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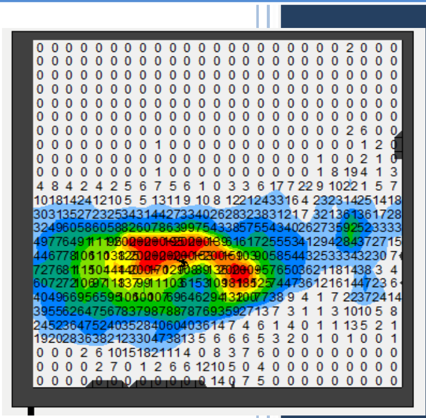
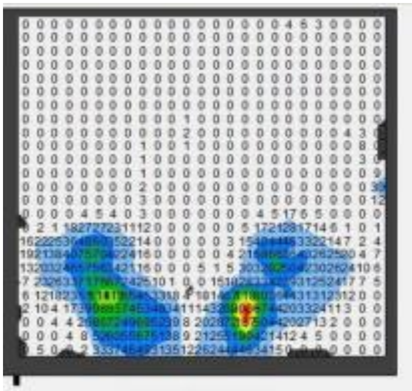
A new design of the positioning system during hip arthroscopy operation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Lisa & Tirza

Abstract

Over a period of 5 years (2006-2010) there was an increase of more than 600% in performed hip arthroscopies. During hip arthroscopy a perineal post is placed between the legs, to counter the generated pulling force and to make sure the patient stays in position. Due to this dislocation procedure several complications can occur. The most occurring complication is the pinching of the pudendal nerve. This pinching can lead to months of nerve failure. Therefore a redesign of this perineal post was made to reduction of this complication.

Different conclusions have been made from the analysis phase. At the current perineal post the pressure is mostly located at the perineal area, instead of the tuberculum ischiadicae. The main goal of the redesign of the perineal post was a reduction of at least 20% of the pressure distribution at the perineal area.

With the help of the analysis phase the list of requirements was set up. With those requirements in mind many sketches were drawn and four concepts were selected. The ideas ranged from a beanbag to a saddle concept. With a cardinal method the best concept was chosen; the saddle concept was the most progressive and was redesigned and improved. Mock-up models were made from the four selected concepts to visualize the function of each concept. With the help of the mock-up models the final concept was chosen: ‘the improved saddle concept’.

The final design was manufactured as proof of concept and was subsequently tested on seven subjects. To this end and operation look-a-like setting was built. A pressure mat was placed between the subjects, and both perineal posts, to visualize the pressure. Both perineal posts were randomly tested for all subjects.

The redesigned perineal post reduced the pressure distribution at the perineal area with 83%. The pressure distribution at the tuberculum ischiadicum of the operated leg, increased with 30%. However, the pressure distribution at the tuberculum ischiadicum of the non-operated leg, decreased with 16%. The mean maximum pressure increased with 28%. Finally, the preferences of the subjects were noted as well. The females preferred the redesigned perineal post (five female subjects), and the male subjects did not have a preference (two male subjects).

The goal of the 20% reduction of the pressure distribution in the perineal area was achieved with the redesign of the perineal post. This goal was achieved as a pressure distribution reduction of 83% was achieved.

The redesign meets almost all the setup requirements, for example the redesign can be used for both left as right hip arthroscopy, and three different sizes have been designed.

The measurements were done by a operation room look-a-like setting, therefore more research has to be done to finalise the product, and a prototype should be made and tested in a OR setting.

Samenvatting

Over een periode van vijf jaar (2006-2010) is het aantal uitgevoerde heupartroscopieën met 600% gestegen. Tijdens deze operatie wordt er een perineal post tussen de benen van die patiënt geplaatst om te zorgen dat de patiënt op de operatietafel blijft liggen. Door deze perineal post kunnen er verschillende complicaties optreden. De meest voorkomende complicatie is de beknelling van de nervus pudendes, dit kan leiden tot maanden lang uitval van deze zenuw. Om deze complicatie te doen verminderen, werd er een herontwerp gemaakt van deze perineal post.

Uit de analysefase kwam naar voren dat bij de huidige perineal post deze druk vooral gelokaliseerd wordt op de genitaliën, in plaats van de tuberculum ischiadicae. Het doel van het herontwerp was om minstens 20% minder druk te laten plaatsvinden in het perineum gebied.

Uit de analysefase kwamen de eisen naar voren, deze zijn opgesteld in het pakket van eisen. Met behulp van het pakket van eisen werden er ideeën gegenereerd en schetsen gemaakt. Deze schetsen liepen uit één van een pittenzak tot een zadel concept. Met behulp van de kardinale methode werd het beste ontwerp gekozen. Het zadel concept werd gezien als meest vooruitstrevend concept. Dit concept is herontworpen en verbeterd. Vier nieuwe concepten kwamen hier vervolgens uit voort, van deze concepten zijn mock-up modellen gemaakt om de concepten te visualiseren. Op basis van de mock-up modellen kon het eindontwerp gekozen worden.

Het eindontwerp werd vervaardigd als een proof-of-concept. Vervolgens is deze getest op zeven proefpersonen. Tijdens deze metingen zijn de proefpersonen in een nagemaakte operatie setting geplaatst. Om de druk verdeling waar te nemen is er een drukmat geplaatst tussen de proefpersoon en de post. De twee verschillende perineal posts werden blind getest onder de proefpersonen.

Het herontwerp vermindert de drukverdeling van het perineum gebied met 83%. De drukverdeling op de tuberculum ischiadicum van het geopereerde been, nam met 30% toe bij het herontwerp. Echter verminderde de drukverdeling op de tuberculum ischiadicum van het niet geopereerde been met 16). De gemiddelde maximale druk van de zeven proefpersonen nam met 28% toe bij het herontwerp. Dit komt door de verplaatsing van de druk van het perineum gebied naar de tuberculum ischiadicum. Ten slotte zijn ook de voorkeuren van de proefpersonen genoteerd. De vijf vrouwelijke proefpersonen hadden een voorkeur voor het herontwerp en de twee mannelijke proefpersonen hadden geen voorkeur.

Het belangrijkste doel van dit onderzoek was om een drukvermindering van ten minste 20% in het perineum gebied te bereiken. Dit doel is bereikt: er is een drukvermindering van maar liefst 83% bereikt in het perineum gebied.

Aan de meeste opgestelde eisen is voldaan met het herontwerp, het herontwerp kan onder andere gebruikt worden voor zowel de linker als de rechter heuparthroscopie en er zijn drie maten gecreëerd.

De metingen zijn gedaan in een nagebouwde operatie kamer setting. Het product zal eerst verder ontwikkeld moeten worden waarna een prototype gemaakt kan worden. Deze zou dan getest moeten worden op de OK.

Index

1. Introduction

The articulation coxae (hip joint) forms a connection between the lower extremities, the torso and pelvis. Important functions of the hip are supporting the body during mobility and providing stability during daily activities (1;2). Hip joint stability relies upon a complex interplay between bony congruency, the suction seal of the hip, the muscular forces, and capsular restraints. Abnormalities in one of these structures affect the instability of the hip joint (1). To diagnose and treat the abnormalities, at the Reinier de Graaf Gasthuis (RdGG) Hospital in Delft, hip arthroscopies are performed.

Hip arthroscopy is a minimal invasive surgical technique with expanding intervention options and growing possibilities where the surgeon has a clear view of the joint, to diagnose and treat joint problems, through different portals (figure 1). With the help of the camera (arthroscope) the orthopaedic surgeon can visualize the inner hip joint. At least two portals are necessary to display the hip joint during hip arthroscopy, one of the portals is for the insertion of an arthroscope, and the other portals are for irrigating and/or trimming instruments. Generally three portals are used to make sure that the tools can reach every spot of the inner hip joint.

Since the surgical techniques and possibilities are improving, the indications for whom this surgical procedure is applicable are also expanding (3;4). Over a period of 5 years (2006-2010) there was an increase of more than 600% in performed hip arthroscopies (5).

Figure 1 Hip arthroscopy (6)

Hip arthroscopy is a relatively complex surgical intervention because of the deep position of the hip in the human body. The surrounding thick soft tissue mantel, and the strong articular capsule make it hard to reach. Moreover, there is a small intra-articular volume and in the proximity of the os coxae there are two neurovascular bundles which makes it susceptible for nerve damage (7). The hip joint capsule is relatively strong as it has the role to seal the joint and therefore limits the available workspace inside the joint (7). The joint capsule of the articulation (art.) coxae consists of three important ligaments (1;8): lig. Iliofemorale, lig. pubofemorale, and lig. capitis femoris. These distinct hip ligaments have the function to independently stabilize the hip during motion, without constant muscular action (1;2;2;8).

The acetabulum is shaped by three parts, the os ilium, os ischia and os pubis, and is covered with a thick cartilage ring, called the labrum. The labrum is a cartilage area between the caput femur and the acetabulum and it ensures stability (figure 2).

