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New Conceptual Approaches in the Orthopaedic Knee Brace Supply

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Abstract

In recent years an increasing interest in customizing medical and orthopaedic products in connection with an individual treatment of each patient can be noticed. This trend also includes the sector of knee orthosis. Furthermore it comes along with the desire of applying modern measurement techniques in the existing supply processes or creating new modern ways of patient treatment.

Nowadays the orthopaedist measures the width of the patient´s thigh, knee and shank by hand and can choose a knee brace of a selection consisting of three up to five different brace sizes. Afterwards the orthopaedist has to adapt the brace to the patient´s leg by bending it into the right form. So, the complete process is strictly addicted to the orthopaedist's experience, power and accuracy. That implies that the result is not measurable or reproducible.

This research work presents an approach for a new modular knee brace system which offers the possibility of adapting the orthosis to the needs of different cases of injury and the phases during the therapy. Due to the importance of the well-fitting of the orthosis a measurement technique is developed to improve a high fitting accuracy independent from the orthopaedist's experience. So, that the results are measurable and reproducible.

Keywords: Orthopaedic Supply, Knee Brace Design, Biomedical Design

1 Introduction

In 2014 220.100 knee injuries are counted in Germany (Statistisches Bundesamt Deutschland, 2016). In 78% of cases of injuries effecting the cruciate ligaments a prescription of knee braces follows (Decoster & Vailas, 2003).

The biomechanical effectiveness of a knee brace is mainly characterized by an optimal individual fit of the brace shells (Regalbuto, Rovick & Walker, 1989; Pierrat et al., 2015) and a dynamic adaption of the orthosis due to the dynamic behaviour of the leg during gait (Hochmann, 2012). None of the state of the art rigid or custom made braces could fulfil both properties. The rigid braces do not match the patient´s anthropometry well and the custom made ones are not offering enough adaption which is necessary for an optimal agreement between the pathological knee kinematic and the brace joint kinematic (Wojtys & Huston, 2001; Soma, Cawley, Liu & Wangsness, 2004).

As one can see, there is a need of a new brace concept which significantly increases the biomechanical effectiveness, which is also demanded from the health insurance companies (Barmer GEK, 2012).

According to these findings a solution concept regarding to the biomechanical and therapeutically requirements and requirements of health insurances is required. This paper presents the author´s solution for a new brace design concept and the results of the previous biomechanical research. This concept was developed by following a research-oriented design process and includes on the one hand the idea of partly reducing the extent of the brace and on the other hand the approach of adding modern measurement techniques and the regarding use of mobile devices.

2 Biomechanical Background

Nowadays the patient gets a brace from an orthopaedist either in the hospital after an operation or he/she has to go to a local orthopaedist. In both cases the technician measures the patient´s thigh, knee and shank by hand using a tape measure. Afterwards the orthopaedist chooses a brace from the aid health supplier's stock. These braces are pre-configured in up to five different sizes and have a normative correlation between the shank and thigh circumference. Because of this most of the time the knee orthosis needs a lot of adjustment. This is done by bending the brace into the right form for which the orthopaedist needs enough power. Even if the technician has a lot of experience and works accurate the brace would never fit optimal according to the patient´s anthropometry. So, at the end of the adjustment the patient has to wear a non-optimal fitted knee brace during rehabilitation of the knee.

In a few cases the patient gets an individually prepared brace, e.g. if a supply with a standard orthosis is not possible because of the patient´s anthropometry or the patient has a special kind of injury and needs a specific brace. But this individual preparation is time-spending and expensive. Though the health insurance companies mostly do not pay for them.

The main limitation factors of the biomechanical effectiveness of a knee brace are the force and moment transfer between the knee brace and the soft tissue fabric and the missing congruence between the pathological knee kinematic and the brace kinematic (Cawley, France & Paulos, 1991). These two characteristics are discussed in the following sections. Furthermore specific orthosis and the risk of injury recurrence are discussed.

2.1 Force and moment transfer

A favourable force and moment transfer and a good support effect of the brace can be achieved by an accurate fit. But this force and moment transfer between the knee brace and the soft tissue fabric is one of the main problems of the existing rigid knee braces:

- During gait the force transfer is changing considerably because of the physiological variation of volume and stiffness of the muscles, the shape transformation of the soft tissue fabric and skin movement. Due to the unsatisfactory fitting of the brace migration of the orthosis starts after a few steps. The migration process is also supported by the weight of the knee brace, the conical shape of the thigh and the low static friction of the skin.

