets of Atesos, as depicted in figure 1, protects the spheres from being soiled. The markers have an evenly reflecting surface which is accomplished by the coating applied [4].

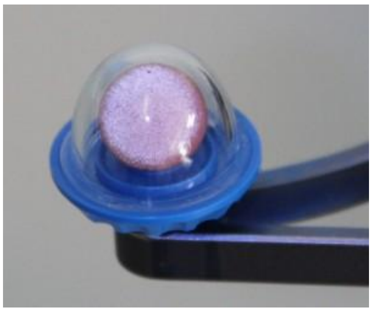

Figure 1 Optical active target [1]

The main task of Atesos is quality control, so to exclude the targets which are out of range in their measured position. The target supplier for Atesos is Thermoplast Hänggli, Termoplast AG, siehe. After the measurements are done by Atesos, they also pack the targets. Then the targets are sterilized by gamma radiation and sold to customers.

A new setup with a new position tracking camera and reference system was made by Atesos to perform the quality control.

Definition of the problem

In this assignment, the accuracy of a new spatial measurement system has to be found and compared with another spatial measurement system which is already in use. The results of the measurements have to be interpreted and a conclusion has to be drawn about whether the new system is adequate enough to be used to perform quality control of the targets.

Goal of the new measurement system

The purpose of the new measurement system is to have Thermoplast Hänggli, which is producing the targets, also measure the targets. By using this new system, they hoped that the measurements will be made easy enough for people of this company to perform. Since Atesos will then have less control over the measurements, the measurement system should be very robust and easy to handle. The measurements will have to be carried out in a shorter amount of time compared to the old measurements. This should be possible with this new measurement system.

The new measurement system will be validated using the older measurement system. From here on in the report, the new system will be named after the new camera used namely CamBar and the old system after the old camera used, namely Polaris.

Background research

What is to be measured?

What will be measured are SORT's, which stands for Sterile One-way Reflective Target. These are sterile and disposable intra-operative washable reflective balls as can be seen in figure 1. The targets have a high quality reflective surface. They have to be dirt resistant, easily washable and must have a high measurement reliability and accuracy.

The SORT targets are intended to be used for the surgical navigation system Pi-Galileo (see figure 2). Such a system works on the principle of photogrammetry. The function of these targets is to reflect the light as precisely as possible in the direction of incidence (retro-reflection) with accurate mapping of the geometry of the target. The measurement system works with infrared light. The reflected light by the target is measured and evaluated in a computer. This evaluation consists of the calculation of the position of the targets in the measurement volumes. By using three targets or more, a unique location in the measurement volume can be calculated. The use of the targets during an operation can be seen in figure 3.

Figure 2 Navigation system Pi- Galileo left, Generation (Polaris NDI)

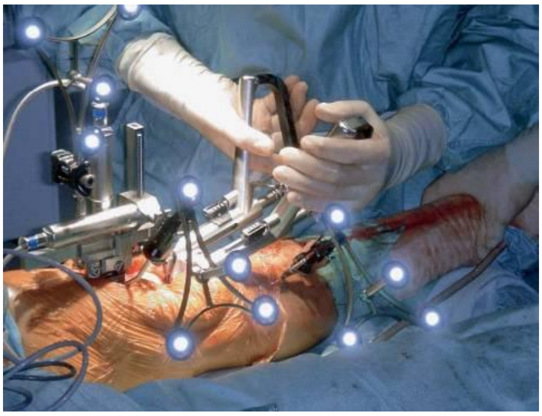

Figure 3 Operation while using optical active targets

Measurement system

The targets are measured by a position tracking system. The assessment and interpretation of an optical tracking system is done by mathematical models, which convert the raw sensor data to a position and orientation. These are not well-known models, which makes error interpretation of these systems especially hard. [5]

The two different measurement systems used

At the start of my internship, the SORT targets were measured by using the Polaris system. The goal is to measure them with the CamBar system. At the moment, the CamBar system is still a prototype system. Both systems are explained below.

Polaris system

At the moment I started my internship at Atesos, the targets were statistically measured with the Polaris Spectra camera (figure 5). This means that not all targets were measured but only a selection of it. To be able to do this, a reference system (locator mount) was built, which can be seen in figure 4. In this figure a target is already attached to the locator mount (target holder of which the geometry is known). The target can now be turned from -70° to +70°. The four other (white) targets are reference targets. The locator mount is to be placed in the measuring volume of the Polaris camera.

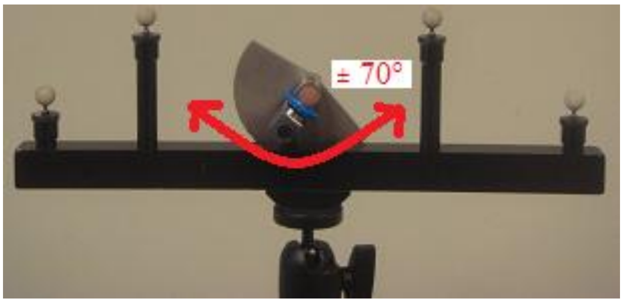

Figure 4 The locator mount of the Polaris system.

Figure 5 The Polaris camera together with the locator mount already seen in figure 4.

With this system, one target is measured at a time. Data is saved by pressing a foot switch. This is done, while turning the target by 10°. The results of one target measurement then consists of position values at -70°, - 60°, …, 0°, 10°, …, 70°, meaning thirteen values in total. To be able to compare these data with the CamBar system, the worst found value of these thirteen values will be taken.

A lot, which consists of all targets produced on a day, is put in smaller bags with around 23 targets in every bag. As said earlier, when measuring with the Polaris system, the quality control is carried out statistically. This means that normally only three targets out of such a small bag are tested. A target is labelled as inadequate when the target gives a value higher than 0.5 mm within -50° until +50° or when the target gives a value higher than 0.7 mm from -70° until -50° or from +50° until +70°. When such a target is found, the whole bag of about 23 targets is sorted out. When all three targets are labelled as adequate, then the bag is included to be packed and sold. When one of the measured targets has a value of 0.5 mm to 0.7 mm between -50° to +50° and the other two targets are adequate, then another three targets are measured. When one of these new three targets is inadequate, the bag is sorted out. When these three new targets are adequate then the bag is included to be packed and sold to the customer.

CamBar system

For measuring with the CamBar camera a prototype reference system was built, this can be seen in figure 7. A plate (figure 6), able to hold 23 targets, is to be put onto a table which is able to be turned around its axis. In the past it has been shown that targets are measured best under 50° so this table is put under 50° for all measurements reported here, except when mentioned otherwise.

To carry out a full measurement, the plate has to be turned 90° four times so that every side of the target is measured. These four sub-measurements are then converted via software and an excel file into one position value. This is thus different for the Polaris system, since there thirteen positions values (for every 10° one) are the result of a full measurement. For all measurements reported here, a measurement is a full measurement and thus consists of four sub-measurements. When a measurement consists of only one sub-measurement, it will be referred to as a single measurement.

Figure 6 The table onto which 23 targets can be mounted in order to be measured. The whole table can be turned. Normally a measurement is carried out at 50°.

Figure 7 The CamBar system. On top the CamBar camera can be seen.

Since only one value is given as a result, a target will be labelled as inadequate when the position value is equal to or higher than a certain limit value. This limit value will be found later in this report to be best equal to 2.7.

Known influences on the Polaris system

During measuring it appeared that an error had slipped into the Polaris system. The error and other possible errors of the Polaris system will now be explained, just to show how sensitive such optical tracking systems are and how hard it can be to find a certain error.

While measuring, the rotating part of the measuring rod got stuck due to corrosion and a bad initial design. The measuring rod was redesigned and produced. When using this new rod for measuring, though, the system appeared to have an error. The measuring rod was calibrated twice and no errors were found. Different parts in the system are sensitive to errors, namely the measuring rod, the reference targets, the software and the camera. Furthermore, also the temperature and the measuring environment have influences on the measuring system such as reflecting objects in the measuring volume or lighting. These elements are hard to be tested separately. In the end it appeared that the reference targets were not as good any more as they were supposed to be. For the CamBar system it is important to exclude as many errors as possible by the right mechanics and software since the operators will be inexperienced with the measurement system and they will thus not find errors readily.

Work plan

Objectives

The objective of this work plan is to validate the CamBar optical tracking measurement system. The validation of the CamBar system will be done by using the Polaris system. There are a couple of sub-objectives which are stated below:

- Confirm that there is a correlation between values found on the Polaris system and for values found on the CamBar system;
- Find a limit value by which targets can be labelled as adequate or inadequate;
- Find out what the camera measuring bandwidth is;
- Find out what the total measuring bandwidth is;
- Find out whether the position of a target on the plate has any influence on the position value found for a target;
- Find out what the influence is of the angle under which is measured.

The camera measuring bandwidth is the difference between measurements done with the same target without it being touched or moved. The total measuring bandwidth is the difference between measurements done when performing a full measurement, thus consisting of four sub-measurements.

How to accomplish these objectives?

Targets should be measured with both measuring systems and the values should be compared. It should be checked whether there is a correlation between the values found with the Polaris system and with the CamBar system by plotting both values with two different axes. Statistics will have to show how well CamBar can find targets labelled as inadequate by the Polaris system. When this gives satisfying values, a limit value can be found. The camera measuring bandwidth can be found by doing single measurements on the same targets more than once without changing anything. The software has to be changed to be able to do this (since the software is set as for a full measurement). The total measuring bandwidth can be found by doing full measurements for the same targets more than once. Changes in values found for different positions can be found when the positions of targets on the plate are changed. The influence of the angle of measurement can be found by taking live images of the targets can be used to see whether there is any visible difference.

To conclude the assignment the CamBar system and measurements with this system should be made as robust and easy as possible so that no mistakes could be made when measuring and a measuring protocol should be established.

What kind of targets should be measured?

Different kinds of targets should be measured to make sure that all different targets can be measured well with the CamBar system. Targets can be put in groups by using their Polaris values. The following groups are decided upon: <0.5 mm, 0.5-0.6 mm, 0.6-0.7 mm, 0.8-1.0 mm, >1.0 mm. All groups should have a sufficient amount of targets measured. This amount will be set at least 100 targets. Inadequate targets by having defects in the centre and having defects on the edges should be included so that it can be checked whether the CamBar system is able to find both types of failure.