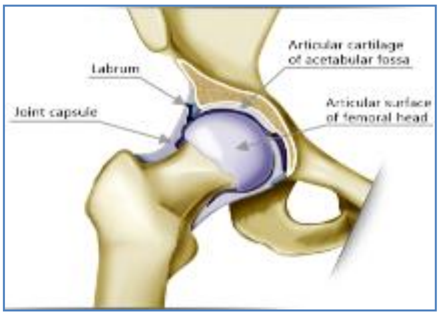

Figure 2 The hip joint anatomy (9)

In 51 percent of cases femoroacetabular impingement (FAI) is the indication for hip arthroscopy (10). The next common diagnosis are labrum tears (44%) and chondral leasions (8%) (10). The diagnosis FAI means that the bones of the joint are deformed, this can cause pain and stiffness (11). FAI can be found at two places (12). It can be found at the femoral neck-head (which is called cam deformity). Cam deformity occurs when a non-spherical femoral head locks against the anterior acetabulum. The other variant is pincer deformity; this deformity is located at the upper lip of the acetabulum cup. It is also possible to have both deformities at the same time, this is called a mixed impingement. Figure 3 gives an overview of the impingements types.

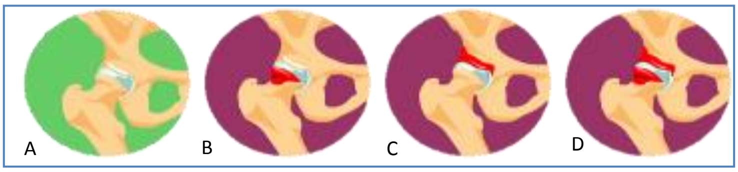

Figure 3 An overview of the impingement types; A: Normal, B: Cam, C: Pincer and D: Mixed impingement (9)

The labrum tear indications means that the labrum is damaged or delaminated. The deformity of the labrum occurs when abnormalities are present at the femoral or acetabulum, for instance labrum tear mostly occurs as a result of FAI (12). The labrum can also be damaged during abnormal loadings in the joint, which frequently happens to professional athletes (12). The last common diagnosis is chondral lesions. This is a lesion of the articular cartilage, either at the femoral head or at the acetabulum. Those lesions also may occur in combination with FAI, and can cause pain in the hip.

Compared to shoulder and knee arthroscopy hip arthroscopy has more challenges. One of the big challenges is the placing of camera and other devices. This is because the limited space within the hip joint, to reach the areas of interest for hip arthroscopy, the acetabulum and the caput femur, can only be reached when the hip is dislocated.(13).

The dislocation is performed through traction and separation. During the hip arthroscopy procedure the patient will be placed in a special hip distractor table. In the RdGG the Smith and Nephew hip distractor system is used. With this traction table the caput femur will be dislocated from the acetabulum. A pulling force at the operate leg will be applied to achieve this dislocation. Between the legs a perineal post is placed to counter the generated pulling force, and to make sure the patient stays in position (figure 4). Due to this dislocation procedure, several complications can occur. There is a complication rate up to 8% of the hip arthroscopies (10;14-16). Most of these complications are transient (14;16;17). The most mentioned complications are neuropraxia of the pudendal nerve (figure 5) or femoral cutaneous nerve (14;16;17). The neuropraxia of the pudendal nerve is caused by the perineal post. This occurs on the adductor side of the femur because of the high pressure between the inner leg and the perineal post (10;16). The irritated and pinched nerve can result in a temporary (weeks to months) functional and sensory failure. As a result there may occur rehabilitation delay and great distress to the patient with perineal dysthesia or sexual dysfunction (10;16).

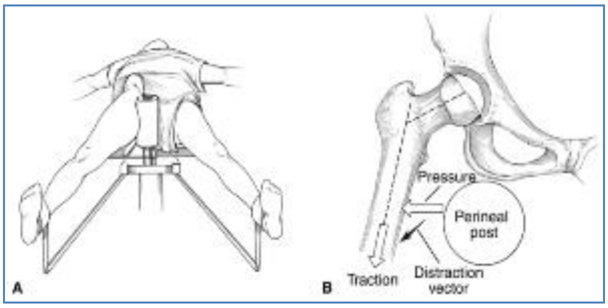

Figure 4 The position of the perineal post (18)

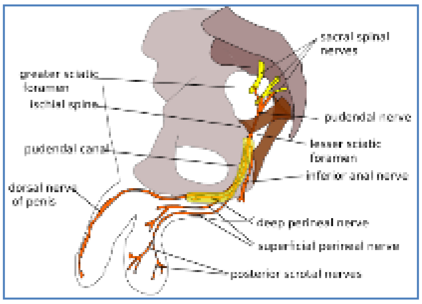

Figure 5 The location of the pudendal nerve (19)

The goal of this graduation project is to develop a new perineal post to reduce the pinching of the pudendal nerve. With a redesign the presence of this complication after surgery might be reduced, and a pressure distribution reduction of 20% of the perineal area, due to the current post should be achieved. To check if the new design reduces the pressure at the pudendal nerve, a proof of concept will be made. The proof of concept and the current perineal post will be tested, and can be compared. To reach the main goal, multiple sub questions are made.

Sub questions

- Which part of the body can handle the forces of the perineal post?
- Where is the pudendal nerve located, and what innervates it?
- Which patients have complications due to the perineal post?
- Which current hip distractor systems are there available? And what are the pros and cons?
- How does the current system works? And can it be improved?
- What forces does the perineal post needs to handle?
- What are the requirements for a part at the operation room?

This report has been divided into four parts: the first section is the analysis phase, in this section several sub questions will be answered. Based on this analysis there will be established a list of requirements, and the design goal will be defined. The second section is the design phase. The design phase is an iterative process and therefore the design process will be a continuous one. The main goal of the design phase is making a final design which meets the requirements. One concept will be further detailed during the next phase, the product-detailing phase. This detailed product will be realized in the realization phase, and a proof of concept will be manufactured. The next step is testing the current, and new design of the perineal post in a test setting. The final chapter will be the results, in this phase the outcome of the testing will be presented.

2. Analysis phase

In the analysis phase the uncertainties and sub questions conceived in the introduction will be answered. In this first chapter literature study will be done and eventually this will lead to the list of requirements. The first part consist of the anatomy of the hip, also the pudendal nerve, the pressure points of the perineal post, variety in patients, and the proper pressure point will be discussed as well. The second part is about the different hip distractor systems and their pros and cons. In the third part the system used in the RdGG is further analysed. The last two chapters discuss the forces and pressure at the perineal post and the restrictions of the operation room.

2.1. Anatomy of the hip and patients

The anatomy of the hip is complex, due to the many different structures, which are located around the hip. The most important structures of the art. coxae, due to the new design of the perineal post, will be explained in the following paragraphs. The following important part is the pressure points of the perineal post, also the position, location and innervation of the pudendal nerve will be explained. The hip will be analysed to find out which parts of the hip anatomy can handle the forces of the perineal post.

2.1.1. Nerves

As mentioned in the introduction the perineal post causes the neuropraxia of the pudendal nerve. This complication on the adductor side of the femur occurs because of the high pressure between the inner leg and the perineal post. What nerve is involved with this complication, and where is it located? The pudendal nerve is a motoric, and sensory nerve. In both women and men, it carries the sensation of the genitalia, the anus and perineum. The pudendal nerve enters from the sacral nerves (S2, S3 and S4), and continues into the: inferior rectal nerves, perineal nerves, and dorsal nerve of the penis/clitoris.

2.1.2. Pressure points

To avoid nerve palsy the compressive neuropathy is identified. The location for compression and relation between different traction positions and forces are clarified. The pudendal nerve palsy is due to the high pressure of the perineal post. The pressure in the three branches of the pudendal nerve is examined by Kocaoglu (14). Three sensors are placed at three branches of the pudendal nerve (figure 6). They concluded that the voltage in the first sensor is low and that there is no relation between the traction force, the neuropraxia, and the inferior rectal nerve. In sensor two and three there is a relation between the traction force, the neuropraxia, and the inferior rectal nerve. In the new design the compression in the sensor two and three must be reduced.

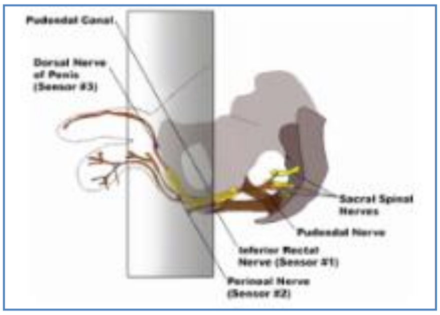

Figure 6 Sagittal view of the pelvis, showing the pudendal nerve and branches with respect to the perineal post used during hip arthroscopy. The anatomic point for each sensor is noted by an asterisk (14).

Perineal nerve and the dorsal nerve of the penis/clitoris

In the new design of the perineal post the compression of the perineal nerve, and the dorsal nerve of the penis/clitoris must be reduced.

The area shown in red, the perineal area (figure 7), must be avoided. But what are proper and usable pressure points for the new design? Bone structures are able to handle a lot of force. The best pressure points in the small hip area are the tuberculae ischiaicae, and the os pubis (figure 8). In hip arthroscopy there is no possibility for using the femur to absorb the pressure; in hip arthroscopy it is necessary to dislocate the femur. Therefore movement of the femur with respect to the perineal post is required.

