Implementation of a non-fusion scoliosis correction system in a hospital; a constructive technology assessment

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Abstract

A new innovative non-fusion scoliosis correction system is being developed at the University of Twente. The technology looks promising, but there is still a great chance that it will not be implemented. A Constructive Technology Assessment (CTA) was used to analyse the implementation of the technology. Part 1 of the CTA process was directed at the social-environment; is the environment willing and able to implement this technology? This study concluded that, when the technology is proven effective, the costs can be a bottleneck. Part 2 was directed at the technology. The Analytical Hierarchical Process (AHP) was used to question the experts and compare their demands with the aspects of the technology. It can be concluded that the experts prefer this new treatment over the current treatment.

Keywords: Scoliosis Surgery, Constructive Technology Assessment, Early Technology Assessment Analytical Hierarchical Process, Implementation of innovations.

Introduction

Health Technology Assessment (HTA) is an evaluation method for medical technology. In this article a technology is evaluated that is currently in development. For this reason, it can be reviewed if the technology is meeting the demands and desires, already in an early stage. Generally HTA is used for evaluating technologies in a later stadium; after implementation. As a result of this HTA research, some aspects of the potential success can be predicted and the results can be helpful in further development. This is of interest, since research shows that only 25-60% of the users of medical technology is satisfied with technological applications in health care. Also only 1 out of 3000 ideas will lead to a successful technology (Rosenau, 1999) (Stevens & Burley, 1997)

This assessment is the result of a new line of research of the department Health Technology and Service Research of the University of Twente, where formal HTA methods are used for assessing emerging technologies. The assessed technology is a scoliosis correction system, which is currently in development by a research group of Biomechanical Engineering of the University of Twente. This scoliosis correction system will be named SCS in this article. A goal of the study is to support the further product development of the SCS.

This thesis is organized as follows. First an overview of the current diagnosis and treatment of scoliosis is given. Secondly the technology is addressed. We continue with the methodology and results. Finally the conclusion and discussion are given.

Background

The subject of this study is a new scoliosis correction system (SCS), which is currently in development. The expectations about the new technology are promising. After implementation the current treatment process changes radically. This has several reasons, for example the SCS is effective at a very young age. To make a comparison between the current treatment and the SCS, it is necessary to know the current process. This is divided in several stages; figure 1 can be used as a guide.

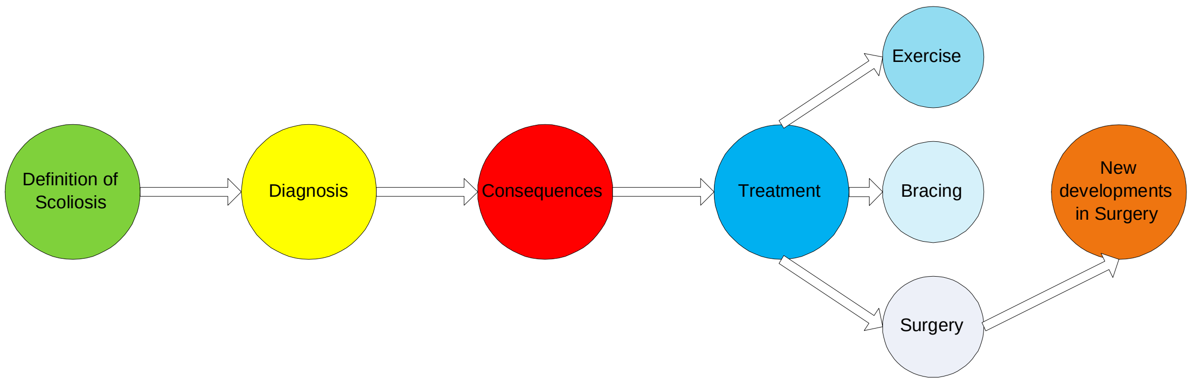
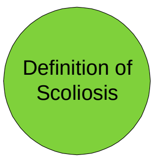


Figure 1 Guide of the current process of scoliosis



Scoliosis is a complex three-dimensional deformity of the spine and thorax. The spine has a lateral curvature, the vertebrae are axial rotated and when looking sideways to the spine, there is a decrease of the normal curve (kyphose) and inward curve (lordosis) (Veldhuizen, 2008). There are different types of scoliosis; structural or non-structural. The non-structural type can be fully corrected and is for example caused by uneven leg length (Bourgoyne & Fairbank, 2001). In the structural scoliosis, there are different types to distinguish. These are among others congenital, neuromuscular, syndromic, mechanical and trauma scoliosis. But in most of cases (80%) the cause of the scoliosis is unknown, also called idiopathic. Idiopathic scoliosis can occur in three stages, depending upon the age of onset.

1. Infantile idiopathic scoliosis – from birth till the age of three

   In 70-90% of the cases this type of scoliosis will pass by spontaneously.

2. Juvenile idiopathic scoliosis – from the age of three till puberty

   The treatment is directed to stop the progression; further treatment will be done in the period of adolescence.

3. Adolescent idiopathic scoliosis – from puberty till end of growth (McMaster, 1983)

Cobb Angle

The Scoliosis Research Society has defined scoliosis as a lateral curvature of the spine greater than 10° as measured using the Cobb method on a standing radiograph (Reamy & Slakey, 2001). The severity of the condition (curve) is represented by the Cobb angle. To use this method, the end-vertebrae of the curve were pointed out on an X-ray by the orthopedic surgeon or radiologist. These end-vertebrae are the vertebrae at the upper and lower limits of the curve which tilt most severely toward the concavity of the curve. Once these vertebrae have been selected, a line is drawn along the upper endplate of the upper body and along the lower endplate of the lower body. The angle between these lines is the Cobb Angle (figure 2) (University of Washington, department of Radiology, 2008).

