TECHNOLOGICAL INNOVATION AT SALUS ORTOPÉDTECHNIKA KFT. REGARDING THE GERINCOR PROJECT

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Abstract
In this article we tried to introduce our renewed technology regarding the Gerincor project. Instead of the old technology the new provides much cleaner, more accurate, and more comfortable procedure for our young patients. Moreover data could be archived much easier.

Keywords: Imageware, RapidformXOR, plastering, milling, spinal deformity

1. Introduction

The GERINCO2 project – started in 2009, with 5 different company and Research Institute – got a problem to solve: how to simplify manufacturing of the aid for spinal deformities, and how to improve the brace. Our company, Salus Orthopedic Ltd. is one of the leading hungarian orthopedic companies, medicating thousands of patients in Hungary and beyond the borders.

Wearing a brace is not easy. It is a firm, rigid device, that has to be worn from the detection of spinal deformity until the end of the ossification. Our company is leader of manufacturing these devices in Hungary, Europe and even in the whole World.

Spinal deformities are diseases, which are weed variation of phisiological spinal curvatures. Weed variations could be: *scoliosis*, and *Scheuermann disease*.

2. Spinal Deformity Types

Scoliosis means spinal weed deformity mostly in the frontal plane. It could be divided into functional and structural scoliosis. In both cases there are weed lateral deformities on the spine, but in case of funtional scoliosis there are problems only in two dimensions, so there isn't any rotation. Therefore no rib deformations can be observed with stoop, as it is hard to remark. In general angle of that deformity won't deteriorate. In most cases it can be cured with special physiotherapy. With asymmetrical strengthening of the back muscles the curvatures could get better. If there is not a simple reason, it is a primer scoliosis. In case of secondary scoliosis a cause could be found, for example difference between the length of the legs, muscles weakness. Liquidation of cases is very important for an effective treatment.[1-2]

By structural scoliosis there are weed lateral deformities on the spine with minor or large torsion. Researchers has not found any cases to complain the development of the disease. Young girls are more often affected than boys by this disease. It could be discovered in rapid growth phase of the bones, mostly at teenagers. Rarely it has appeared by younger 3-4 years old kids, where the opportunity of recovery is less.

As a result of vertebrae torsion, rib or chest deformations can be observed. The physiological sagittal curvatures seems to be reduced. Without treatment structural scoliosis could be even worse until the end of ossification. For teenage girls the ossification ends two years after the first menstruation. To verify it X-ray photographs are needed, that can show the developed Rissel mark on the pelvis. Scoliosis without treatment can cause pain, aesthetic problems, diasbility and even failures in blood circulation.

The Cobb angle is measured on plane radiographs by drawing a line through the superior endplate of the superior end vertebra of a scoliotic curve, and another line through the inferior endplate of the inferiormost vertebra of the same scoliotic curve, and then measuring the angle between these lines.[3]

The second type of spine deformity is the Scheuermann disease. In case of this disease the spine has a normal curvature in the frontal plain, but the kyphosis could be rounder than at healthy people, or a kyphosis will develop near the groin on the spine. It is hard to discover, while it is often mistaken with simple negligent posture, and it remains without treatment. In general, shapes of vertebrae change on the inner side of spine, they are shorter and the collagen combination is changed in the endplates, so the cartilage rift become tight between vertebrae. Sometimes Schmorl lumps could be found. It means that a piece from cartilage disc go under the border plates. It is not an important alteration, however medicals take it for a sure symptom of the disease.

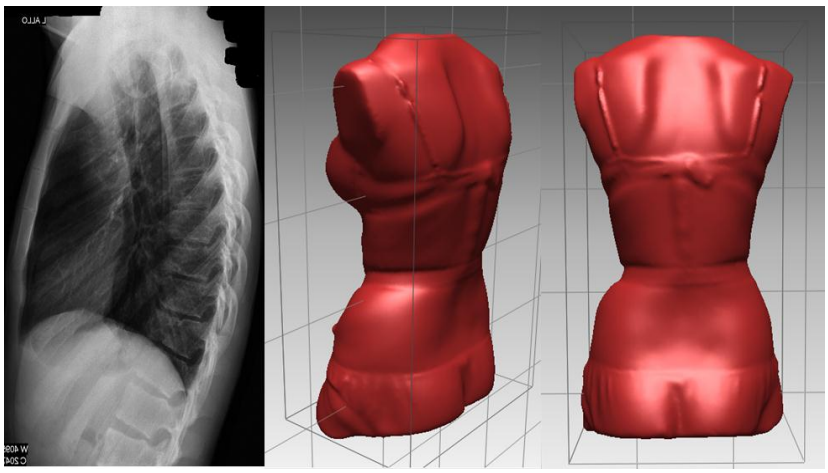

Figure 1. 0

3. Treatment of The Spinal Deformations

There are more alternatives for the treatment, but it's important to take the condition of the disease into consideration.

Under 20 Cobb degree physiotherapy is recommended. It is built up from very special exercises, muscles are strengthen asymmetrically, so they could stand the weed curvatures in the normal position. A few special exercises can be learned and have to be practiced 5 to 7 times a week to get better.