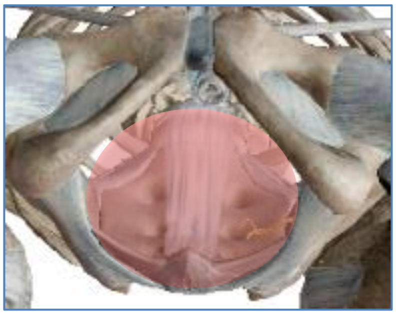

Figure 7 Areas where pressure should be avoided

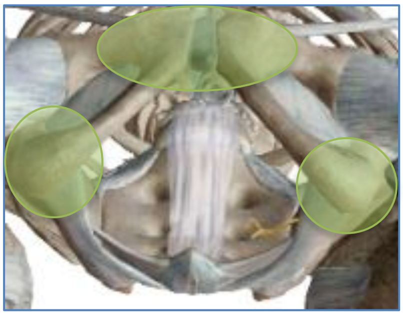

Figure 8 Areas where pressure can be applied

2.1.3. Patients

To design a new perineal post it is important to know the variety of patients. The patients that are diagnosed with abnormalities in the hip joint and treated by hip arthroscopy are relative young. The average age of the patients was 37 years (range, 6–80 years; median, 35 years) (17;20). In 45-50% of the cases hip arthroscopy is performed on women (10;20). The relative young age of the patients is caused by the fact that the injuries often occur during sports, when the joint suffers abnormal stress due to extreme movements. Patients that undergo hip arthroscopy are frequently young athletic man and active middle aged women (11). This results in a wide range of patients that can undergo hip arthroscopy, with the youngest patient at an age of 6. The maximum length of people that can be placed at the Smith and Nephew hip distractor system is 187 cm, this is the maximum length given by the manufacturer. The mean length of a six years old child is 1284 mm (21), therefore the minimum height will be 128 cm.

Conclusion

The perineal post should not pinch the pudendal nerve. In the new design of the perineal post the compression of the perineal nerve, and the dorsal nerve of the penis/clitoris must be reduced. In the new design the pressure at the perineal, red highlighted, areas needs to be reduced (figure 7). At the green areas the pressure can be applied (figure 8). The variety of the patients in hip arthroscopy is wide. The new design of the perineal post must come in different sizes that will support all patients in different groups. It will be usable for patients aged six years and older, with the height of 128 cm till 187 cm. There should be one product, which can be used for both left and right hip arthroscopy.

2.2. Market research

There are several different systems available for the positioning of the patient during hip arthroscopy. The differences in the position systems will be discussed. Also the current system for which the new perineal post will be designed will be discussed.

2.2.1. Supine position with perineal post

Most of the hip distraction tables are supine systems; this means that the patients are positioned on their back. There are many different systems for the supine position with hip arthroscopy e.g.: Smith and Nephew (figure 9), Maquet (figure 10), Arthrex, Mizuho/OSI, IOT.

The pros of a supine system

Advantages of the supine position in hip arthroscopy are the easy setup and ability. The traction systems (e.g. Smith and Nephew, Maquet) can be applied on any standard traction table in the operation room. The patient enters the operation room, with a user-friendly layout of the operating room, the traction system will be attached later (22;23). The use of reliable, established portals and supplemental portals, the ease of repositioning is a major advantage of this approach and the place for three portals (22;23). The explanation of the portals will follow in chapter 2.3.

Cons supine approach

The disadvantages with the supine position is that neuropraxia of the perineal region due to pressure from the perineal post can occur. Also it is more difficult to access in obese patients, and can it be more difficult to access intra-articular in the presence of large anterolateral osteophytes.

Figure 9 The hip distraction table of Smith and Nephew (24)

Figure 10 The Maquet distraction table (25)

2.2.2. Supine position without perineal post

In the supine position there is a complication rate of 8% (10;14;16). Merrel et al. (26) tried to find a safer technique for hip distraction during hip arthroscopy. In this new technique the patient is placed in supine position on the fracture table, with a beanbag from the torso to the iliac crest (figure 11). With tape the patient and beanbag are secured to the operative table. The feet are still placed in the distraction system (fig. 9-10). The taped bag fits snug around the torso, and provides enough widely displaced friction and stabilization to achieve the necessary distraction (26). This method was tested at 30 patients, the complication of a pinched pudendal nerve was not found. The beanbag is a method of positioning the patient, which costs a lot of time, due to the placing of the patient and the taping around the patient and the operation table. Also all the forces are placed at the chest, which can lead to breathing problems.

Figure 11 Bean bag for hip arthroscopy without perineal post (26)

2.2.3. Lateral decubitus position

A following method for hip arthroscopy is the lateral decubitus position. Only one system, the McCarthy Hip distractor of Innomed is a lateral decubitus position (figure 12). With this system the patient lays on his side.

Pros lateral decubitus position

The benefits of this approach are that it is relative easy to use with obese patients and in navigating around anterolateral osteophytes. Besides that the facilitation around the trochanter (peritrochanteric) is easier to approach, direct access to the superior, anterior, and posterior femoral neck is a major advantages (22;23).

Cons lateral decubitus position

Hip arthroscopy in the lateral decubitus position requires a traction device, perineal post, and typically uses two portals: one over the greater trochanter and one just anterior. Positioning of the patient is not as easy as the supine position. This is caused by the difficulty in establishing supplemental portals, longer time for patient setup, and risks for accumulation of intra-abdominal fluid with associated compartment syndrome (22;23).

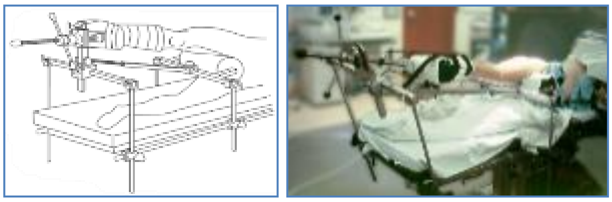

Figure 12 Innomed, McCarthy hip distractor (27)

Conclusion

In the RdGG, the Smith and Nephew system is used. The redesign of the perineal post must be designed for the Smith and Nephew hip distractor system.

2.3. Current system

The current used system in the RdGG, and an explanation of the perineal post will be given in this chapter. The RdGG currently uses the hip positioning system of Smith and Nephew (figure 13). This system is designed with a universal mounting, whereby it can be mounted to almost all the operation tables.

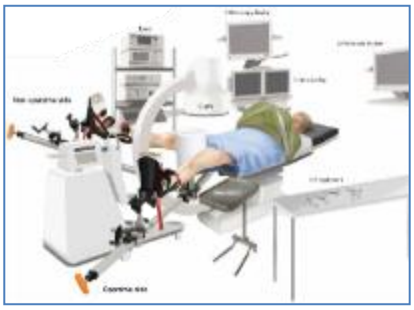

Figure 13 Hip positioning system of Smith and Nephew in the operation room (24)

When the patient arrives at the operation room the hip distractor system is not mounted yet, and the patient will be placed at the regular operation table. The patient will receive a general anaesthetic and muscle relaxants. These relaxants are necessary for the traction procedure, without those, dislocation is not possible. Afterwards the foot parts of the operation table are removed, and the hip distractor system will be mounted at the universal adaptor at the operation table. The patient's feet are placed in special foam socks to protect their feet from the strapping. Next, the feet are placed into the boots, and strapped very tightly. The perineal post is mounted at the hip distractor system as well, the mounting of the perineal post consist of two different size tubes, sliding over each other. The mounting of a new designed perineal post should happen at the same moment as the current, and should not take more time than the current perineal post. The legs will be placed in 30° abduction (28). Before the procedure, an x-ray of the hip is made to determine the space in the hip joint. To exclude the pelvic tilt and to make sure that the patient will stay in place, a little pulling force is applied at the non-operated side. Finally a huge amount of force will be applied at the operated leg, to create some space inside the hip joint. To see how much the dislocation of the caput femur is, the orthopaedic surgeon checks it with another x-ray. The orthopaedic surgeon keeps applying traction until he is satisfied. If the orthopaedic surgeon is satisfied, the boot will be locked at that point and the caput femur will stay dislocated. During the procedure the surgeon uses two or three portals. To display the hip joint one of the portals is to insert an arthroscope (figure 14). The other portals are, for example, for irrigating or trimming instruments.

Figure 14 Space created inside the hip joint (29)

The location of the portals is shown in figure 15. The perineal post cannot be positioned as such that it will cover these spots, therefore it should be located somewhere else. In figure 15 the blue area is the area which should be free for the surgery.

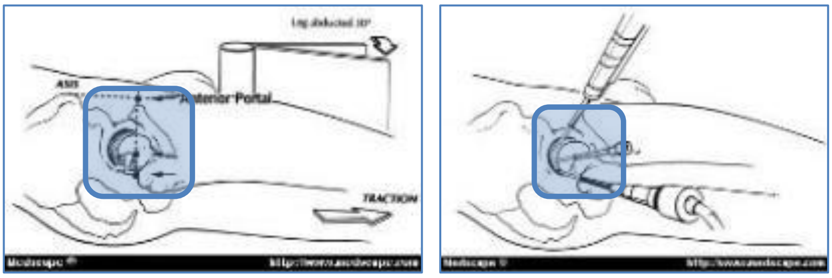

Figure 15 Location of the portals, the blue highlighted area should not be interrupted (28)

During the hip arthroscopy, when the orthopaedic surgeon is finished with inspecting and repairing the inner hip joint, the locking system will be released. The caput femur falls back to its original correct position in the joint.