Attention points

As is the case in every research, there are things to which extra attention should be paid:

- The targets were not grouped before the measurements started. This means that measurements were carried out with both adequate and inadequate targets on the plate. When it appears hard to find enough targets for a certain group, targets can be manipulated in belonging to that group by for example damaging the protecting globe.
- The Polaris system camera has a measuring bandwidth of ±0.2 mm. The total measuring bandwidth is maximum ±0.4 mm. This makes is harder to validate the CamBar measuring system. Especially for the group of 0.5-0.7 mm, since this means that for one measurement a target can be labelled as adequate while in another measurement the same target can be labelled as inadequate.
- It is very important that targets having a Polaris value bigger than 0.8 mm will also be labelled as inadequate by the CamBar system. Missing some of the targets in the groups below 0.8 mm is less important.
- Results of the measurements are given in txt documents and will be processed and evaluated by using Excel.

Results and analysis

The total amount of targets measured with both systems is 1478.

Correlation

The values found per target with the Polaris system and the CamBar system are shown in figure 8. Using two different axes, a graph such as found in figure 9 can be made. From this figure it appears that there is indeed a correlation between the values found with both systems. The black horizontal line shows the value of 0.5 mm for the Polaris system from which targets are valued as inadequate (between ±50°). At the CamBar axis this results at a value between 2.7 and 2.8. This is a first indication around which number the limit value should be.

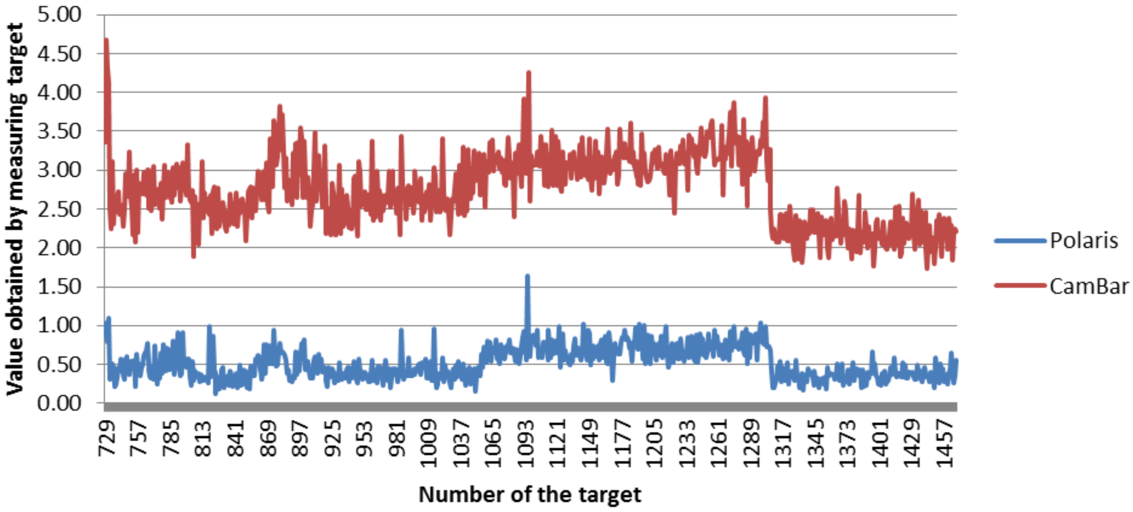

Figure 8 Values obtained by measuring the target is plotted for both the Polaris system and the CamBar system. On the y-axis the value obtained by measuring can be found, on the x-axis, the number of the target is displayed. This figure thus shows which CamBar value and which Polaris value belong to a certain target.

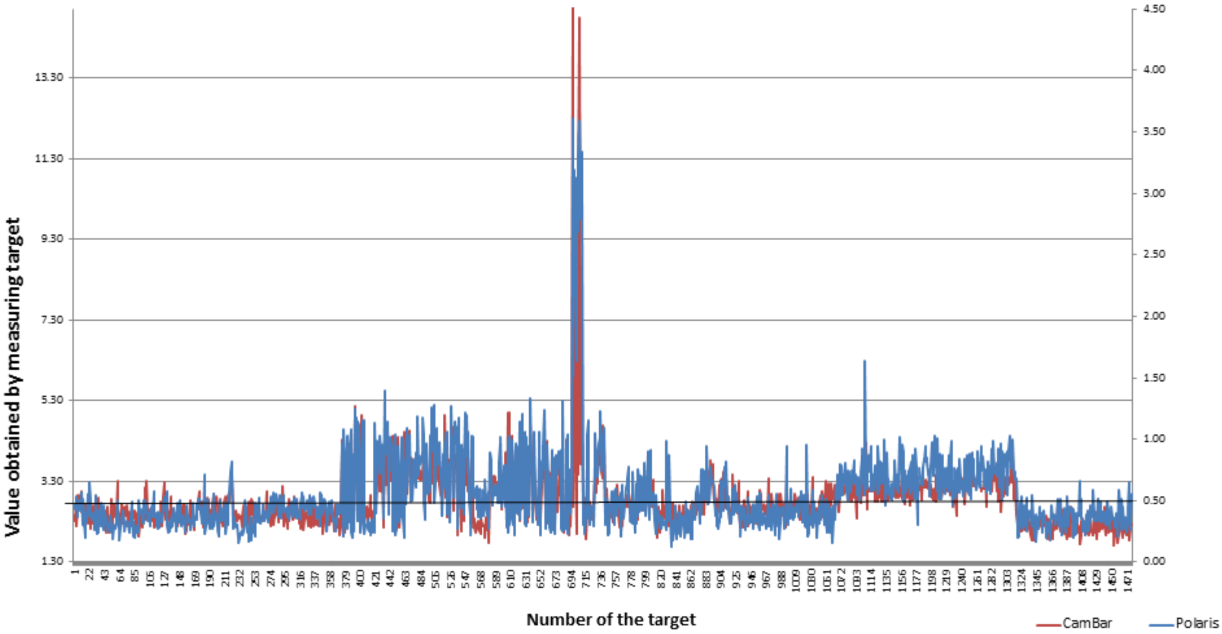

Figure 9 The same results as shown in figure 8, but now values obtained by both systems have a separate axis. Thereby, it can be seen that there does exist a correlation between both measured values.

In the end a limit value of 2.7 will be chosen and therefore the results shown in the following part of this report are obtained by using this value. By using this value it will be shown that the CamBar system is adequate enough to find inadequate targets.

As said earlier, a total amount of 1478 targets are measured. Of these targets, 905 were valued as adequate and 573 as inadequate by the Polaris system. 944 Targets were valued as adequate and 534 as inadequate by the CamBar system, taking a limit value of 2.7. A total overview of the numbers can be found in table 1. In this table, the targets are grouped by their found Polaris value, being found in the top row of the table. The results of this table are also shown in figure 10, figure 11 and figure 12. In these figures, OK stands for adequate targets and NOK (not OK) for inadequate targets.

	Total	<0.5	0.5-0.6	0.6-0.7	0.7-0.8	0.8-1.0	1.0>
Polaris OK	905	833	60	12	-	-	-
Polaris NOK	573	-	123	103	107	155	85
From which CamBar also NOK	510	-	78	94	103	152	83
From which CamBar OK	63	-	45	9	4	3	2
Percentage found inadequate targets by CamBar	89	-	63	91	96	98	98

Table 1 Overview of the results, using a limit value of 2.7 for the values found with the CamBar system

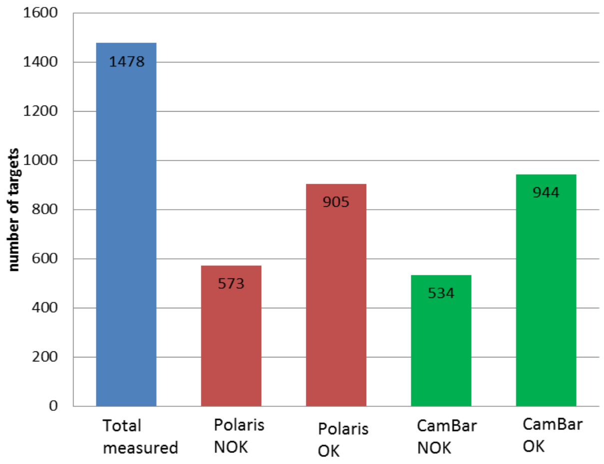

Figure 10 Total overview of measured targets

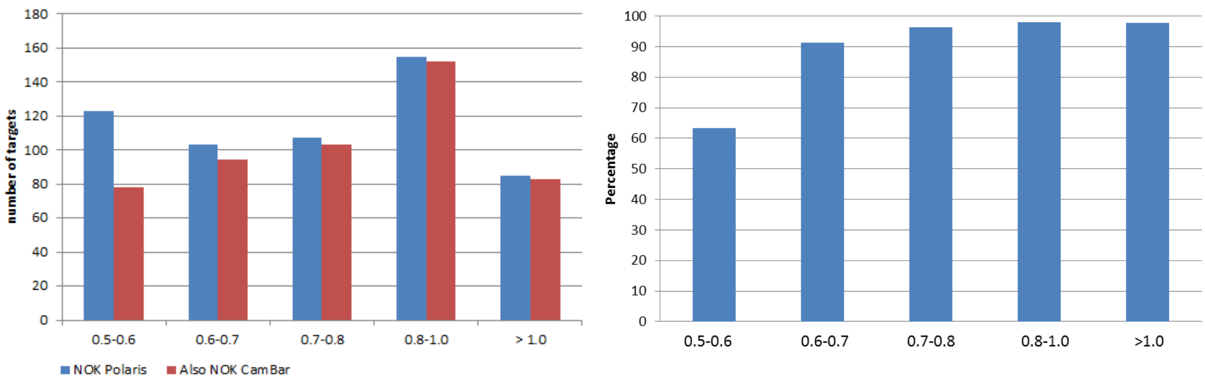

Figure 11 An overview of the total amount of targets measured, organized per group. These groups are based on Polaris value. In red, the amount of targets valued also as NOK by the CamBar system can be found. On the right this is again displayed but then the amount of NOK of the CamBar system as a percentage of the NOK amount by the Polaris system.