- Because of the changeable swelling of the knee and the atrophy and hypertrophy of the muscles during the first weeks of therapy the shape of the knee, thigh and shank is variable (see Figure 1.). So, there is no constant fitting throughout the therapy time.

- Furthermore there are fitting problems for patient´s without a normative correlation between thigh and shank circumference. These differences for example are contributed by training of the thigh more than the shank like athletes do or due to patient having overweight. In those cases an accurate knee brace supply is not possible with the braces available on market.

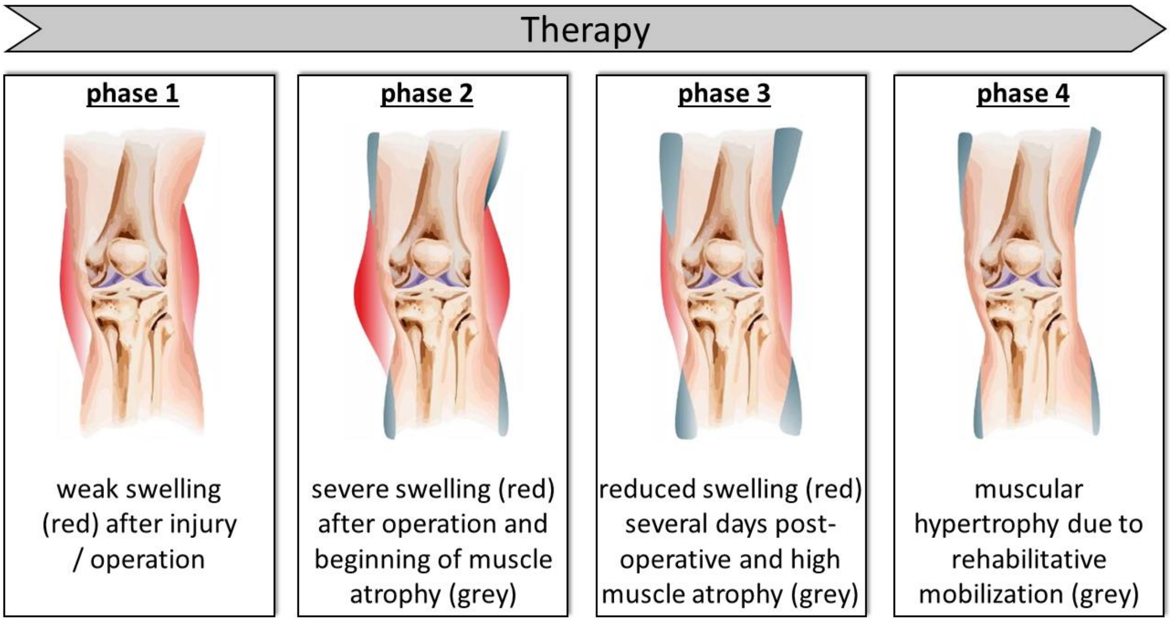

Figure 1. Variation of the knee, thigh and shank shape during therapy.

2.2 Joint kinematic

The design of the knee brace joint needs to offer a high level of accordance of the individual kinematic of the knee joint and the joint axis of the orthosis. Several studies show that even a small incongruence of these joints leads to constraint forces into the knee during gait (Grifka & Jutka, 1994). Following this the knee suffers from an additional load what leads to pain and could evoke permanent injuries (Hochmann, 2012).

Depending on the brace design available orthosis have either a monocentric joint or a polycentric joint. Monocentric joints are used with a pushed back position axis regarding to the compromise rotation axis. However, polycentric joints are adapting the principle of the four-bar chain (Grifka, 1995). An individual adaption is only possible by the extension and flexion limitation and not for the individual knee kinematic.

In addition to the conflicts mentioned before the available knee braces have also the following problems:

- Both joint types are not able to imitate the complex three-dimensional and very individual course of the physiological knee axis.

- The physiological knee movement itself is very complex and differs according to each individual patient. Furthermore, if the patient has a pathological knee movement because of an injury the knee kinematic changes again. The behavior and extent of the new pathological kinematic depends on the type of injury and could not be predicted.

- Even when the kinematic of the brace matches to the individual knee kinematic there is still the shape variation of the knee, thigh and shank during therapy treatment. This leads to an incongruence of the knee joint axis and the brace axis which has to be prevent by frequently re-fitting the brace during therapy.

- An incongruence of the knee joint axis and the brace axis appears also if the patient does not have a normative connection between thigh and shank circumference.