2.3.1. Perineal post

The perineal post is a part of the hip distractor system, with this part the traction will be countered, and the patient will be kept in place (figure 16). The perineal post consists of a foam cylinder, with a metal tube in the middle for the mounting. During the traction, the caput femur needs to be dislocated from the acetabular, therefore the pelvic should be kept in place, and force will be given at the operated leg. To keep the patient in position and avoid a pelvic tilt, the perineal post is needed. To avoid a pelvic tilt, the perineal post should touch the pelvic, and not the femur. When the post is countering the force at the femur, even more pulling force is needed. During the traction procedure an abduction component of the leg is necessary. If only traction will be applied at the leg, the caput femur will not dislocate. Therefore a big abduction component is needed, a combination of traction and abduction will make the caput femur dislocate. The perineal post has to make sure that the hip will go in abduction. The perineal post has to be symmetric, because of the use at both sides. The perineal post is not placed at the centre, but at the side of the operated leg, this will generate the abduction component, which is needed. When the foot is placed at the boot, the leg can still be moved: abduction/adduction (hip), flexion/extension (knee), and endorotation/exorotation (hip). During the hip arthroscopy the knee will be positioned in flexion many times, because of the visibility of the caput femur. Therefore the perineal post should not block a flexion movement.
For a new design of the perineal post more sizes should be made to make the perineal post fit regardless of patient size.

Figure 16 The perineal post blue circled (24)

Due to the perineal post complications such as neuropraxia occur. The pudendal nerve (chapter 2.1.2.) is partial damaged. Recommendations are made to avoid the complication (10;14):

- Limit the traction time >120 min
- Use a well-padded perineal post >9cm, to better distribute the pressure
- Use the lowest amount of traction force as possible

Conclusion

During the placing of the hip distractor system several things should be kept in mind. First of all, the legs should be positioned in a 30° abduction. Also a pelvic tilt should be prevented, by giving some traction at the not-operated side as well. The orthopaedic surgeon needs to be able to perform the surgery, therefore a certain area should be kept free. Finally, the mounting of a newly designed perineal post should not take longer to mount than the current perineal post. The flexion movement of the knee should still be possible with the perineal post. The new design of the perineal post should be in different sizes that will fit all patients, regardless size of shape.

2.4. Forces at the perineal post

The perineal post has to be able to cope with strong forces in different directions. The design and materials should be designed to handle those forces. First a schematic overview will be given of the directions of the force, than the values of the forces will be researched in literature. The goal of the perineal post is to counter the pulling force of dislocating the caput femur. With the help of the perineal post the patient stays in place. The only external force applied is the pulling force. The legs are in a 30° abduction position, therefore the pulling force is not immediately the force working at the perineal post. With the help of the abduction angles the force can be calculated.
The values of the pulling forces of traction are not widely researched yet, but fortunately some smaller studies have be done. L. Cornelisse has done a pilot study of three measurements, a mean value of 650 N is found for the pulling force. A peak force of 1000 N (performed in one subject) was found in another study (30). Research has also been done at cadavers; traction to dislocate the hip is around 400 N (14).
However, as this setting is unrealistic due to measurements done at cadavers, this value will not be used for the calculation. The found values in the studies give an indication of the pulling force, but an extensive study has not yet been performed. As such, a higher force will be used for the calculation. Expected is that the traction forces reach up to 1200 N (31). Including an ample safety margin, a force of 2000 N was used for the calculations. The abduction angle in the traction system is 30° (31).
A schematic overview of the different forces is given in figure 17.

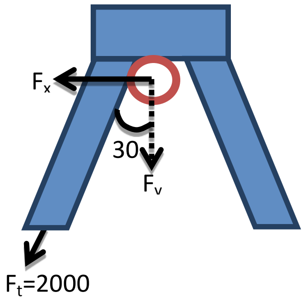

Figure 17 A schematic overview of the forces at the perineal post

Calculation

The abduction angle is 30°, with an average pulling fore of 2000 N. With the Pythagorean theorem the forces working at the perineal post can be calculated.

$$\text{Force at the perineal post} = \cos(30°) * 2000 = 1732\ N$$

The force the perineal post has to withstand is 1732 N. For the safety of the new design of the perineal post, the design load, given in N/mm^2, is calculated, this requires the factor of safety and the material strength.

For the factor of safety a value of two is chosen. For buildings a factor of 2 is mostly used, a higher value is often found for pressure vessels, the factor will be 4. For the car industry a factor of 3 is often used. A lower factor is found in the aircraft and spacecraft, the plane has to be lightweight. Therefore a factor of 1,5 is used. In this situation a factor of two will be chosen, because it should not be too heavy weight, but it should be strong enough.
The current material for the mounting is aluminium. For the new design the material can still be chosen, but it has to handle the calculated loads. With the material strength of aluminium (215 N/mm^2), the design load can be calculated with:

$$Design\ load\ of\ the\ perineal\ post = \frac{material\ strength}{factor\ of\ safety} = \frac{215}{2} = 107{,}5\ N/mm^2$$

The design load can be 107,5 N/mm^2.

Conclusion

The force the perineal post has to withstand is 1732 N, and the design load is 107,5 N/mm^2

2.5. Operation room requirements

For a medical product it is important to comply with several required rules and regulations since the risks of a product related to the patient can have high impact on a patient's safety. With the new design of the perineal post it is necessary it comply with the rules of safety to be used in the operation room. In the operation room the most important rules are the rules for sterility; all items used within the sterile field must be sterile. The material, the cleaning possibilities and the shape can affect the sterility.

CE certificate

A new device in Europe needs a Conformité Européenne (CE) certificate. To achieve the CE certificate the product must comply with the rules of the Medical Device Directive (MDD). The general rules of the MDD are shown beneath. The specific rules are based on the product class of the device. Medical devices are divided in different classes by the MDD (table 1), the perineal post belongs to class IIa.

- The devices must be designed and manufactured in such a way that, when used under the conditions and purposes intended, they will not compromise the health or safety of patients, users or other personal.
- Safety principles must be utilized for the design and construction, and they should include state-of-the-art technologies.
- The devices must meet all claimed performance criteria.
- The devices must continue to function as intended, without compromising safety or health, when subjected to normal conditions of use.
- The devices must not be adversely affected during defined transport and storage conditions.
- Any undesirable side effects must constitute an acceptable risk when weighed against intended performance.

Table 1 The classes of the MDD

Class I	Medical Devices are regarded as "low risk" devices, e.g. non-evasive medical devices that do not touch the patient or contact skin only.
Class IIa	Medical Devices are regarded as "low-medium risk" devices, e.g. active therapeutic devices intended to administer or exchange energy in a non-hazardous way.
Class IIb	Medical Devices are regarded as "medium-high risk" medical devices, e.g. active devices for monitoring of vital physiological parameters.
Class III	Devices are regarded as "high-risk" devices, e.g. devices incorporating a medicinal substance.

Conclusion

The product should fit the rules and regulations of the MDD class IIa. Sterilisation should be able following the current sterilisation techniques and the product should be made of a material that does not have any influence on the human body.

3. List of requirements

Requirements

Setting
The product should be used for patient aged 6 and older
The product should be used for the patient height between 128 cm and 200 cm
The product should be the same for right and left hip arthroscopy
The product cannot be placed in or interrupt the operative area, see figure 15
The product should be mountable at the Smith and Nephew hip distractor system
The mounting and placing of the new product should be intuitive. The introduction and explanation should be very limited.
More sizes of the product can be made, due to the variety in patients

Safety
The product should fit the rules and regulations of the MDD class IIa
• The product should be able to sterilized by following the current sterilisation techniques
• The product should be made of materials that do not have any influence on the human body (like allergic reactions)
The material, the cleaning possibility and the shape may not affect the influence of the sterility
The product is able to hold a load of 107,5 N/mm^2
The product should be able to sterilized by following the current sterilisation techniques

Functional/technical aspects
A pressure distribution reduction of the perineal area of 20% due to the current post should be achieved
Maximum 30 seconds can be used for the mounting
The operated leg should be forced to abduction by the product
The force the perineal post has to withstand is 1732 Newton
The flexion of the knee movement should not be interrupted
The product should reduce the pressure at the perineal (red highlighted) area, and can be applied at the green highlighted areas (figure 7 and 8)

Wishes

Wishes
The product should not cost more than three times as much of the production of the current perineal post
The new design is producible with the current manufacturing methods at Smith and Nephew
The product should have a universal mounting system, so that it can be mounted at different suppliers

4. Design phase

The design phase is an iterative process; this means there will be a continuous ongoing cycle to create the best solution. The main goal of the design phase is, by following the different steps, to make a final design which meets the setup requirements. The list of requirements is created during the analyse process. The iterative steps of this design phase are explained in the design cycle (figure 18). The design phase starts with the list of requirements, with those requirements in mind the design phase can start, and sketches will be made. Those sketches will not be perfect from the beginning. The design needs an optimalisation, at this point the process will start all over again. The concepts will be adjusted and adjusted, via the design circle, until a certain point, when the design will be accepted.

Figure 18 Design circle of the iterative design process

4.1. Start design phase

To conduct a successful design phase, there is started with a brainstorm, and questionnaire phase session. The main reason for those sessions is to open the mind, and increase the creativity.

4.1.1. Brainstorm

Brainstorming is an approach of trying to find several solutions for a problem. It encourages finding ideas, thoughts, and ideas that looks impossible and crazy. This can help people to get unstuck by getting out of their normal ways of thinking. The most important part in a brainstorm session is trying to open the mind, possibilities, and creativity.
The brainstorm session was started with a mind-map, with the word ‘perineal post’ placed at the centre. All words, which have something to do with the perineal post, and which popped up in mind were written down. The mind map is shown in appendix I.

4.1.2. Questionnaire phase

The questionnaire phase is a bit like the brainstorm session. In the brainstorm session there was started with a word, in this questionnaire phase there is searched for problems in the brainstorm session. Problems found during the brainstorm session were written down, every solution for this problem that popped up in mind were noted. This can lead to more input for the sketch phase. The made questions and answers are shown in appendix II.