Between 20 and 50 Cobbs it's very important to use a brace[4-5] combined with Schroth physiotherapy. The brace is a rigid device. It puts pressure on the trunk to upright carriage.[6-9] Opposit of these it is very important to make moving areas, it's because of moving the trunk. It helps patients to use their own muscles, as they feel pain on pressurized areas, so they try to get in a position where they don't feel pain. It is important to do special excercises to strengthen the muscles. Doing other sports (swimming for example) while wearing brace could be also effective, as muscles of the spine get stronger asymmetrically, just like with physiotherapy.

Figure 2. Cheneau brace [12]

Above 50 degree Cobb spine surgery shall be needed. In case of a considerable deformity with large rotation the spine have to be stretched during weeks before the operation. Under the operation surgeon lay a metal device onto vertebrae and connect it with the spine. This device removes weed curvatures and keep the spine in a fixed position. It is only suggested in case of a very serious disease.

4. Modeling

Our technology changed a lot with the project's help. Modern scanning is used by modelling, and carving is also digitalized. It ensures more comfort for patients and technicians as well.

The patients have a conversation with the leader our technicians', Ferenc Marlok. The discussion gives us informations about the children, for example about their hobbies, sport activities. It all helps us to make the best, individual brace. Another very important reason is that children know that we deal with their personality.

According to the old technology modeling a brace was a long, dirty process, and it was very uncomfortable for young girl patients. Children had to take off almost all of their dress to let technicians put pen marks on their hips. Then they got a slim, transparent, stretch cotton T-shirt, named tube tricot. After orthopedic technician wound their trunk round with plaster bandage, they marked the hips before the plaster became solid. They cut this negative from the patient,

and produce the trunk model from plaster using that negative. Later this model was carved by technicians' hands. During this process the model was made flat to produce pressure areas, to produce moving areas the model had to be fatten by plaster. Around the finished model technician laid a warmed polyethylene sheet and it was tightened onto the model with vakuum. It became the final form of the brace. After the unnecessary parts were cut off, patient could get the individual device after last fitting and final formation.

Figure 3. Plastering

The first technical modernization was the digital modeling. Old, uncomfortable plastering is being followed by 3D scanning.

With the new technology patients have to take off their dress until underwear, then they have to step on a rounding podium. During rounding a 3D scanner takes photographs of their bodies. The frequence is 2 frames per seconds. This table turns round 360 ° in 40-50 seconds, so it can take pictures from many sides. In this way information is enough for the program to produce a 3D model of the patient. There are some sponge disc markers used to point at some important bones. These are the hip bones, to point at the base of the brace. In addition the 7th neck vertebra, vertex of both sholuder-blades, intersection of the spine and the line between the marked shoulder-blades, spina iliaca posterios superiors, and endpoints of claviculas near the arms.

Markers help us to compare the X-ray photographs and the 3D models. With this we can find out the real degrees of the curvatures, because it is an important problem, that X-ray assistants stand patients in the right posture, so the spine problem seems lighter, than it is in real.

To produce a brace, first step after scanning is to duplicate the original scan. So we can look the original conditions during the production. After that the unnecessary parts have to be cut off. The final model is a trunk without arms and legs, it's base line is under the hips. The rumpled, crushed parts have to be made smoother, for example borderlines of underwear. This step is important by milling the model.

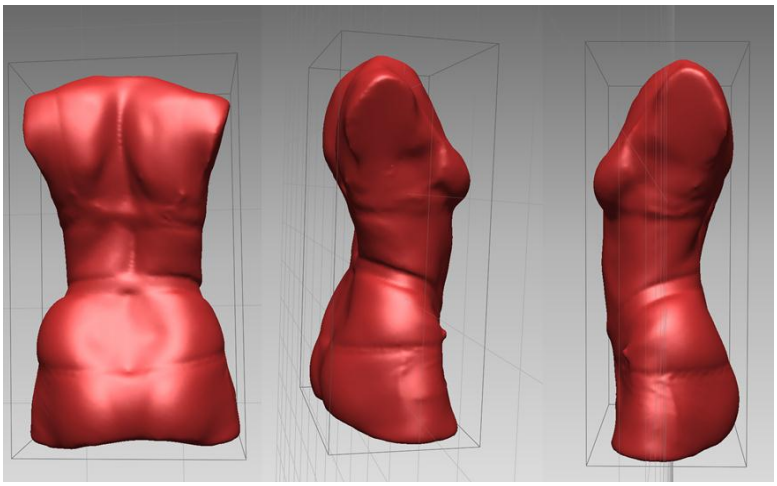

Figure 4. Scanned trunk

5. Transformation Using Imageware Software

The Imageware program[10] can transform the scanned 3D point cloud. An .STL Binary file have to be opened from the program, so we get the original scanned point cloud. We have to produce horizontal slides, then the vertical axis has to be defined. After that the program helps us to lay a skin on the cloud. The model is ready to use it in Rapidform XOR software.