As a general rule the functional requirements on well-fitting of the orthosis and the congruence of the joint axis are contrary to each other. In case of incongruence of the joint axes a harmonizing migration of the orthosis is stopped. But, both factors are important for the biomechanical effectiveness of a knee brace. So, this means for the brace requirements: on the hand the anatomical fitting of the brace shells and on the other hand the congruence of the joint axes must be adaptable to the patient´s individual anthropometry to offer a best possible therapy success and to prevent consequential damages of the knee. None of the available rigid knee braces offer the option of a solution for the before mentioned problems.

2.3 Specific orthosis

Besides the standard braces there are a lot of specific orthosis which fit special tasks – for example varus / valgus braces and orthosis for osteoarthritis of the knee. On the one hand those knee braces normally have the option of an individual brace fitting. But on the other hand they have problems, too:

- A good supply for more than one case of injury is not possible, because the braces are too specific and optimized for special cases.

- It is not possible for an orthopaedist to have every brace in each size in stock. This is too expensive and needs a lot of space. So, an immediate supply is not possible for every supply case.

Instead of offering a brace for each case it would be much easier to have a knee brace which is adaptable to different cases of injury.

2.4 Risk of injury recurrence

After treatment with a rigid brace the risk of a new recurrence increases immediately without a step by step mobilisation of the patient and a reduction of the brace support. Nowadays this reduction is realised by shortening the time of wearing the knee brace or by often changing the whole brace during treatment. But this requires braces with a variation of support effectiveness and increases time-spending and costs.

Regarding to a therapeutic correct therapy treatment the state of the art supply shows the following problems:

- The reduction of time of wearing the knee brace leads to a radical switch between full loading and moderate loading as well as between full flexion and extension and moderate flexion and extension. From the orthopaedists point of view is this unsatisfactory.

- The high exchange rate of knee braces leads to high costs which would not be borne by the health care system.

So, a knee brace is needed which is flexible and adaptable during therapy. An approach for such a brace is presented in the following section.

3 Innovative approach for knee brace design and measuring techniques

In the following section the author´s approach for the innovative knee brace concept is described as well as the possibilities of adding modern measuring techniques.

3.1 Knee brace design

Due to the results of the analysis of the biomechanical effectiveness the following requirements to a knee brace exist:

- Optimal fitting to the individual anthropometry of the patient to guarantee a favourable force and moment transfer and a good support effect.

- Adaptable congruence between the knee joint axis and the brace joint axis regarding to the patient´s individual anthropometry.

- Usable for different cases of injury and for different cases of supply.

- Flexibility of the orthosis during therapy to offer a step by step mobilisation of the patient and a reduction of the brace support.

The resulting approach is a modular knee brace system which on the one hand consists of several parts to enable a flexible, patient-individual brace configuration and has on the other hand the possibilities of an accurate setting. In addition the brace should support the necessary range of migration for an optimal agreement between the joint kinematics. Furthermore the therapeutic benefit should be increased by offering a system which could be partly reduced during the ongoing therapy. This approach of a modular knee brace offers the following opportunities:

- In contrast to the rigid knee braces which are only available with a normative correlation between thigh and shank circumference the modular orthosis kit offers the option of an individual knee brace supply. This is done by a selection out of some standard modules. That concept bases on a division of the orthosis into the following parts: the thigh and the shank shell, the left and right orthosis splint as well as parts to connect the other modules. All of these parts are offered in different sizes and materials in the modular knee brace kit to build up an orthosis which could be perfectly adapted to the patient´s anthropometry and case of injury.

- The left and right orthosis splints are designed with the option of adjusting them to the leg shape of the patient during the whole therapy time – for example by extra joints or defined bending areas. This guarantees on the one hand always an optimal fitting of the brace and on the other hand a high level of accordance of the individual kinematic of the knee joint and the joint axis of the orthosis. Another advantage of this flexible adjusting is the possibility of designing an individual orthosis for varus / valgus treatment.

- Furthermore the concept has an option for replacing the rigid shells with soft straps. This grants the reduction support during therapy treatment without changing the whole brace. Also the splints could be used in a bandage. These factors reduce the costs of an orthosis supply immense.

Figure 2 shows the design and concept of the new orthosis. The brace shells (painted in blue) should be available in at least five sizes each. The splints are portrayed in white and the strap mounts in orange. At these mounts the fixating straps are attached. With the green painted coupling elements the shells and the splints can be connected. The red marked areas are the zones where the orthopaedist should bend the brace into the right form.