From the groups 0.8-1.0 mm and >1.0 mm, there are in total four targets which are not found by the CamBar system. It is possible that when measuring these targets with the Polaris system, an error was made by which the target got a higher value than really should be the case (this is for example possible by having part of the target covered by a glove or finger). Though, it cannot be proven that this is what happened in these cases. Four targets are during an operation instead of the necessary three. Therefore, it is not a big problem when one of those four targets is a bit worse than required since the error will be vanished or found. In Figure 11 it can also be seen that for targets valued between 0.5 and 0.6 mm and being valued as inadequate by the Polaris system, only 63% is valued as inadequate by the CamBar system. It has to be taken into account that both measurement systems have a measuring bandwidth. For the Polaris system this has been shown in the past to be around 0.2 mm. For the CamBar system, this bandwidth will be shown later on in this paper and will appear to range from around ±0.02 to ±0.75. As explained later, ±0.75 is too high and the CamBar system will have to be adjusted to make this bandwidth smaller. Therefore, it is not strange that not all of the targets in the group are found inadequate by the CamBar system. For this group the effects of using such a target in an operation are not dramatic since the error is still on the edge of adequate and inadequate.

Figure 12 shows that 905 targets are valued as adequate by the Polaris system, while 215 of these targets are being valued as inadequate by the CamBar system. Again, the measuring bandwidths play a role in this number. Also, some targets having a great difference in values for the both systems have been found to have incomplete coatings, damaged globes or spots on them. In the past it was already shown that these targets were not always found by the Polaris system. Apparently, the CamBar system is better in finding these kinds of failures, which is a good thing.

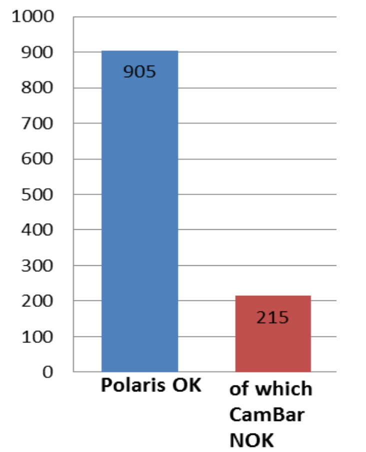

Figure 12 This figure shows the amount of targets valued as OK by the Polaris system in blue. When these targets were measured with the CamBar system, it appeared that 215 of these targets were valued as NOK.

Until now the measurements have shown good results. However, the measuring bandwidths have not been looked at yet. The two different bandwidths to be found are the camera measuring bandwidth and the total measuring bandwidth.

Measuring ten times the same

Ten full measurements were done consecutively on a plate with 23 targets. During these measurements, the targets would be kept stationary (targets were not touched during the measurement). The difference was found between the maximum and minimum value of these ten measurements, which in figure 9 is called the maximum difference found. On the x-axis, the minimum value found in these ten measurements is displayed. In total, 29 plates (and thus 667 targets) were measured this way. A maximum difference of 0.75 was found. This is about 30% of the limit value (again, a limit value of 2.7 is assumed), which is a very big number.

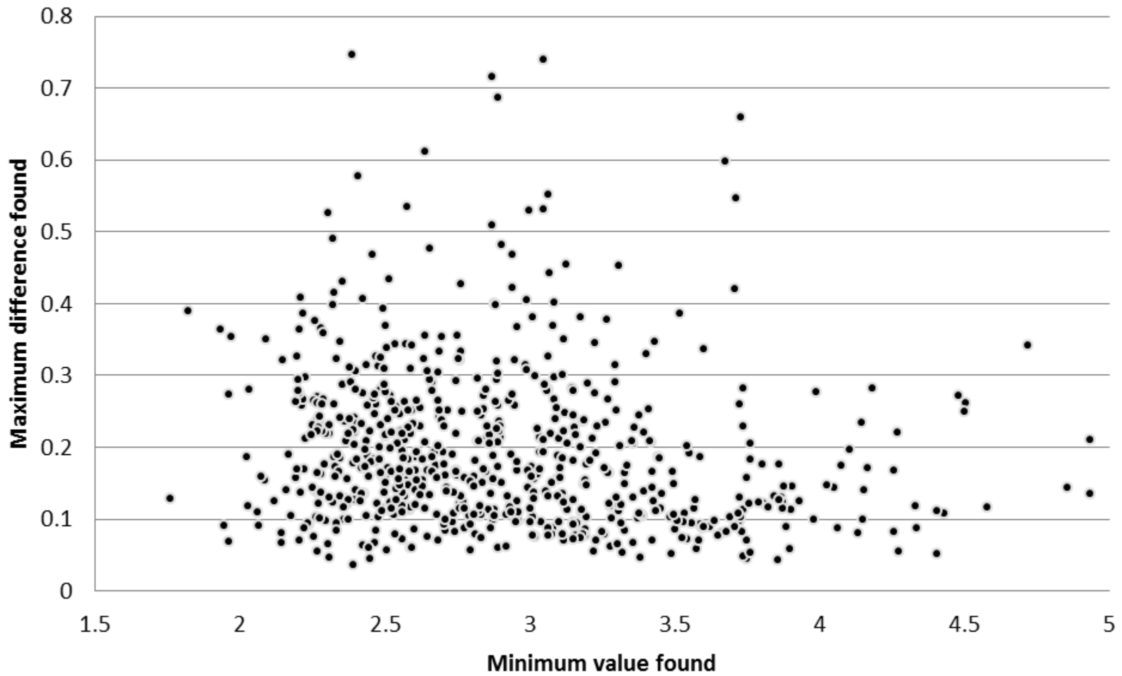

Figure 13 The maximum difference found in between the values obtained from ten measurements is plotted on the y-axis. On the x-axis, the minimum value found in these ten measurements is plotted. Important is to notice that the x-axis does not start at zero.

The average difference is found to lie around 0.2. Differences up to 0.3 will be accepted, but these results show, that when measurements are repeated, a too big of a difference is found for the same target.

Especially when zooming in on a critical part of figure 13 (shown in figure 14) it can be understood why these differences are too big. The targets in between the red lines (left from the vertical red line and above the diagonal red line), will be valued as adequate in one measurement, but will be valued as inadequate in the next. This way targets that are actually inadequate could be included to be sold to the customer. This could be accepted for a small amount of targets (with small differences found), but these results show that this is the case for about 18%, which is an unacceptable high value.

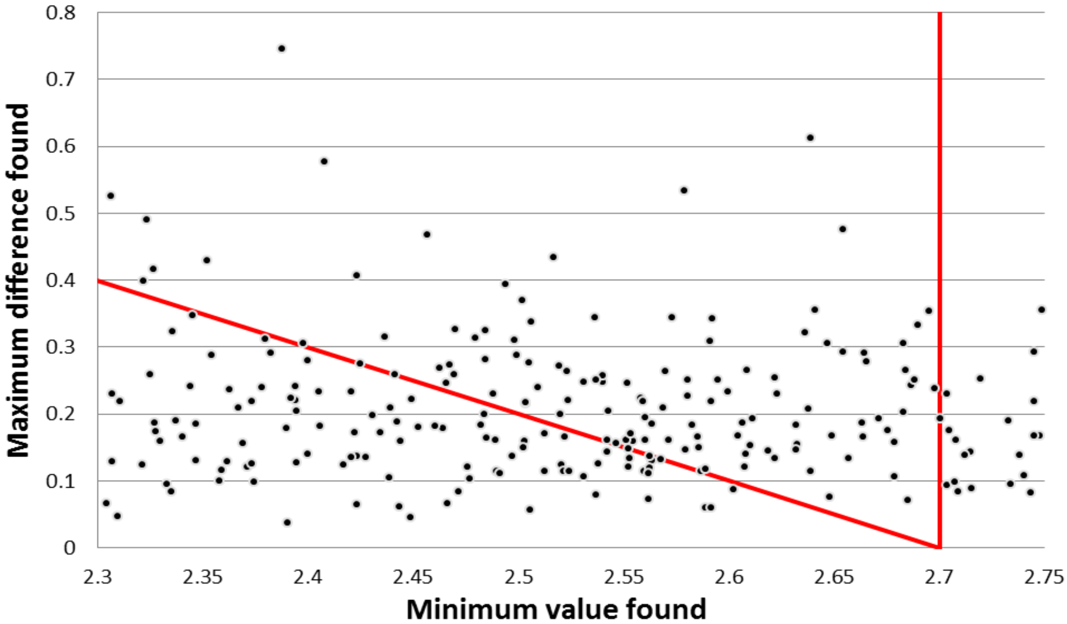

Figure 14 Critical part of figure 13. The points in between the two red lines stand for targets which could be measured as adequate in one measurement and as inadequate in the next measurement.

Measuring ten times while turning the targets for every full measurement

In figure 15 a plot is shown with results of measurements as in figure 13, but now, the targets were turned around its axis for every full measurement. This turning was done randomly. Again, 29 plates were measured (although these are not all the same plates as for the previous “ten times the same’’ measurement). This again comes down to a total of 667 targets measured.