4.2. Sketches

The list of requirements shows which requirements the new design should meet. In the above chapter inspiration, and information has been gathered. With this creativity in mind the sketching phase can be started. With the help of the questionnaire phase the sketches are drawn. Those sketches are shown in appendix III.

From all those different sketches, four concepts ended up. This is a process that can be achieved in several ways. Remarkable at the sketches is that, there are four different kinds of found solutions to the problem; concept one the saddle shape, concept two the top-bottom system, concept three, the beanbag pole, concept four the different shaping system. These concepts will be further analysed in paragraph 4.3.

4.3. Concepts

In this chapter the four concepts will be further analysed, and tested by the list of requirements. The analysing of the concepts is for each concept specifically done, the pros, cons, and characteristics features are described.

The test of the list of requirements is done by the cardinal method. The design with the best progressive possibilities will be further developed.
The mounting of every system is creatable for the Smith and Nephew system. The materials of each product are adjustable to the requirements, the sterility and the influence to the human body. Therefore those requirements are applicable to all 4 concepts, and will not be specially mentioned.

Concept 1

Concept one is an idea of a vertical place saddle (figure 19). In the middle of the saddle there is created a hole for the genitals of women. The lower sides of the saddle are for both left and right tuberculum ischiadicae. The os pubis can be placed against the upper part of the 'saddle'. The saddle exist of different materials, the top part of the saddle is a gel coat. The gel is to divide pressure over multiple structure points.

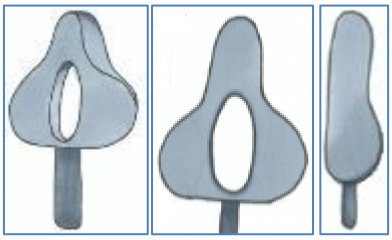

Figure 19 Concept 1 The saddle shape, A: 3D view, B: front view, C: side view

Pros

- Divides pressure
- Special hole for the genitals of women
- Can be used for both left, and right hip arthroscopy
- Different abduction angles can be achieved
- The difference in weight of patients is not a problem
- It is not interrupting the operative area
- The use and placing of this concept is very intuitive, and there it creates not extra learning curve for the orthopaedic surgeons

Cons

- For smaller people the system is more difficult, the tuberculum ichiadicae of bigger people are more spread, therefore a bigger saddle may be needed, different sizes are needed to solve this problem
- The genitals of men may get pressed

Concept 2

This system is supporting the tuberculum ichiadicae, and os pubis (figure 20). The lower part will be placed at the tuberculum ichiadicae, at this point the most force will be located. The upper part makes sure that a pelvic tilt in anterior posterior position will be prevented; therefore the upper part will be positioned at the os pubis. The genitals will be free, because of the U-shape, there will be no pressure positioned here. Different materials will be used in this design to divide the pressure. An inner core will be made to handle, and divide the forces, and to keep the right shape. This core will have a U-form, and will be made from metal or hard plastic. The part of the design where the genitals will touch the design, will be made of soft foam. At the points where the tuberculum ichiadicae, and the os pubis will touch, harder foam will be placed.

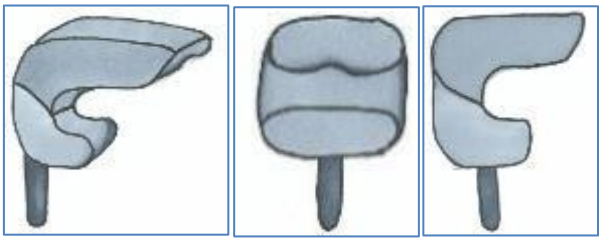

Figure 20 Concept 2 The top-bottom system, A: 3D view, D: front view, C: side view

Pros

- Pressure points at the tuberculum

Cons

- An abduction of 30° is reachable, but smaller

ichiadicae, and os pubis
- Can be used for both left, and right hip arthroscopy
- With a little explanation the system can be easily used
- There is no pelvic tilt able

than 30° is not possible with this design
- Different sizes of genitals of the man can be harder to position
- Variety of people is hard to fit in, with obese patients the positioning can be harder
- The placing of a patient is more difficult

Concept 3

Concept three consists of a harder core, with a bag around the core (figure 21). The core will be made from metal, and the bag will be filled with small beans (can also be filled with water or air). A few centimetres around this pole are used to soften the perineal post. This concept looks the same like the perineal pole, but there are different materials around the pole. The idea came from the beanbag, when a weight is placed at a beanbag, the beans spread, and divides the pressure automatically. With this idea, the beans will form around the legs by itself, and therefore spread the pressure. The perineal post will be mounted at a certain height, whereby the beans will drop by gravity. Therefore multiple compartments will be made inside the beanbag, that will make sure that the beans will not drop down by gravity, but stays in its own compartment. The differences in pressure dividing can be made by the placing of different sizes of beans in the compartments. In the perineal area, layers of the beanbag softer filling will be used. The lower layers needs to handle the force at the tuberculum ichiadicae, which makes it more necessary to place harder/bigger beans in here.

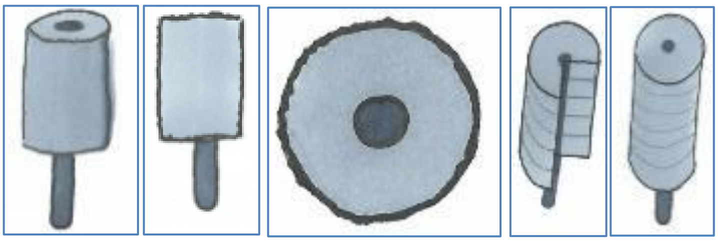

Figure 21 Concept 3 The beanbag, A: 3D view, B: front view, C: top view, D: compartments

Pros
- The filled bag can easily shape around the human body, therefore it fits all human sizes
- Can be used for left, and right hip arthroscopy
- It is not interrupting the operative area
- There is no extra learning curve, the use is quite similar to the old one
- The mounting does not take more time than the current one
- Different abduction angles can be achieved

Cons
- The bag could tear
- Pelvic tilt can occur when the bean bag caves
- The beans try to go to the opposite side because of the pressure
- The beans can move in relative to the post, with as a consequence that the human body could still move

Concept 4

With the fourth concept the major changes with the old design is the shape of the post (figure 22). The tuberculum ischiadicae are both supported, instead of one of the tuberculum ischiadicae. The tuberculum part is round shaped, this follow from the round shaped pelvis. In a square variant there are only two pressure points, the left and right tuberculum ischiadicae, with a more circled form the pressure is divided around pelvis. The materials used for this system are different kinds of foam. Softer foam at the area where the perineal post meet the genitals, and harder foam at the area were the perineal post meet bones.

Figure 22 Concept 4 The different shaping A: 3D view, B: side view, C: front view

Pros
- Can be used for both left, and right hip arthroscopy
- It is not interrupting the operative area
- Easily mountable
- No pelvic tilt

Cons
- Difficult to fit it to all kinds of human variety
- The placing of a patient is more difficult

4.3.1. Cardinal method

Each concept will be tested to the requirements (Chapter 3 List of Requirements). The cardinal method is a method to test each concept to the requirements, and find the most promising concept. De cardinal method is shown in appendix IV. The factor shows the independency of each requirement, there are three different factors: factor 1 equals 'Not important', factor 2 equals 'Neutral', and factor 3 equals 'Important'. The fulfilment of the requirements is scored to three different points: score 0 equals 'Not satisfying at all', score 1 equals ' Neutral/is able to meet the requirement', and score 2 equals 'Fully meet the requirement'
Concept 1 (The saddle shape) has the highest score with the cardinal method, with 56 points. Second is concept 3 (The beanbag) with 50 points. Third will be concept 4 (The different shaping) with 45 points, and last will be concept 2 (The top-bottom system) with 42 points. Therefore the saddle shape concept will be further developed.

4.4. Detailing concept

With the cardinal method concept 1 was chosen as the most progressive concept. In the detailing concept phase, this concept was more adjusted, and detailed to achieve a more advanced system. The saddle is a symmetric post, with different materials for pressure points, and avoids the areas where pressure should be reduced. In the beginning an inspiration phase was started. The adjusting of this concept will go through the design circle. This process continues until the design is good enough for the testing with the proof of concept.

4.4.1. Inspiration phase

The basic idea of concept 1 is the saddle. To improve the concept, an inspiration phase will be held. In this phase a brainstorm session will be held again, but now in the box of concept 1. This brainstorm session will be started with the orthopaedic surgeon, and the research team of the RdGG. In this inspiration phase, all kinds of already existing saddles will be printed, and shown as an inspiration (appendix V). With those models in mind, a new form and design will be thought off, which will meet the requirements.

4.4.2. Problem and solutions

In this redesign paragraph requirements, and problems are analysed and improved by the design circle (figure 18). In the beginning of the design circle the problem is analysed, what is needed to solve the problem and what could be a solution for this problem. These possible solutions will be designed in to a new concept, which is tested to the list of requirements again.

Pressure reducing

The first important demand for the new design is reducing the pressure distribution at the perineal area. To solve this problem, the force at the red-highlighted areas (figure 7) must be reduced, and the pressure at the green- highlighted areas (figure 8) must be used. The solution for these problems can be searched at different shapes and materials.

Material

The material of the new design does not have to consist of only one material, it could consist of different materials to divide pressure over the different areas. The perineal area needs a decrease in pressure, with softer, and low-pressure material. The tuberculum ischiadicae are able to handle much more pressure, than the perineal area, this can be achieved with a harder pressure resistant material.