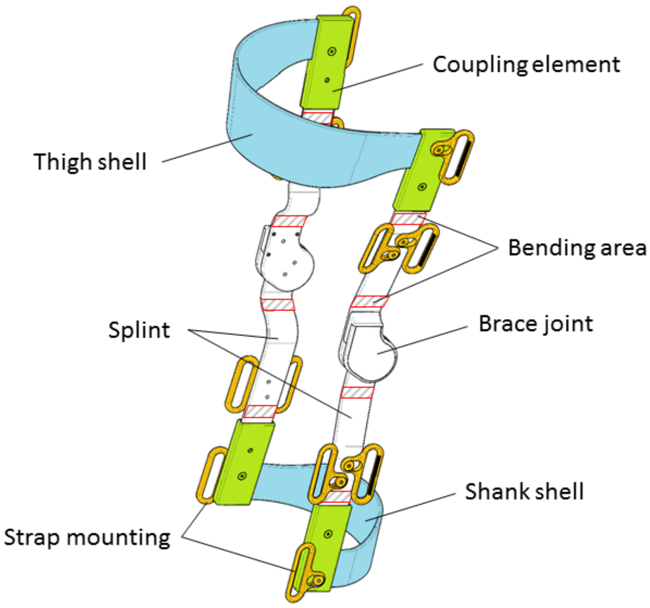

Figure 2. Drawing of the new modular brace concept.

3.2 Software support

In addition to the knee brace system a supporting measuring software for an optimal combination and setting of the brace modules is developed. The software facilitates the fitting process for the orthopaedist and the process gets more measurable and reproducible.

This software support also fits the continuous trend of digitization which can be noticed in many business lines and in the orthopaedic supply sector, too (Beu, 2014; acatech, 2014; Carloni Vitali, Germani, Mandolini & Raffaeli, 2014; Marinelli, Mandolini & Germani, 2015).

Due to the functionality of the measuring application the following requirements exist:

- Loading or adding patient files.
- Saving and measuring up to two pictures of the patient – frontal and lateral.
- Setting the marks of the points which should be used for the calculation of the angles of the left and right splint.
- Calculating the angle adjustments of the left and right splint.
- Determining the thigh, knee and shank circumferences and announcement of the shell size.

Regarding to the before mentioned requirements figure 3 shows the flowchart of the 2D picture analysis. An optional requirement is the flexible use of the measurement application. Therefore an implementation for mobile devices is preferred.