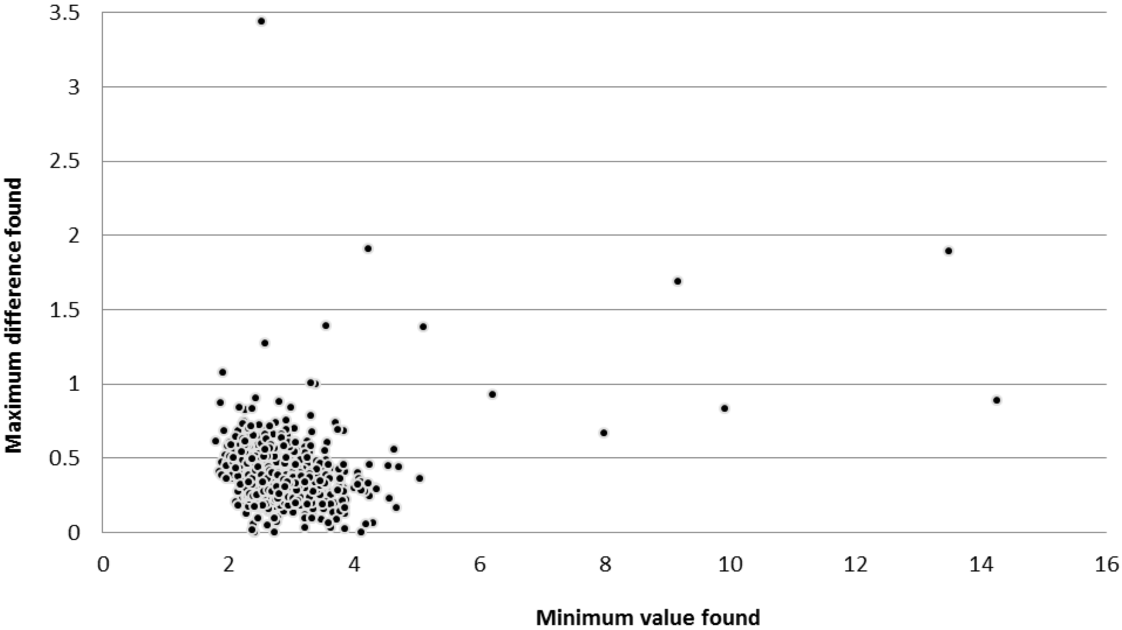

Figure 15 The results are shown of ten full measurements while turning the targets in between the full measurements. Again, the Maximum difference found between these measurements is plotted on the y-axis and the minimum value found is plotted on the x-axis.

The total measuring bandwidth can be found by using figure 15. It can clearly be seen that the differences found between measurements are a lot bigger than when not turning the targets (as seen in figure 13). For these measurements, the average difference is to be found around a value of 0.4, which is the double of the previous measurement without turning the targets. It is weird, though, that such bigger differences are found compared to the measurements done without turning the targets. One full measurement namely consists of measuring four different sides of the target and the resulting value should thus incorporate all sides

It can be stated again that this kind of differences between measurements of the same targets are too high. The percentage of targets being adequate in one measurement and inadequate in another now lays at about 30%.

Measuring two times while interchanging the target's position

It can also be checked whether the position on the plate has any influence on the values obtained. Measurements were done in which the position of the targets on the plate were interchanged. The target on position number one would interchange position with target on position number 23, the target on position number two with target position number 22, etc. This manner was chosen since it was a convenient way to remember which target went were. Though, this way, target number twelve had no changed position. One measurement was done after which the targets were interchanged position and then another measurement was done. The difference between the two values obtained was calculated and plotted on the y-axis of figure 16**.** On the x-axis the minimum value of the two obtained values is plotted. It is hard to interpret these results since they cannot really be compared to the results found when doing ten measurements. The average difference found is again about 0.2, which does not seem that bad, but again, comparison between results is hard. 28 Plates were measured in this way. Excluding target number 12 from every plate, this results in 616 targets (28*22=616). The percentage of targets being adequate in one measurement and inadequate in another now lays at about 16%.

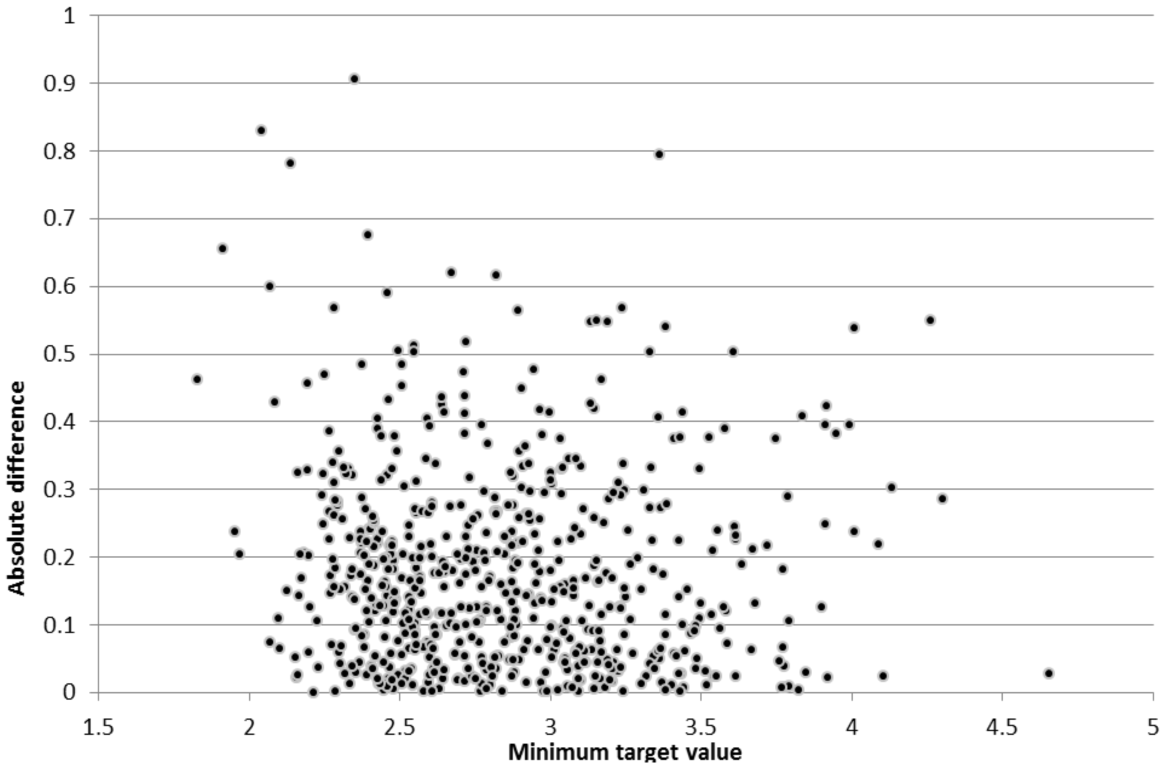

Figure 16 This figure shows the results obtained when doing two full measurements when interchanging the target`s positions. On the y-axis, the absolute difference between the two values plotted, while on the x-axis the minimum value of the two values obtained is plotted.

Maximum difference found for single measurements

Two plates were used to perform ten single measurements from the same side. The difference between the minimum and maximum value found was deducted and is plotted in figure 17.

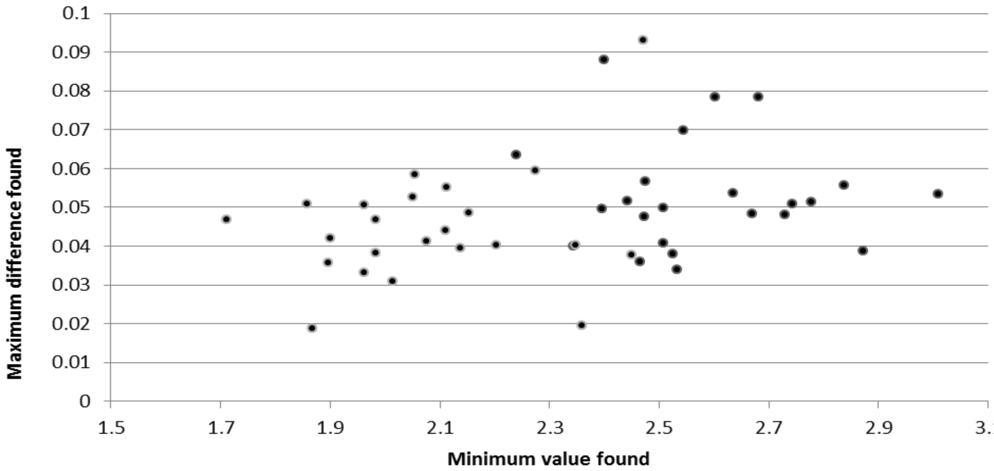

Figure 17 Results are shown of the maximum difference found when doing ten single measurements.

Figure 17 can be used to find out about what causes the major differences between the ten measurements. When doing the measurement like this, the bandwidth of the camera can be found, which appears to be lying around 0.05. The high differences found between measurements thus have to come from repositioning the plate three times for every measurement.

Live images

Also it has been thought that reflection takes place at the targets. This can be seen in appendix 1. At 50° the reflection seems to be attached to the target, at 40° the reflection is separated from the target image and at 20° this reflection seems to have (almost) disappeared. It is thought that these reflections disturb the measurement. Therefore it might be better to measure at 40° or 20°. Though, it has been shown that the 50° angle is the best angle to get most of area of the targets in the view of the camera.

Wrong positioning

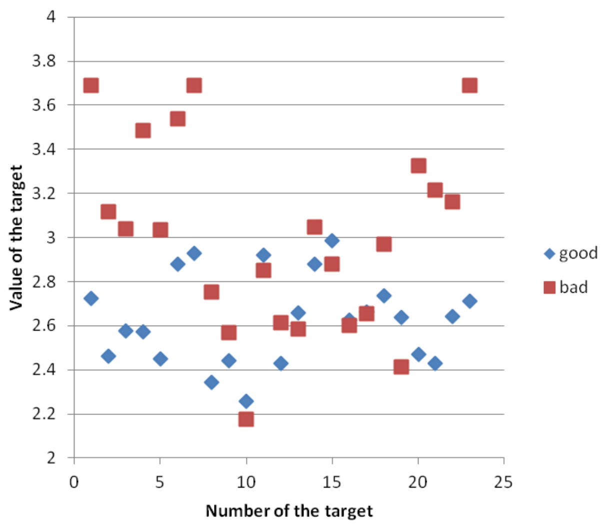

Figure 18 The results obtained when putting the plate into the table rightly (shown in the figure are good) and when putting the plate into the table wrongly (shown in the figure as bad)

As a last measurement, it was checked whether measurements could be done when the plate or a single target was not in its right position. It appeared that when shifting the plate visibly to the right no measurement could be done. Though, when tilting one side of the plate, a measurement could be done. Two different kinds of results were found. The first type was that all targets on the plate would get a very high value (above three), which can easily be recognized. The second type of results is displayed in figure 18. In this case, not all targets turn bad, but only some values seem to increase due to the tilting. Such an error is harder to be found than when all targets on a plate turn bad.