For the perineal area possible materials are: polyether, polyurethane, pantera foam, and NASA foam. These materials have a high and dynamic elasticity. The cell structure of the foam makes sure that, it is possible to adjust to the human body, and divides the pressure over a larger area.

For the core are rigid materials needed, like: PVC foam, plastic, and aluminium. The core make sure that the general form will be held, and give the strength to the product. More force can be applied at the green marked areas (figure 8), therefore the core can be closer to those areas. But still the part, which will touch the human, will be soft foam, as a coating.

Shape

The shape of the system must be adjusted; the perineal nerve and the dorsal nerve of the penis/clitoris must remain unobstructed. The bone structures should be used for the location of the pressure. In the next sketches there is thought of the new system (figure 23).
At the concept shape 1, there is a hole in the middle of the saddle to relieve the pressure at the nerves. Concept shape 2 has an opening at the front, to relieve the pressure at the nerves. The main differences with concept shape 1, and concept shape 2 is that concept shape 1 is closed in the front, and concept shape 2 is open. Therefore with concept 1 the force can also be located at the os pubis.

Concept shape 3 is a whole different way to relieve the pressure. At the back, were the tuberculum ischiadicae are located, there is a hard material, at the front there is a softer material.

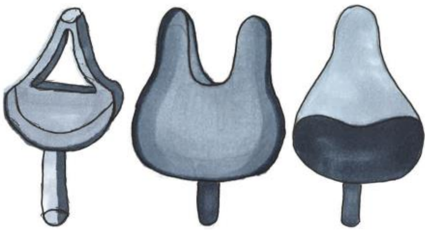

Figure 23 New designed shapes, A: Concept shape 1, B: concept shape 2, C: concept shape 3

Abduction

The second important problem of the concept is that the operated leg should be forced to abduction by the new product. The most common abduction angle of the post is 30°. A possible solution for the abduction angle is to design this into the saddle concept. In the inspiration phase a few ideas came forward, like the riding saddle and the barber chair.

Three concepts are designed to achieve the abduction angle (figure 24). The first concept is like a riding saddle, the top is shaped to the human body, the sides are in an abduction. The second concept is like a barber chair, the middle/inner part is higher than the sides. The third concept is a thicker saddle for the abduction. Eventually those three concept are combined to one concept.

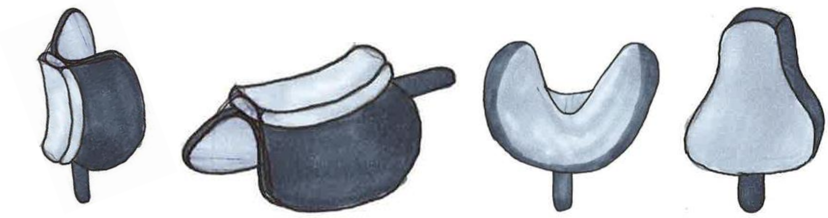

Figure 24 Concepts for abduction, First two: riding saddle, second: barber, third: thicker saddle

Mounting

The current system is the Smith and Nephew hip distractor system. The new design of the perineal post must fit the same system. To make this fit to the current mounting system, the dimensions should be known. The dimensions and materials of the mounting are measured, and noted. The perineal post is mounted at the Smith and Nephew hip distractor system with a hollow aluminium tube with diameter of 30 mm, a thickness of 3 mm, and the length of 150 mm (figure 25A). This aluminium tube is sliding over the node of the table, the dimensions, and shape of the perineal post are shown in figure 25.

The foam around the perineal post consist of two layers, the inner layer, placed against the aluminium pole (dark grey), is a hard foam (light grey), the outside layer consist of s a softer foam (white). The diameter of the post is 220 mm, the height of the post is 280 mm.

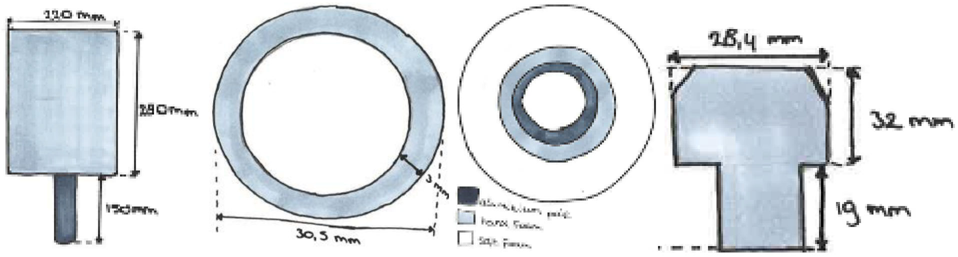

Figure 25 A: The dimensions of the perineal post, B: The front view of the perineal post, C: The aluminium hole tube, the top view of the perineal post with the different layers, D: The node of the mounting system of the perineal post

The dimensions of the mounting of the new designed perineal post have to be the same as the current perineal post.

Figure 26 The current perineal post. A: The perineal post, B: The pole of the perineal post, B: The mounting system of the Smith and Nephew hip distractor with the node

Material

The outside material of the perineal post must comply the rules of sterility, has easy cleaning possibilities, and material that does not have any influence on the human body (like allergic free material). Due to the hygienic purposes a disposable under-pad will be placed around the perineal post. This under-pad will be replaced after every surgery, therefore every patient will receive a new, clean, and hygienic under-pad. The under-pad will touch the skin of the patient, therefore the outer material does not contact the skin immediately. Still the outer material has to be smooth, and easy cleanable.

4.5. Redesign

The analysed problems, and their solutions are discussed above. With the help of this analysing, mock-up model are made for visualisation. Mock-up models are scale models that are used to visualize the form, and shapes. The mock-up models are made from special modelling foam, this is a hard and light foam, which is easy adjustable. The different mock-up models are discussed in this chapter.

4.5.1. Mock-up models

The different concepts of a new perineal post, have many shapes, and rounding's. Therefore it is quite hard to visualize those forms, and shapes. Mock-up models are made to give a better overview of the pros and cons of the concepts, and helps choosing the final concept.

Model 1

The first model has a hole for the genitals at the centre. An abduction angle has been generated, any further the part where the tuberculum ischiadicae touches the concept, are made more prominent. Therefore this part will first touch the body, and will handle the most forces. After visualising this model, it became clear that this model was not able to meet the requirements. The perineal post is not placed in the centre of the Smith and Nephew hip distractor system, but at the operating side. Therefore the hole will not be at the right position for the genitals (figure 27).

Figure 27 Model 1, first row left to right: front view, side view, rear view, side view. Second row, left to right: top view, bottom view, 3D view.

Model 2

The second model has many round shapes for the leg. The abduction is positioned the same, but the part that will touch the groin, are made rounder. Also the parts for the tuberculum ischiadicae are more to the front. The part where the genitals will touch the post, are made more round. This part will be covered with NASA foam, to spread the pressure evenly (figure 28).

Figure 28 Model 2, first row left to right: front view, side view, rear view, side view. Second row, left to right: top view, bottom view, 3D view.

Model 3

The third model is the 'horse riding saddle' model. He round shape of the horse riding saddle is applied, and the abduction angle as well. In this model the tuberculum ischiadicae, do not have a solid point to handle the pressure, therefore the pressure will still be a lot at the genitals (figure 29).

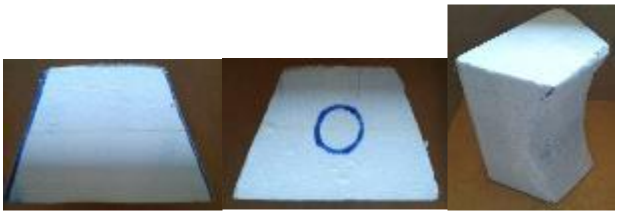

Figure 29 Model 3, first row left to right: front view, side view, rear view, side view. Second row, left to right: top view, bottom view, 3D view.

Model 4

The last model is the saddle model, but then a little upgraded. The top of the model is shaped as a bike saddle, the sides of the model are longer, and have the abduction component in it. The rounding of the leg is made as well, and a solid place for the tuberculum ischiadicae is also included (figure 30).

Figure 30 Model 4, first row left to right: front view, side view, rear view, side view. Second row, left to right: top view, bottom view, 3D view.

4.5.2. Choosing final concept

To choose the final concept with the help of the mock-ups, the pros, and cons of each design are discussed. Concept 1 is not able to meet the list of requirements, because of the hole that is designed at the middle, but the post is not placed at the centre. Therefore the hole will not be right positioned. The pros of concept 2 are the solid support of the tuberculum ischiadicae, and the abduction angle. The con of this concept is that the upper front part is still really wide, therefore the genitals needs to handle a lot of pressure to. Concept 3 has the riding horse shape, and the abduction angle. The con of this concept is, that there is no solid positioning for the tuberculum ischiadicae, therefore more pressure will be divided at the genitals. Concept 4 has the saddle shape form, pros are that the tuberculum ischiadicae are well supported, and the genitals will divide pressure at just a small area, also the abduction angle is good in this model.
Concept 1, and concept 3 are not meeting the list of requirements, therefore those two will not be used. Concept 2, and concept 4 are both good concept, and are even quite similar, therefore those concepts will be combined to a final concept (figure 31).

Figure 31 the final concept, a combination of concept two and four.

The final concept has the small saddle form in the front at the top, but still the tuberculum ischiadicae part will be more prominent to the front.

4.6. Final design

The final design will be further explained in this chapter, such as materials, sizes & dimensions. A final sketch, and a section view are shown in figure 32, the different colours represent the different layers of foam.