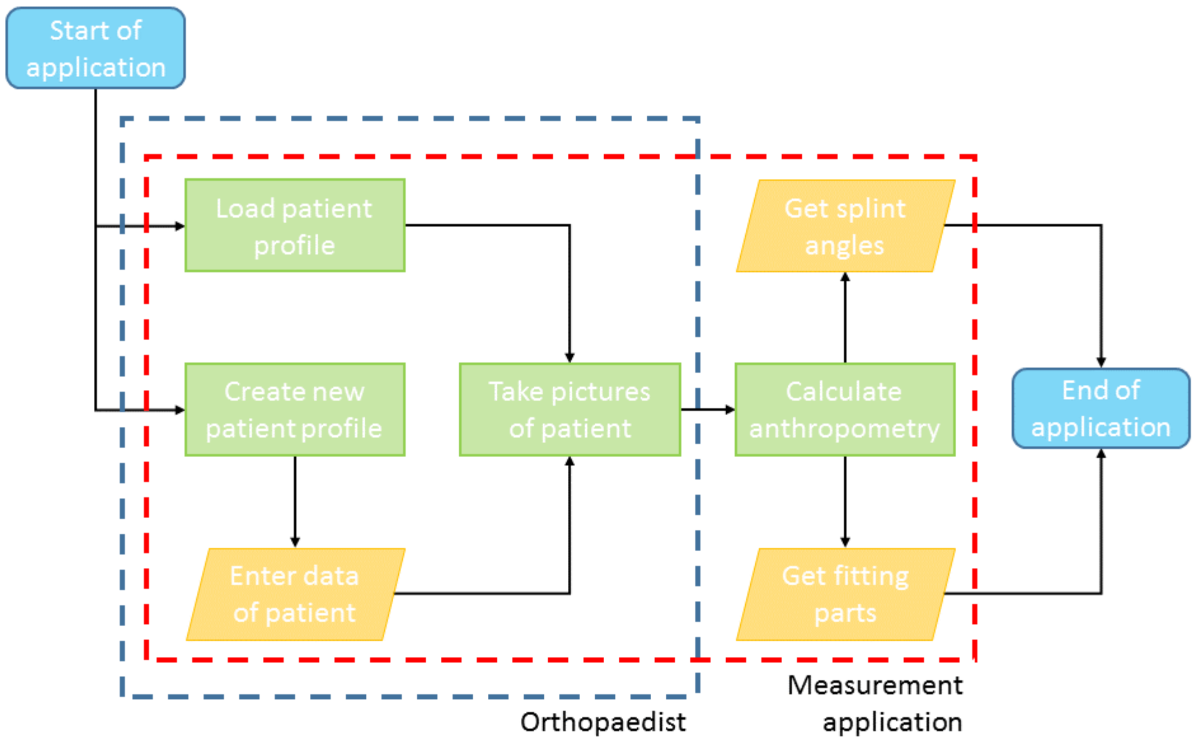

Figure 3. Flowchart for the 2D picture analysis.

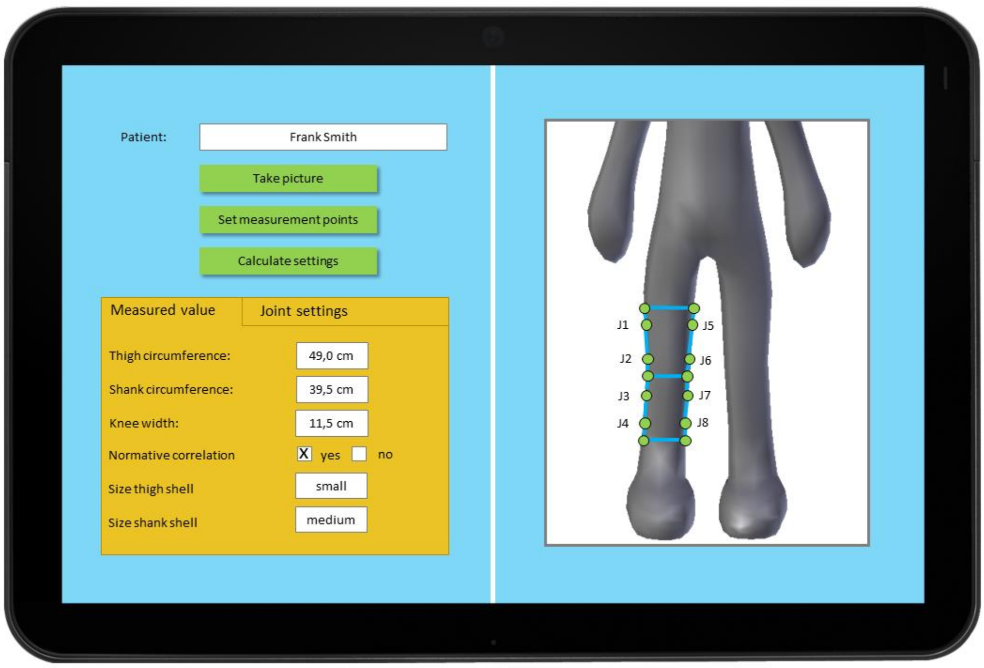

Figure 4. Design of the graphical user interface of the measuring application.

Due to the preferred use of mobile devices an example of the graphical user interface of the application configured for tablets is shown in figure 4. On the left side the patient´s name is listed and the results of the calculation of the thigh, knee and shank circumferences. Also the required shell sizes are appropriated. Furthermore there are some buttons to set off different activities: taking pictures, set measurement points and start calculating. On the right sight there is an example of a frontal picture of the patient. The green dots are symbolizing the joints of the left and right splint. Also the blue connecting lines between the dots are symbolizing the outer shape of the knee brace.

At the moment the measuring application is developed for Android devices only. The app can be adapted in any way and can be easily extended to offer more possibilities, e.g. a link to an online shop or instructing material.

The interaction between the orthosis system and the measurement technique can be described as follows:

- The selection of the shell sizes is supported by the measurement application: the algorithm calculates the thigh and shank circumferences and the app shows the needed shell size. So, measuring by hand using a tape measure is needed no more.

- The settings of the joint angles is calculated by the application: the algorithm determines the angles between the measurement points and shows the needed joint angles for an optimal fit of the orthosis.

So, the innovative approach of a modular knee brace system and the system supporting measurement software perfectly complement each other and a new way of an individual knee brace supply can be achieved.