Also, a single target can be put in a faulty position. A value of about two times higher than the actual value could be found for the target. This is a less important error than putting a whole plate wrong since only one target will be sorted out instead of more targets.

Conclusion

Different conclusions can be drawn from these measurements. First of all, the results shown in figure 11 give good enough results that the targets could be measured with the CamBar measurement system. Second, the results in figure 13 show that the difference when repeating a measurement is too high. This means that the measurement system is not reliable enough since results are not reproducible. Figure 17 shows that the camera measuring bandwidth is sufficient and that thus the bad total measuring bandwidth mainly comes from repositioning the plate in the reference system.

In figure 16 the results are shown of measurements in which the targets have interchanged positions on the plate. This seems to give good enough results, though no real conclusions can be drawn from these results. Appendix 1 shows us that there are reflection effects to be found on the plate. It is not known what effect these reflections have on the values found for the targets. What is also not known is why the results of figure 13 (ten full measurements without turning) and figure 15(ten full measurements when turning the targets) differ this much.

Discussion

The first point of discussion is that it is not understood how the reproducibility is this bad, while the correlation is good. The total measuring bandwidth has been found to be ±0.4 on average, which is really big. Maybe, this correlation was found because such a great amount of targets was measured. Still, it is very important that this total measuring bandwidth decreases.

Another point for discussion is the that the average for the maximum difference found for ten full measurements was half of the value of the average for the maximum difference found for ten full measurements with turning the targets. There could be two reasons for this. The first reason could be that targets influence each other. For example, when one target is inadequate, it could in some way influence the measurement by which the value found for the target next to it becomes worse than it actually is. Such a scenario could have something to do with the seen mirroring effect of appendix 1. Measurements were done in which targets interchanged positions, but unfortunately, nothing could really be concluded from these measurements. The second reason could be that four measurements are not enough. This would mean that not all sides are measured well enough within four measurements. This is not really expected but should still be kept in mind when the other reason is found not to cause it.

To make sure that the reproducibility is bettered and hopefully becomes good enough, some recommendations are made. Also recommendations will be done to hopefully find the reason for the doubling of the found maximum difference when measuring ten times.

Recommendations

During my internship it has become clear how valuable but also unstable an optical tracking measurement system can be. Errors were and still are easily made and they are hard to be found. A lot of different factors have influence on the values found for the targets and different errors can also cancel each other out.

Without a perfect reference system, errors will not readily be detected. Since it is impossible to make a perfect reference system, a hundreds of a millimetre are allowed, which is often still very hard to be reached. It seems that the tool shop of Atesos is able to make the reference system in a good enough tolerance. Though, this did not always work out well during my internship. A solution would be to have the mechanics sent to another company who will definitely be able to make it within the tolerances but during my internship there was often no time to do this. The best solution, in my opinion, is therefore to show the mechanic of the tool shop the whole measuring system so that he knows what it exactly does, how it is used, and what the critical points of the system are. This will take about an hour probably and will in my opinion pay off.

As already found out in the background research part of this chapter, often the underlying mathematical models of a measuring system are not known. This also appeared to be the case for Atesos. It is known how a position value is found by the CamBar system, but this was not known for the Polaris system. This information is not known because the software is developed by another company who will off course not give away how it is done since that is their business. When this information would be known it can easier be explained why and how some failures of targets are found by a measurement system or why not. It is good that this information is known for the CamBar system. The problem is that this information is not easy to be understood without a lot of experience and that the knowledge is not easily carried over to another person. In my opinion, every measurer should know as much as possible about the system and its difficulties. Time should be taken to hand over the knowledge about the system which is often not done.

Also, it might be helpful for Atesos and the supplier of the software to have a meeting to discuss whether it will able to adapt the software and hardware in such a way that errors are more readily detected. Such a meeting kind of took place when an error appeared. In this meeting it was only checked whether the hardware could be changed and not the software. It is important to check all possible errors and see how these could be detected. For the changes on hardware already mentioned, action should be taken. Some solutions were found but these were not executed.

Since I do not think that new operator will ever know the same about the system as my supervisor does, she should always be checking the measurements and results. This will be effective, not only because she has more knowledge about the system, but also because the operator might start to focus more and more on quantity instead of quality after some time. This will happen because doing the measurements is monotonous after a while.

I have seen how really small errors can make big differences in the measurements. Plans have been made to replace the CamBar prototype with a new end product system (with the same camera). In this system, a turning table would be used instead of turning the plate by the operator. Also, the plate will be put horizontal and the camera under an angle, to ensure better positioning of the target on the plate. This does help but does not prevent the misplacing, and thus, care should still be taken to place the targets good on the plate. Also, the plate will be made bigger so that the targets have more space between each other so that the mirroring will not be as present. When this has been done it can be checked whether the difference between the maximum difference found for measurements with and without turning becomes less. This would mean that this big difference would be caused by influences of targets on each other. When this has no effect, it should be checked whether better results are found when more than four measurements are done. Unfortunately, doing this is not that easy since the table should be able to be turned in other angles and the software should be adapted to these measurements.

My recommendations are that people should only measure one lot at a time and not like I did measure lot after lot, since small mistakes will slip into such a routine. As I said, the goal of the operator might shift from quality to quantity, which should definitely not happen.

In the end the goal is to hand over the measurements to the producing company, Thermoplast. It will be good to have a measuring and calibrating manual. Also, it will be best when one person at this company measures and not every week another person since that way one person can acquire a lot of knowledge about the system.

7. Literature research short stem (short vs long stem)

The plan is that Atesos is going to design and produce a short stem hip implant. To be able to do this a literature search had to be done.

The age with which people need a hip implant is declining and suppliers are looking for a way to supply this demand. The problems are the life time of the implant (which is too short to have the patient live with only one implant, a follow up implant will be needed) and that the patients will be more active than the older patients [6]. Also, a solution is still to be found to make the operation of hip implants less invasive [7] [8] [9] [10] [11] [12]. So, patients nowadays demand more of their hip implant due to increased activity and they also demand more out of their hip reconstruction.

Long stem implants are for now to be used most, but their disadvantages are that a longer stem is more difficult to insert and its reduced bone stock for future revision [13]. A solution is having an implant with a short stem. Such an implant is bone conserving [6] [8] [9] [14] [15] [16] [12] [17] [18] and soft tissue conserving [15] [16] [12] [17] and therefore it gives better revision possibilities [19]. The short stem design has a stable metaphyseal fit [7] [8] and an optimized load transmission [9] [14] which is more physiological [8] [20] [21] [22], which results a reduction of stress shielding [20] [23] [22] [18] [24] which in turn may reduce the risk of aseptic loosening [20]. The distal loads are avoided [15] [21] [17]. It is also suggested that a shorter stem might limit the possibility of squeaking of the implant as lubrication deteriorates in ceramic-on-ceramic (COC) implants [25]. The short stem design causes less blood loss than its long stem equivalent [19] and it needs more conservative surgery [8] [9]. Also, these kind of implants have been associated with proximal bone remodelling closer to the metaphysic when compared to conventional stems [7] [23]. A high level of patient functioning can be achieved [7]. The short stem appears to be more resistant to micro migration [8]. The short stem has a versatile applicability due to its unique geometry, mechanism of fixation, and modularity [9]. The short stem appears to give less thigh pain than the conventional stem [15] [26]. Due to a combination of these advantages, these short stems are suggested for younger patients [20].

Though all these short term effects seem to be very advantageous, long-term effectiveness still needs further observation [19] [8] [14] [22] [18] [24]. The stability and alignment of the implant are by some resources still questioned [21]. For example, reference [28] states that there is no subjective better stem, since the type of implant to be chosen for a certain patient depends also on other factors than stem length such as diagnosis, bone type and condition, patient age, and surgeon preference [28].

Figure 19 Anteroposterior radiograph of a patient with standard-length and short cementless femoral components. [27]

The length of a short stem should be short enough to avoid distal locking and distal load transfer but it should be long enough to make sure that primary stability is reached [29]. Stability is related to micro motion. Motion at the bone-implant interface above 40 µm leads to partial bone ingrowth, while motion exceeding 150µm inhibits bone ingrowth [10]. Femoral stem length as well as stem design influence stability directly [10]. It appears that the length of the stem can be reduced substantially without compromising the primary stability [10] [18].

8. Rat implants with a new anti infection coating

One of the problems with implants is infections. Atesos together with a couple of other companies is developing a new kind of coating by which the number of infections should reduce. This will be accomplished by a chemical reaction by which the pH level will be reduced so that cells die. This means that the cells causing the infection die as well as some of the patient`s healthy cells. It is very important to find a concentration of this substance which will be enough to be effective against infections but which will not be as extreme to really damage the patient`s own tissue. An important issue with implants is osseointegration. This will not happen as long as cells around the implant are damaged by the pH level. Therefore, osseointegration will happen later during recovery after the surgery and thus an optimum time span for the lowered pH level has to be found.

As with a lot of medical research, the coating will be tested by implanting implants into rats. There will be three groups of implants, each having another type of coating. To keep the implants with the coating clean and so that the coating will not get affected in any way, holders will have to be made for these implants. These holders need to be clean and need to hold the implant well, but also should be able to release the implant when wanted.
It is important that the holders are made of material which is able to withstand sterilization by using gamma radiation but which can also be machined well. A hundred of these holders should be made.

The holder will be made of a metal with a thread to put the implant on. This will be glued onto a plastic cap with a Loctite glue. To shield the implant, an aluminium tube is put onto the plastic cap. The implant holder and protector can be seen in figure 20.