Figure 32 The final design

4.6.1. Materials final design

In this chapter the materials for the final design will be defined. The perineal post has to handle a lot of forces, during the traction procedure. Therefore the materials should be strong as well. The mounting of the perineal post will be the same as the current, because it has to be mounted at the same system. The mounting will be an aluminium tube (as mentioned in chapter 4.4.2.). This aluminium tube will be the centre of the perineal post, and will continue over the whole length of the post. This will gain the stability, and stiffness that is needed. Around this aluminium core, hard and solid foam (PVC foam) will be positioned. This foam will continue to the backside of the design, and will keep the form, and shape of the rigidness. At the position where the tuberculum ischiadicae will be located, the hard foam will continue, but the top layer (the layer that touches the body) will be covered with softer (polyether) foam. The part where the genitals will be positioned will be covered with multiple layers of foam. Inside the hard foam will be placed, over that layer softer foam (polyether) will be placed, and as a top layer NASA foam will be placed. This foam copies the shape of the body, and therefore will give a good spread pressure.

4.6.2. Dimensions

The post is usable for a variety of patients (6 years and older, and 128-187 cm). To make sure the new design has a better fit for the patients, there will be more sizes of the product, due to the variety in patients. Three sizes will be made, S, M, and L. The different dimensions are explained.

Bottom width

The bottom of the new design supports the tuberculum ischiadicae. The width between both tuberculum ischiadicae is important for the width of the design. The distance between the tuberculum ischiadicae for an adult male is 90 mm to 115 mm, and for an adult female, 110 mm to 150 mm. That results in a difference of 60 mm. The width of the new design should be bigger, because the tuberculum ischiadicae needs to be fully covered at both sides, therefore 20 mm at each side will be added.

There will be made three different sizes; the smallest size is 140 mm, the medium size 160 mm, and the largest size is 180 mm.

Length post

The length of the new design of the perineal post will be the same as the current used post. The length of the current perineal post is 280 mm. With this length, movement in anterior posterior direction will be excluded.

Abduction angle

The abduction of the legs during hip arthroscopy is 30 degrees. The new design must support the abduction; therefore there will be an abduction angle of 30 degrees.

Diameter of the post

The diameter of the perineal post is 220 mm, in the new design this cannot be exceeded.

5. Realisation phase

In the realisation phase the proof of concept is manufactured, the manufacturing took place at the workshop of Sophia Rehabilitation Delft. As the current perineal post, there was started with an aluminium pole in the centre, this will be for the mounting, and for the stiffness of the design. Foam of a saddle was used as inner core, this foam was adjusted to the desirable abduction angles, and shapes. The pole was placed in this piece of foam. Any further, different layers of foam are placed at the saddle foam, hard foam where the tubers will be located, and soft foam for the perineum. Finally, NASA foam was placed at the top layer. The process of manufacturing is shown in the picture timeline beneath (figure 33).

Figure 33 Timeline of the realisation of the perineal post

6. Testing

The proof of concept was compared to the current perineal post, therefore a test setting was made (figure 34). The test setup was a simple, and small measurement, just to proof if the proof of concept was giving promising results comparing to the current perineal post.
The most important requirements for the design of a new perineal post, was the reducing of the pressure in the perineal area. Both the proof of concept, and the current perineal post were tested with a pressure mat surrounding it. The testing could not be done at hip arthroscopy patients; to measure at patients, an approval of the METC (Medical Ethical Testing Commission) is required. Therefore an operation look-a-like setting was created. During hip arthroscopy the patients were given full anaesthetics, and muscle relaxants to apply around 800 N force at the leg for dislocation. At this test setting seven subjects were used, those high forces cannot be applied; therefore a traction force op 150N was applied to all subjects. The traction will be achieved by pulling in the direction of the leg, at the end of the leg there will be placed a pulley, with 15 kilograms attached it.

A pressure mat (BodiTrak 1510 seat) surrounded both the current, and the new designed perineal post. The order of testing both perineal post, was randomized per subject. The Boditrak 1510 seat pressure mat has a scan rate of 100 Hz. Every measurement was recorded, and took three minutes per post, whereby every 30 seconds, starting at 0;00 seconds, the VAS score was asked, and noted. Afterwards subjects were asked to give their preference for the current or redesigned perineal post. The output data, and results are discussed in the next chapter. The test protocol can be found in appendix VI.

Figure 34 Test setting: redesigned post is placed between the legs, at the right leg traction of 15 kg is applied

7. Results

The following outcome parameters are analysed: maximum pressure, pressure distribution of the left and right tuberculum ischiadicum, the pressure distribution at the perineal area, and the subject's preferences. All the raw output data can be found in appendix VIII.

7.1. Maximum pressure

Maximum pressure is presented in mmHg, which is transferred to $^{N}/_{cm^2}$. The maximum measurable pressure with the BodiTrak pressure mat, was 2,67 $^{N}/_{cm^2}$ per sensor. The maximum pressure at the seven subjects was compared every 30 seconds for 3:00 minutes (figure 35). As shown in the graph, the pressure does not change much during time, therefore the results are compared at 2:00 minutes. At both perineal posts, the current and redesign, traction of 15 kg was generated. The mean maximum pressure of seven subjects of the current post was 1,8 $^{N}/_{cm^2}$ (SD: 0,71). The mean maximum pressure of the seven subjects of the redesign was 2,3 $^{N}/_{cm^2}$ (SD: 0,42), which is an increase of 28% compared to the current used post.

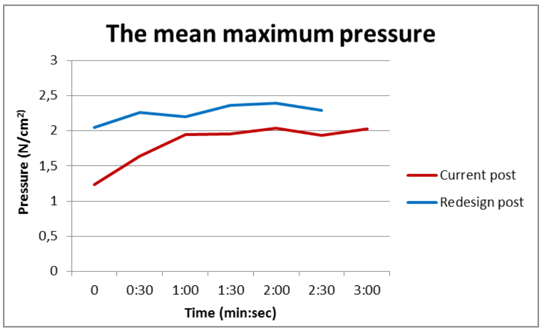

Figure 35 Mean maximum pressure, of the current post (Red) and the redesign (blue)

7.2. Pressure distribution

The pressure distribution is the most important outcome parameter to compare both perineal posts. In figure 36 the pressure distributions of one subject is shown, left the current perineal post, and right the redesigned perineal post. The red-highlighted area, presents an area of high pressure, blue presents the lowest pressure. Red areas are located at the perineal area of the current perineal post. At the redesigned post, almost no pressure is located at the perineal area. Instead the pressure is located at both tuberculum ischiadicae. The traction is given at the right leg, the perineal post is placed out of the centre (centred to the right), therefore at the right tuberculum ischiadicum more pressure is located.

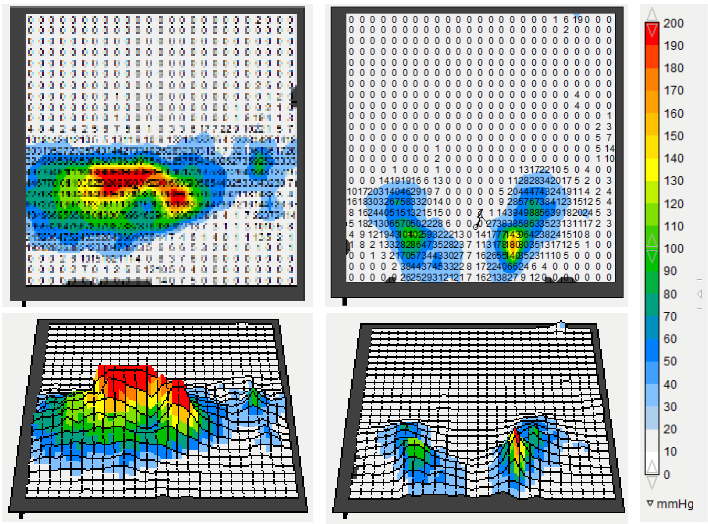

Figure 36 Pressure distribution, left: current, right: redesign

To analyse the data exactly, three areas of interest are defined, and further analysed. The three areas are: the left tuberculum ischiadicum, the right tuberculum ischiadum, and the perineal area. In figure 37 is shown, that the both tuberculum ischiadicae areas are defined as 25 sensors, and the perineal area is defined with 48 sensors. The centre of the tuberculum ischiadicae areas, are defined as the place where the tuberculum ischiadum are located. Traction is applied at the right leg, the right tuberculum ischiadum is shown in purple, the left tuberculum ischiadum is shown in green, and the perineal area is shown in blue. The pressure of the left and right tuberculum ischiadicum and the perineal area defined at 2:00 minutes. The measurements of the current perineal post of subjects one, unfortunately is not saved well. Therefore the measurements of the current post of subject one, current post, will be excluded of the results.

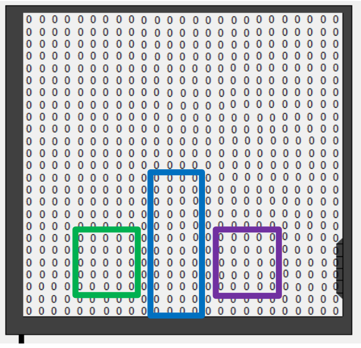

Figure 37 The 3 defined areas: green: the left tuberculum ischiadicum, purple: right tuberculum ischiadicum, and blue the perineal area

7.2.1. Left tuberculum ischiadicum

Figure 38 shows the difference of mean pressure at the left tuberculum ischiadicum of the current, and the redesigned post. The mean pressure of the current post of all seven subjects (0,671 $^{N}/_{cm^2}$, SD: 0,30) is higher than the mean pressure of all the subjects of the redesigned post (0,559 $^{N}/_{cm^2}$, SD: 0,20). That is a decrease of 16%. In figure 38 the pressures per subject is shown, and the mean of the seven subjects is shown.