4 Conclusion and future prospects

In conclusion one can say that for available orthosis far too less attention is paid to the three factors – therapeutically effectiveness, requirements regarding to the health insurances and biomechanical effectiveness – separately and in combination. That leads to the shown deficits due to the knee brace supply. In contrast to this the proposed concept has as shown the potential to fulfill those requirements, but there are still some steps which have to be done:

- Testing a prototype of the orthosis due to evaluating the stability of the brace and the brace concept itself.
- Evaluating the accuracy of the 2D picture analysis application.
- Extending the measurement application with regard to motion capture and 3D scanning.

Regarding to future prospects and the keywords *Big Data*, *Mass Customization* and *Digitization* the above drawn way of supply can be extended in many ways. Therefore products, processes and services have to be digitally enabled to create personalised smart

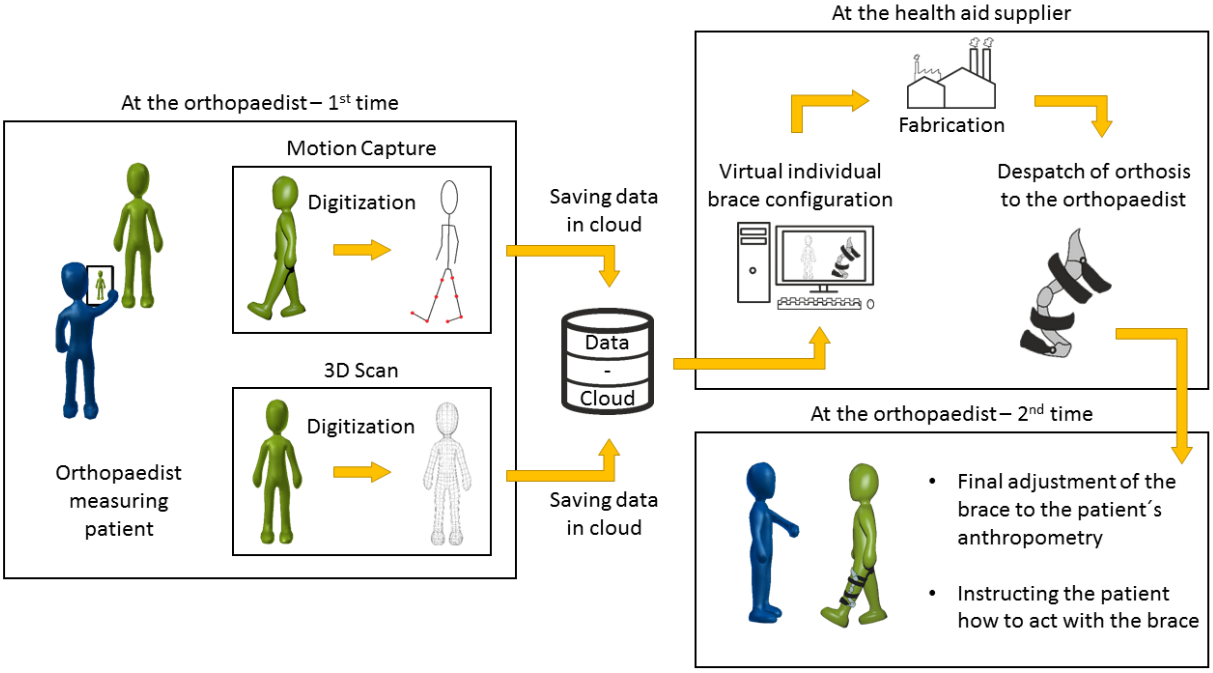

Figure 5. Digitization and Big Data in context of brace supply – an approach.

services. One possible way of digitization is shown in Figure 5.
To further improvement of the measuring application more information should be captured to create an exact model of the patient. This model could be achieved on the one hand by 3D scanning of the patient to get the patient´s anthropometry and on the other hand the individual gait kinematic of the patient could be recognized by motion capture. Both tasks have to be done by the orthopaedist. The recorded patient data could be uploaded into a data cloud. This data could be downloaded by the health aid supplier and a virtual patient model could be created. Onto this model the knee brace could be fitted individual. The configuration data could be sent to the factory where the brace get produced. The finished orthosis could be

despatched to the orthopaedist who does the final adjustment and introduces the patient into acting with an orthosis. This instruction could be supported by online / virtual guidelines. This short introduction into possible digitization shows it potential in the knee brace supply sector.

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