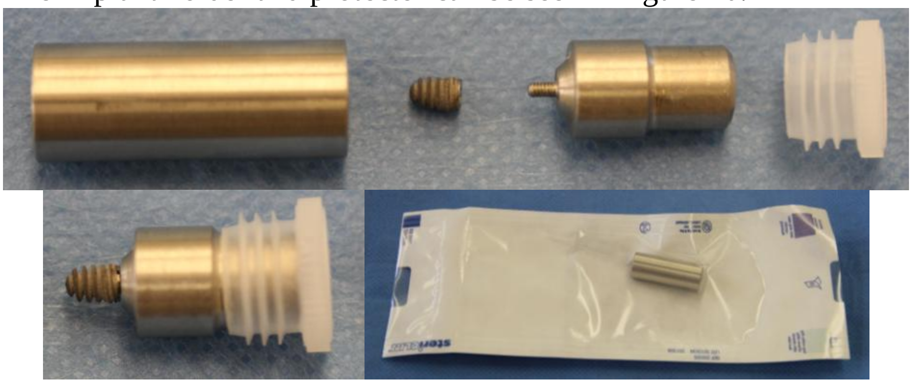

Figure 20 The top picture shows the implant with the implant holder. In the middle picture, the holder is assembled and the implant is put onto the threaded part of the holder. In the bottom picture, the aluminium tube is placed over the holder to protect the implant and the total assembled holder is packed into a sealed bag after which it can be sterilized.

9. Tooth implant

Another project running at the moment at Atesos is a new design of a tooth implant. Tooth implants now exist of two parts. One part is first implanted after which the second part can be put onto the first part under an angle so that it is well aligned with the rest of the teeth. It is not possible to do this aligning well during the placing of the first part of the implant which is the reason that the implants now exist of two parts. A higher chance of infections exists because the implant consists of two parts. Therefore Atesos has thought of a new design in which the implant will only consist of one part. To be able to align the implant well with the other teeth after placement, it will be made of special kind of material which will be strong enough but is also able to be bent into the right angle.

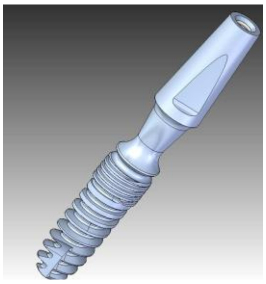

Figure 21 The tooth implant design of Atesos

When an implant just has been implanted it is not good to apply a large force since this might cause problems with the integration of the implant with the jaw bone and soft tissue at this location. Therefore, an instrument has been designed at Atesos that is able to bend the implant without putting (or only a little) force at the surrounding tissue. The implant can be seen in figure 21.

The first assignment done in this project was to calculate whether the implant would withstand the bending forces. By setting up an excel document, diameters could be changed to get the results wanted. Two different force applications were calculated.

Figure 22 shows the first force application, where a force is applied on the left and the implant will be clamped on the right. The purpose of these calculations is to find the diameters at position one and two for which the bending stress will be about equal for both places. The implant is simplified and can be seen in figure 22 on the right.

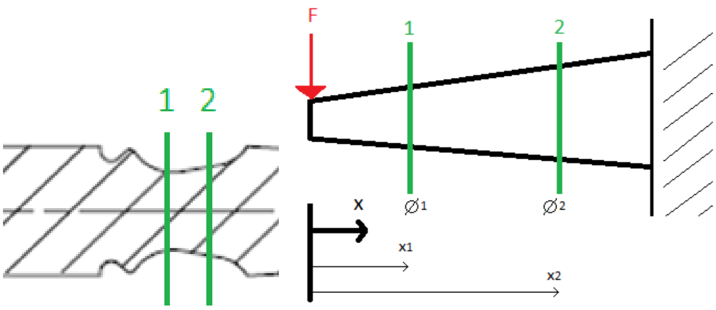

Figure 22 Force situation one

To be able to calculate the stress in such a simplified beam, the following formula can be used:

$$\sigma = \frac{M * y}{I} \qquad \{1\}$$

In this formula, σ stands for the bending stress {N/m^2}, M for the bending moment {Nm}, y for the perpendicular distance to the neutral axis {m} and I for the second moment of inertia {m^4}.

The bending moment can be calculated as follows:

$$M = -F * x \qquad \{2\}$$

In which F stands for the force {N} applied and x for the distance {m}, both shown in figure 22.

The beam will be assumed to be cyllindrical and therefore, the perpendicular distance will equal half the diameter:

$$y = 0.5 * d \qquad \{3\}$$

Where d is the diameter {m}.
The second moment of inertia for a cylinder is calculated as follows:

$$I = \frac{\pi * d^4}{64} \qquad \{4\}$$

These calculations have been done for four different sizes of implants. The results are shown in appendix 2.

The second force applicationwas is shown in figure 23.

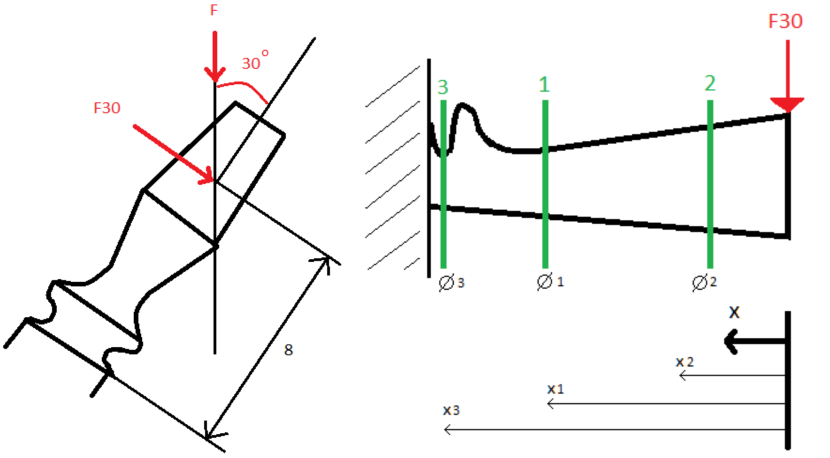

Figure 23 Force situation two

Here, there is a vertical force while the implant is under an angle of 30°. Only theF30 force is needed for the calculations since this one will cause the bending stress. This time also the bending stresses at point three are important. The same formulas as for force situation one were used. The results can be found in appendix 2. The main goal of these calculations was to see the ratio between the bending stress at point one and three.

Also, another bending instrument had to be designed for when the implant is already implanted for quite some time. Since after a while the jaw bone will already be attached to the implant, it was not that important how much force would be on it. A prototype was already built which is shown in figure 24. Though, this instrument was not satisfactory yet. Requirements set are that the instrument should be strong enough, but also it should have a as low mass as possible since then the surgeon will better feel how much force he is putting on the implant and thus will be able to align the implant better. Also, the instrument should be easy to clean and no water or moisture should be able to get stuck somewhere.

Figure 24 Prototype of an instrument which is intended to bend a tooth implant when being already implanted into a jaw for quite some time

In figure 25 a drawing of the design made can be found on the left. On the right the produced instrument is found. The instrument consists of four parts. Three parts are welded together and the last one, the bar through the handle can be taken out if wanted. The full assembly drawing can be found in appendix 3.

A cone is used to surround the implant. A small pin is put onto the axis of this cone to make sure the surgeon can see the angle under which the instrument is. The handle is hollow. Two small holes are found in the handle to make sure that all water can escape the handle after being washed.

The material used is stainless steel, because it is strong and can be cleaned well. To get an idea of the size, the length of the instrument is 12.4 cm.

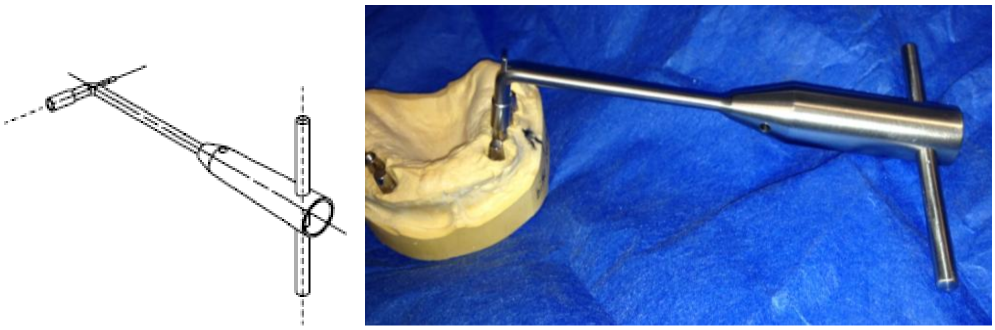

Figure 25 New design of the instrument shown in figure 24

10. List of all projects

Hip implant

- Literature research about a short stem hip implant including a competitor analysis;
  Results: seen in chapter 7. Also, a table containing all competitors has been made together with their basic information.
- Literature research about a constrained liner implant.
  Results: Overview of all different surgical techniques when using a constrained liner, table containing all competitors.
- Changing the design of an instrument called Manipulierschale by making its window smaller and by giving it a small ridge to make it recognizable. This should be done for the sizes 42 to 62;
  Results:
  The Manipulierschale was made in NX6 by using a family part. In figure 26 the old design of the Manipulieschale can be found on the left and the new design on the right.

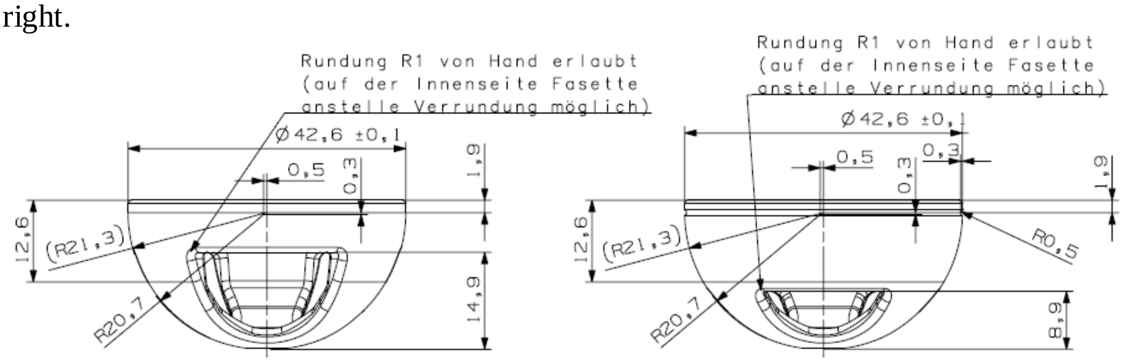

Figure 26 On the left the old design of the Manipulierschale can be found of size 42. On the right, the adapted design is found in which the window is made smaller and a small ridge is added.