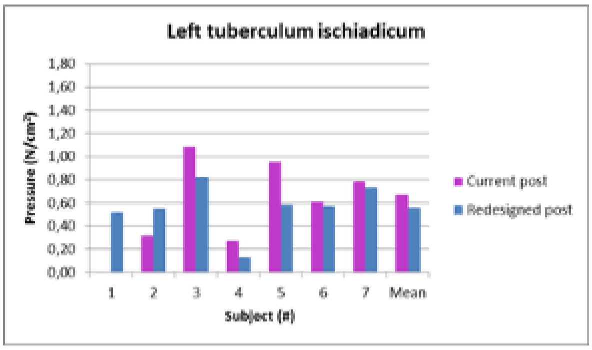

Figure 38 Mean pressure at the left tuberculum ischiadicum

7.2.2. Right tuberculum ischiadicum

The mean pressure at the right tuberculum ischiadicum in the new design is, with 0,924$^{N}/_{cm^2}$ SD: 0,23), higher than the pressure at the current post (0,709$^{N}/_{cm^2}$, SD: 0,40). That is an increase of 30%, shown in figure 39.

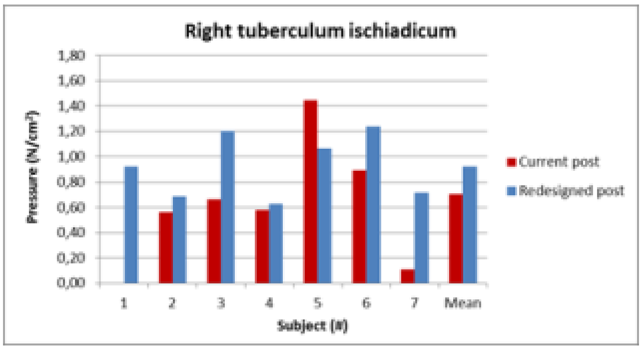

Figure 39 Pressure at the right tuberculum ischiadicum

7.2.3. Perineal area

The mean pressure at the perineal area with the current post is 0,869 $^{N}/_{cm^2}$, (SD: 0,52) in the new design there is a mean pressure of 0,146 $^{N}/_{cm^2}$ (SD: 0,10) (figure 40). That is a decrease of 83%.

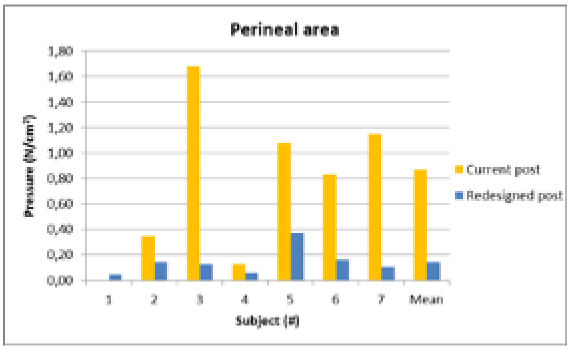

Figure 40 Mean pressure at the perineal area

7.3. Subjects preference

Afterwards, the subjects were asked to give their preference for the current perineal post or the redesigned system. Every female had a preference for the redesigned perineal post (five female subjects). The male subjects did not have a preference (two male subjects).

8. Discussion

Hip arthroscopy is a very new procedure in orthopaedic surgery. For example the shoulder and knee arthroscopy procedures are well developed. Over a period of 5 years (2006-2010) there was an increase of more than 600% in performed hip arthroscopies (5). Compared to shoulder and knee arthroscopy the hip arthroscopy has more challenges, because of the limited space within the hip joint. Therefore, one of the big challenges is positioning the camera and other devices in the hip joint. A lot of traction is needed to create more space for the introduction of those devices needed for surgery. To counter the generated pulling force and to make sure the patient stays in position, a perineal post is placed between the legs during hip arthroscopy. However, several complications can occur because of this dislocation procedure. There is a complication rate up to 8% of the hip arthroscopies (10;14-16). The most common complications are transient neuropraxia of the pudendal nerve, which are caused by the perineal post (14;16;17).

To our knowledge this was the first study in which the pressure distribution was measured within the supine position in hip arthroscopy session. With that information a new perineal post was designed, whereby a reduction of the pinching of the pudendal nerve was achieved. With a redesign redesign a pressure reduction of 20% of the perineal area, compared to the current post was achieved which might reduce the presence of this complication after surgery.

The aim of redesigning the current perineal post was to transfer the pressure from perineal area to the tuberculum ischidicae of the operated leg. The proof of concept showed a transfer of the pressure 30% more pressure was located at the tuberculum ischiadicum of the operated leg. Almost no pressure was located at the perineal area as there was a decrease of pressure of 83% in the perineal area. The pressure was transferred to the tuberculum ischiadicae of the operated leg, freeing the perineal area of the unwanted pressure. The higher maximum pressure located at the redesign can be explained by the higher pressures located at the tuberculum ischiadicae; this is acceptable, since the aim of the design was to locate more pressure at the tuberculum ischiadicae.

During hip arthroscopy traction force can reach up to 1200 N. During the measurements the subjects did not receive any anaesthetics or muscle relaxants. As a result it is unknown what will happen with the redesign when it needs to handle 1200 N. During hip arthroscopy the mean surgery time is 120 minutes; this is not comparable to the measurements of three minutes. The test should be performed at the operation room, with patients positioned at the Smith & Nephew hip distraction system who will receive the necessary traction. Afterwards a better, more realistic, conclusion of comparing both perineal posts can be given. A small number of seven subjects was tested, but for a good validation more subjects are needed to give a clear conclusion.

The pressure mat was placed between the subject and the perineal post. The maximum pressure values of the pressure mat was at 2,67 $^{N}/_{cm^2}$, this value was reached with some subjects, and therefore it is unknown what the 'real' maximum pressure can be. The relocation of the pressure area, from the perineal area to the tuberculum inschiadicum of the operated side was very well shown, also the pressure distribution was better with the redesign. By analysing the results the left and right tuberculum ischiadicum area and the perineal area were chosen. However, those areas can differ between subjects. The distance between the tuberculum ischiadicae of females can be bigger than male tuberculum ischiadicae, therefore a mean value of a sensor area was chosen instead of only one sensor, to make sure the tuberculum ischiadicum was always located in this analysed area.

The iterative design process, followed by the design circle, was a good support during designing and improving the concepts. The circle has been applied many times, and has helped us to achieve a proper and good final design.

Further research has to be done to find out what kind of foam materials can be used best during a longer traction time and higher traction forces. Also measurements at the operation room should be done, with patients positioned at the Smith & Nephew hip distraction system while they, receive the needed traction for at least 120 minutes. Afterwards a better, more realistic, conclusion of the comparison can be given.

9. Conclusion

During the measurements the performance of the proof of concept perineal post was tested. The main goal of the redesign of the perineal post was a reduction of at least 20% of the pressure distribution at the perineal area. The redesigned perineal post reduced the pressure distribution at the perineal area with 83%. The proof of concept showed a transfer of the pressure, 30% more pressure was located at the tuberculum ischiadicum of the operated leg, freeing the perineal area of the unwanted pressure. The pressure distribution at the tuberculum ischiadicum of the non-operated leg, decreased with 16%. The mean maximum pressure increased with 28%. During the three minutes of measuring the pressure did not change much over time. The preference of the subjects was in benefit of the redesigned perineal post. The expectation is that the redesigned perineal post will reduce the complication rate in hip arthroscopy.

The list of requirements is used to reflect the design features and indicate points of improvements. The requirements are rated with -/+/++. With those three categories, the requirements were checked. The table is shown in table 2. The most important conclusion related to the product proposal is the transfer of the pressure of the perineal area to the tuberculum ischiadicae of the operated side.

Table 2 The reflected list of requirements

Setting	-/+/++
The product should be used for patient aged 6 and older	-
The product should be used for the patient height between 128 cm and 200 cm	+
The product should be the same for right and left hip arthroscopy	++
The product cannot be placed in or interrupt the operative area, see figure 15	++
The product should be mountable at the Smith and Nephew hip distractor system	++
The mounting and placing of the new product should be intuitive. The introduction and explanation should be very limited.	+
More sizes of the product can be made, due to the variety in patients	++

Safety	
The product should fit the rules and regulations of the MDD class IIa	+
• The product should be able to sterilized by following the current sterilisation techniques	+
• The product should be made of materials that do not have any influence on the human body (like allergic reactions)	+
The material, the cleaning possibility and the shape may not affect the influence of the sterility	+
The product is able to hold a load of 107,5 N/mm^2	+
The product should be able to sterilized by following the current sterilisation techniques	+

Functional/technical aspects	
A pressure distribution reduction of the perineal area of 20% due to the current post should be achieved	++
Maximum 30 seconds can be used for the mounting	+
The operated leg should be forced to abduction by the product	++
The force the perineal post has to withstand is 1732 Newton	+
The flexion of the knee movement should not be interrupted	++
The product should reduce the pressure at the perineal (red highlighted) area, and can be applied at the green highlighted areas (figure 7 and 8)	++

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Appendix