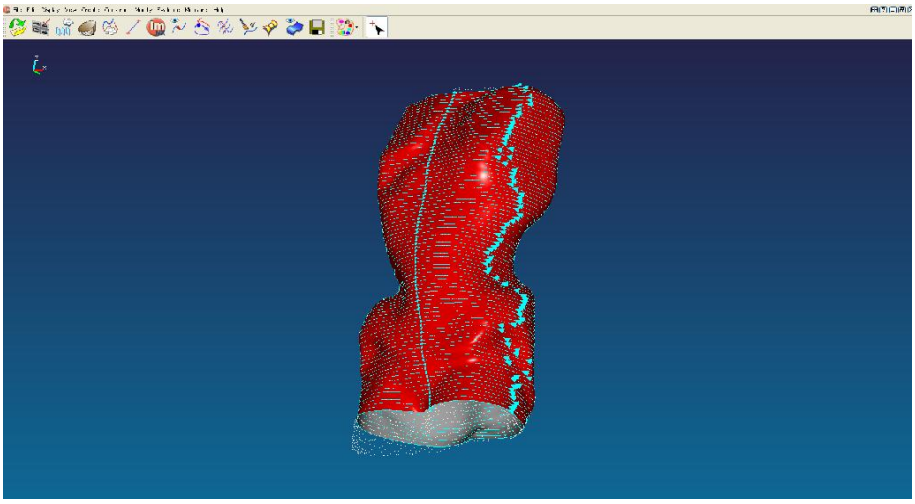

Figure 5. Point cloud after using Imageware

6. Digital carving

To develop the final form of the brace orthopedic technicians' experience and knowledge is needed. The model is imported to the RapidformXOR[11] software, then digital hewing is started. By hewing pressure and movig areas have to be produced to push the spine in the normal

position. First step is also duplication to keep the original conditions, then the model will be digitally fatten and reduce to make the necessary areas. The final model can be compared with the original next to or on each other to show the visible differences. By symmetrical models we can work on a half model first, than we can mirror it to the other side. It can be useful to carwe Gschwand braces for patients with Scauermann disease.

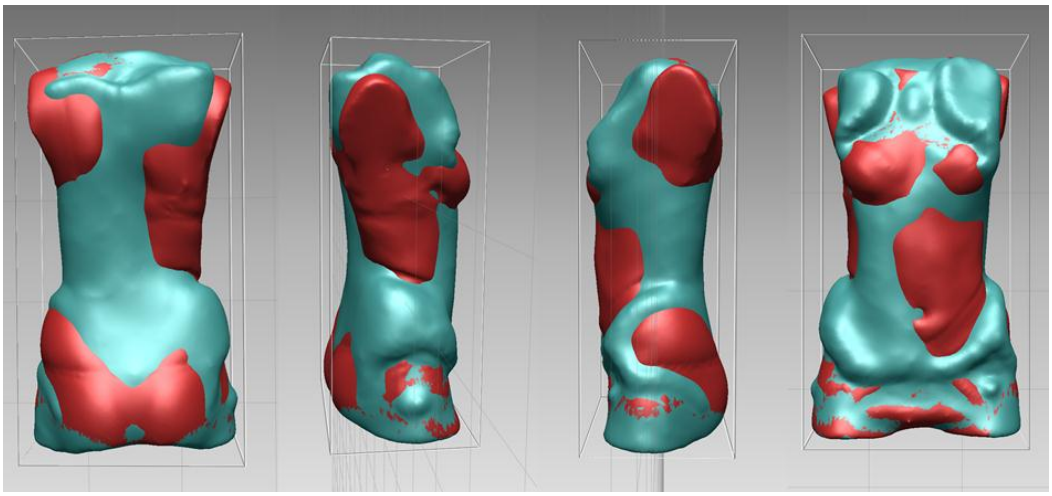

Figure 6. – The carved model (blue) imposed on the original scan (red)

7. Final Form

The next step is to create a millfile in the NX software. We have to create a new model with the name of the patient, then patient's digitally carved model will be imported. The opened model have to be prepared for milling. A line is needed to be moved out 250 mm on the shoulder-side. On the other end of the model the line have to be moved out only 10 mm. After that we can start to create a millfile. The system of co-ordinates has to be placed in the milling body. The program generates the milling courses. It is possible to change the generated courses, but is not recommended. The file now can be saved and sent to the milling machine.

The final file is forwarded to a CNC milling machine - with closed work area. It can produce the 1:1 proportion model of the carved trunk model. This body is made from foam (density 10-12 kg/m^3). After milling it can be perfected by our technicians with plaster. The final body has to be placed on a stand and plastic rods also have to be sticked on the right areas for stiffen the sholulders. A large PE sheet will be warmed to 60 degrees to make it formable but not fluid. This sheet is rounded over the body by technicians and is strengthened using vakuum. After firming the unnecessary parts have to be cut off from the rigid PE trunk model. The brace is ready, but during the planned handing over it will be perfectly formed for the patient's body. Technicians always try to satisfy every demand according to their best knowledge, as device has to be quite comfortable. It has to be wearable more than 20 hour a day.

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