- Making bigger sizes of the trial instrument called Manipulierschale, sizes 64, 66, 68 and 70;
  Results:
  This was done by using a family part in NX.
- Doing literature research for the pyramid shaft for the last couple of years for the repeating clinical assessment;
  Results: A literature overview was made and articles were included and excluded from the clinical assessment.
- Literature research on screws used to attach the cup of a hip implant and looking for different surgical techniques;
  Results: A literature overview was made.
- Think of a way to mechanically test a new design of a cup in the tool shop of Atesos;
  Results: Since Atesos does not have a force tester, a relative force measurement should be done to see whether the force would be less or greater than for the already existing (and force tested) cup. Best would be to do relative impulse test by building a pendulum onto which masses can be attached. To measure the pull out force, a small rope could be attached to both cups and they should be pulled at the same time.

Optical active spheres together with its measurement systems

- Quality control of the new CamBar system;
    - Get to know the (already in use) Polaris measurement system;
    - Get to know the (new) CamBar measurement system;
    - Get to know the targets to be measured;
    - Make a work plan of how to carry out the quality control;
    - Carrying out the work plan by doing measurements;
    - Processing the measurement data;
    - Analysing the processed measurement data;
    - Presenting the measurement data;

  Results: The results can be seen in chapter 6.
- Recalibrate the Polaris measurement rod;
  Results: This was done by using the calibration manual.
- Change the technical drawing of the measurement rod;
  Results: some dimensions were changed on the drawing (made by hand)
- Make technical drawings of the target by hand;
- Change the design of the bottom of the targets;
  Result: This was mainly done by milling away parts of the targets base.

Rat implants, testing a new coating

- Produce the holders which can keep the rat implant and protects them;
- Check of which material they can be made (while keeping in mind that they will be sterilized by using gamma radiation);
- Make the holders in the tool shop;
- Assemble the holders;
- Transport holders to coating company;
- Pack the holders so that they can be sterilized;
- Design an instrument with which the implants can be taken of their screw thread;

Results: Can be found in chapter 8.

Tooth implant

- Stress calculations of the tooth implant;
  Results: Can be found in chapter 9
- Interpreting tooth implant FEM calculations and checking whether these values could be correct;
  Results: The stresses seem to be about equal when calculated as when checked on the Fem calculations.
- Calculations for the strength and stresses of a tooth implant bender;
  Results: With a wall thickness of 0.7 mm, the implant bender would be strong enough. The instrument (also found in appendix 3) was made and tested and indeed was strong enough.
- Designing a tooth implant bender;
  Results: Can be found in chapter 9 and appendix 3.
- Polishing the instrument used to bend a tooth implant;
- Drawing of a sort of screw to hold tooth implant in two different sizes;

Other

- Drawing for adaptations of a saw holder used during knee operations;
- Adapting the design of saw holders used during knee operations;
  Results: this was done in the tool shop of Atesos
- Drawing for adaptations in a bone holder used in shoulder operations;
- Make a drawing for a cloth holder. A surgeon needed a frame to keep the operation cloth from leaning on the patients face, maybe keeping the patient from breathing;
- Processing of external measurement data of the hip cups and inlays using an excel and macro to check the tolerances;
  Results: Can be found in figure 27. The red and green lines give the allowed tolerances. As can be seen, the blue line, giving the actual measured dimension, stays well in between these two lines.

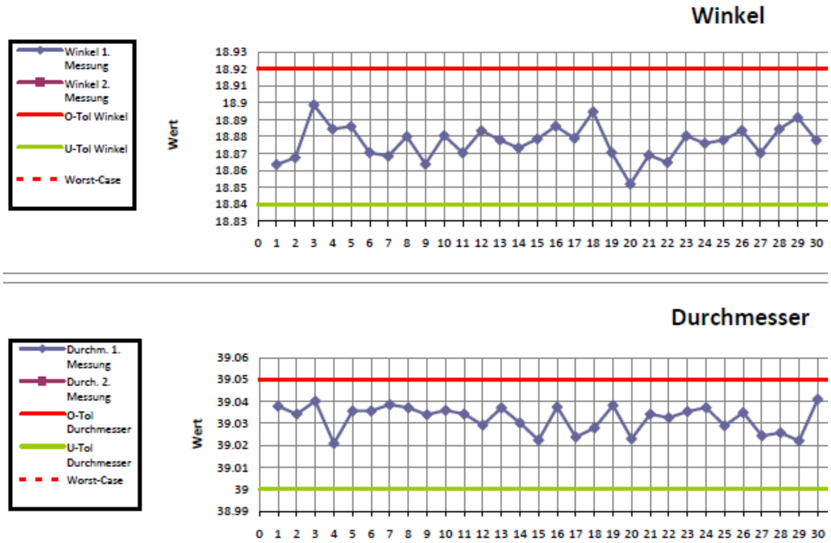

Figure 27 An example of the processed results of measurements done on hip cups and inlays

- Drawing of an intermediate part;
  Results:

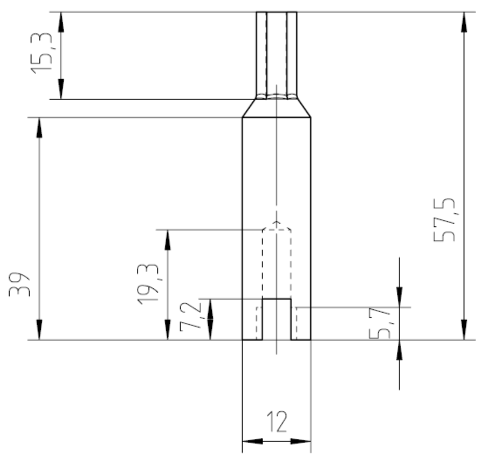

Figure 28 Zwischenstuck

- Make a list of all material delivery companies;
- Handle implants and instruments which came back with defects or complaints;
  Results: filled in complaint forms

- Going to Basel to look at an implant with an electron microscope;
  Results: The implant only had been implanted for eleven days. It is said that osseointegration happens after 14 days. On this implant, bone ingrowth could be seen, though it was not easy to see what the effects were from removing the implant from the patient`s body.
- Assisting in ordering raw materials and parts;
  Results: Metal tubes and springs were ordered
- Make a drawing of a bone saw for knee implant surgery called a Trochlea Fräser;

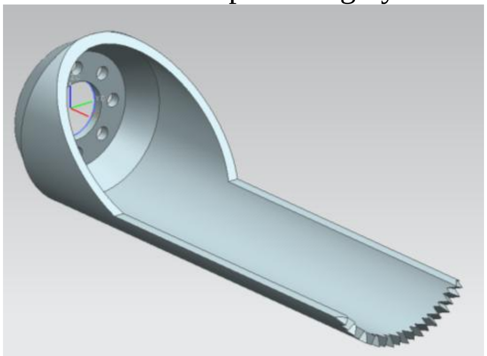

Figure 29 Trochlea Fräser

11. My functioning

Atesos is a well settled company with seven people as a permanent staff and thus not a very big company. This means that you get to talk with all persons in a product design cycle. You, for example, get to talk to the producer of your parts and instruments. This way I also learned a lot about how parts are produced and how to take this into account when drawing the designs. This is not taught to you at the University. Furthermore, it makes you understand some formalities and rules around technical drawings better. Also, how to apply tolerances and seeing when and where they are really necessary is something you can only learn in practice. Also procedures done to get clinical approval and logistics were subjects I got involved in.

I regret it that the transition from Advanced Technology to a Mechanical Engineering master only included one real design and construction course. This way not enough CAD experience and material and processing knowledge were provided for the students to use in practice. This also made it harder to get to know the NX CAD software since the basic knowledge of CAD was minimal and the software was in German which did complicate working with it in the beginning. I am glad there was an opportunity for me to work in the tool shop. This might not exactly be master level, but in my education I never worked in the tool shop. As said, it is important to know how parts will be made when drawing a technical piece and therefore this experience is valuable for me.

Thinking about how and what to measure to validate the new measurement system was hard. For Atesos it was important that not too many targets are excluded since this will cost them time and money. Also, Atesos wants to sell good targets to their customer since otherwise they will not be happy. This means that a too high limit value is not wanted, but it must also not be too low. Also, the results had to be presented to the target producing company and to the customer, which both have very different opinions about this limit value. It is not easy to satisfy both groups.

For me, this was the first company I saw which has employees doing jobs I could see myself doing in the future.

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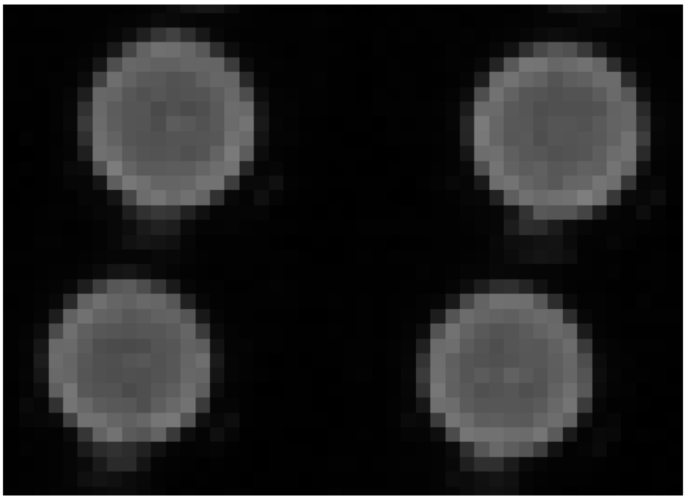
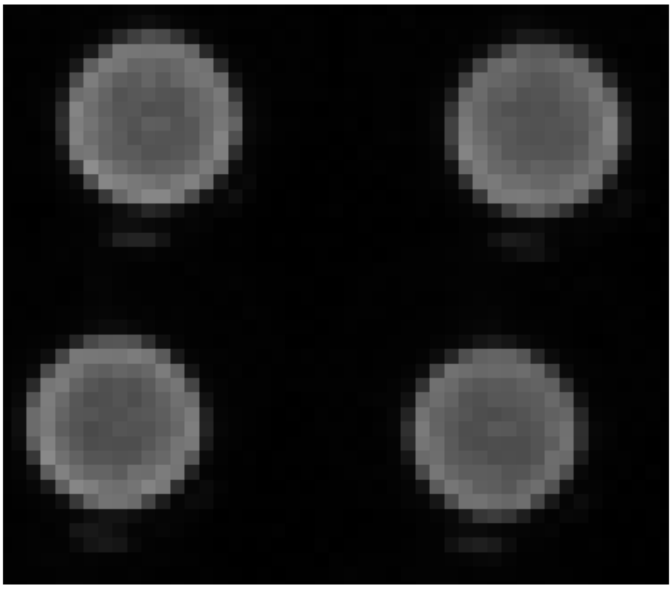
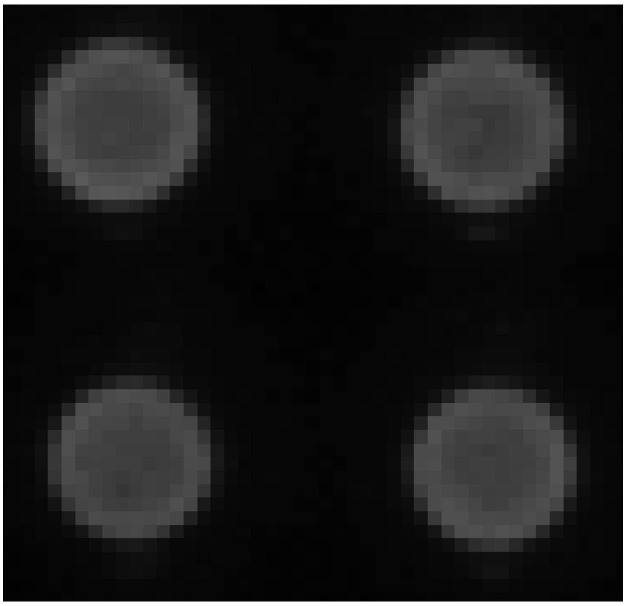
Appendix 1 Live images



50°



40°



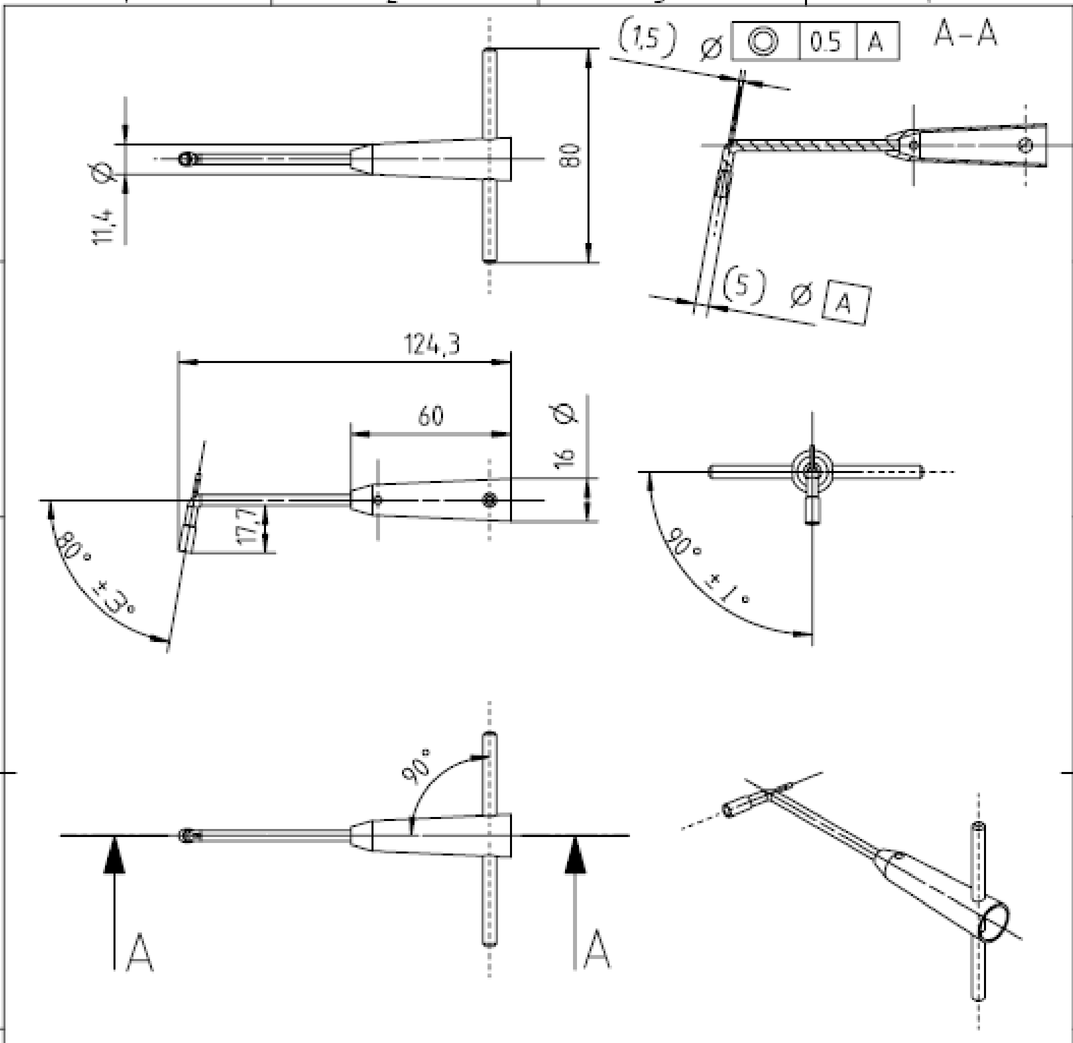
20°

Appendix 2 Results of force measurements

Force situation 1								
Force (F) {N}	**220**		220		290		290	
Bending zone name	3.5-3-6		3.5-4.5-6		4.5-3-6		4.5-4.5-6	
Geometry Position	1	2	1	2	1	2	1	2
Distance (x) {m}	0.0016	0.0028	0.0016	0.0044	0.0016	0.0028	0.0016	0.0045
Diamater (d) {m}	**0.00210**	**0.00254**	**0.00210**	**0.00294**	**0.00230**	**0.00277**	**0.00230**	**0.00326**
Perpendicular distance to neutral axis (y=0,5*d) {m}	0.00105	0.00127	0.00105	0.00147	0.00115	0.00139	0.00115	0.00163
Bending moment (M= -F*x) {Nm}	-0.3500	-0.6167	-0.3500	-0.9596	-0.4614	-0.8074	-0.4614	-1.3125
Second moment of inertia (I=(PI*d^4)/64) {m^4}	9.547E-13	2.034E-12	9.547E-13	3.667E-12	1.374E-12	2.890E-12	1.374E-12	5.537E-12
Bending stress (σ = (M*y)/I) {N/m^2}	-3.850E+08	-3.847E+08	-3.850E+08	-3.847E+08	-3.863E+08	-3.869E+08	-3.863E+08	-3.862E+08
Bending stress {mN/m^2}	-384.9773	-384.6666	-384.9773	-384.6506	-386.2645	-386.9261	-386.2645	-386.2421

Force situation 2												
Force (F) {N}	150			150			200			200		
Force30 (F30) {N} (cos 60° = 0.5)	**75**			**75**			**100**			**100**		
Bending zone name	3.5-3-6			3.5-4.5-6			4.5-3-6			4.5-4.5-6		
Geometry Position	1	2	3	1	2	3	1	2	3	1	2	3
Distance (x) {m}	0.0061	0.0049	0.0077	0.0061	0.0033	0.0077	0.0061	0.0049	0.0077	0.0061	0.0032	0.0077
Diamater (d) {m}	0.00210	0.00254	0.00270	0.00210	0.00294	0.00270	0.00230	0.00277	0.00310	0.00230	0.00326	0.00310
Perpendicular distance to neutral axis (y=0,5*d) {m}	0.00105	0.00127	0.00135	0.00105	0.00147	0.00135	0.00115	0.00139	0.00155	0.00115	0.00163	0.00155
Bending moment (M= -F30*x) {Nm}	-0.4582	-0.3673	-0.5775	-0.4582	-0.2504	-0.5775	-0.6109	-0.4916	-0.7700	-0.6109	-0.3174	-0.7700
Second moment of inertia (I=(PI*d^4)/64) {m^4}	9.547E-13	2.034E-12	2.609E-12	9.547E-13	3.667E-12	2.609E-12	1.374E-12	2.890E-12	4.533E-12	1.374E-12	5.537E-12	4.533E-12
Bending stress (σ = (M*y)/I) {N/m^2}	-5.039E+08	-2.291E+08	-2.989E+08	-5.039E+08	-1.003E+08	-2.989E+08	-5.114E+08	-2.356E+08	-2.633E+08	-5.114E+08	-9.340E+07	-2.633E+08
Bending stress {mN/m^2}	-503.9339	-229.1026	-298.8552	-503.9339	-100.3473	-298.8552	-511.4306	-235.5986	-263.2727	-511.4306	-93.4015	-263.2727
Stress at position 3 divided by the stress at position 1	1.68621446			1.6862145			1.9425892			1.94258922		

Appendix 3 Assembly drawing of tooth implant bending instrument



Pos.	Anzahl	Zeichn.-Nr.	Bezeichnung Stückliste
1	1	011.B041	Stange Biegeschlussel Klinik
2	1	011.B042	Handgriff Biegeschlussel Klinik
3	1	011.B043	Stift 1.5 Biegeschlussel Klinik

FREIGEGEBEN

AM:

DURCH:

Werkstoff

Gewicht

Ersatz für

Entstand aus

Bezeichnung

Biegeschlussel Klinik

Bezeichnung Zusatz

Instrument Atesos medical Art.Nr.

Massstab 1		Datum	Name
(Massstab 2)	Gezeichnet	15.10.2014	Eva
(Massstab 3)	Geprüft	Ø	Ø

Atesos medical AG
Schachenallee 29
CH-5000 Aarau
Switzerland

Format A4

Zeichnungs-Nr. 011.B044-A1

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Blatt 1/1