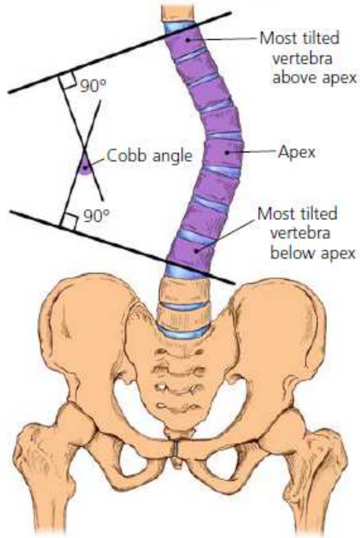


Figure 2 Measurement method of the Cobb Angle (Greiner, 2002)

Prevalence

The prevalence of adolescent idiopathic scoliosis is 2-3%, using the definition of a scoliotic curve bigger than 10°. For curves between 20 and 40°, a mild scoliosis, the percentage is 0.3-0.5% and curves greater than 40°, severe scoliosis, are found in less than 0.1% of the population (Weinstein et al., 2008) (Reamy & Slakey, 2001)(Asher & Burton, 2006) (Weiss et al., 2006)(Welten, 2007). There is a difference in prevalence of scoliosis in males and females. For curves of 15° the prevalence is equal, but for curves of 30° or more, girls have scoliosis 10 times more than boys (Welten, 2007) (Reamy & Slakey, 2001). In other literature the ratios of 7:1 and 5:1 are generally used, the difference is due to an other point of measurement or including infantile and juvenile idiopathic scoliosis (University of Washington, department of Radiology, 2008) (Welten, 2007).

Location of the curve

Scoliosis is generally named by the location of the curve(s), especially the apex of the curve, which is named thoracic, lumbar, thoracolumbar, or double major. The double major curve has a major and a minor curve and also a primary and a secondary curve. The major/minor aspect is based on the size and flexibility and the primary/secondary aspect is based on which curve is progressing. The majority, about 90%, of the curves is right thoracic (Welten, 2007) (Greiner, 2002) (Weinstein, 1999).

Diagnosis

There is no univocal explanation possible about the method of screening and the first diagnosis in The Netherlands. In 2006 the research project 'The Dutch Evaluation Study of Screening on Scoliosis' was executed (RIVM, 2009). The study showed that there is no evidence-based information about the method of screening. NESCIO, 'De Nederlandse Evaluatie Studie van Screening op Scoliose' advised no screening. When there is nevertheless an examination, the NESCIO advices to follow 'the standard research method scoliosis' developed by the youth healthcare organization (Werkgroep JGZ - GGD Nederland, 2003). After this report the GGD[1] of Twente stopped the screening for scoliosis, but the GGD of the region Rivierenland translated the report into a protocol and continued the screening. Concluding, the manner of tracing scoliosis depends on the school region of the child (Werkgroep JGZ - GGD Nederland, 2006)

The advised method of the NESCIO contains the forward bending test. By presence of a gibbus, a hump, additional research with the scoliosis meter is also performed (figure 3). The forward bending test is the most specific test for the detection of scoliosis (Richards & Vitale, 2008). It is not only the inspection of the child in bended position; also the bending process is important. The researcher is standing behind the child and observes the bending process with attention to both back parts. From a side-view the physician sees if there is a gibbus (Werkgroep JGZ - GGD Nederland, 2003). When there is a gibbus, the scoliosis meter is used to detect scoliosis. The semicircle line level is placed on the spine and moved toward to the backside. The difference between the left and right can be read off the scoliosis meter. The difference is a sign for scoliosis.

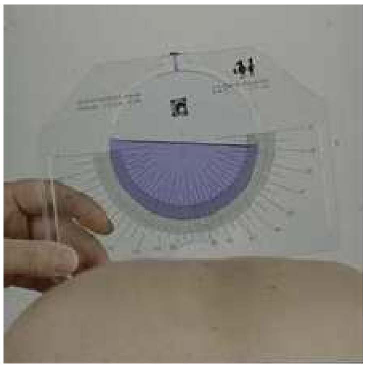


Figure 3 Scoliosis meter (Werkgroep JGZ - GGD Nederland, 2003)

A curve in the spine can be detected by the school doctor, the parents, the general practitioner (GP), the patient or someone else. In all the cases, the GP is the contact point. The GP has two options:

1. The GP refers directly to the orthopedic surgeon
2. The GP does the examination and checks the patient every six months.

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[1]GGD = Gemeentelijke Geneeskundige Dienst: Local Area Health Authority: The authority that is responsible for the Dutch Youth Health Care

When option two is chosen, the GP orders an X-ray of the back. When the Cobb angle is smaller than 10°, the GP will check the patient every six months till end of growth. When the patient has a curve greater than 10 °, the GP refers the patient to the orthopedic surgeon.

It is important to know how the scoliosis evolves when choosing a treatment. There are different aspects for predicting the progression of the scoliosis; the growth potential, the magnitude of the curve, the place of the curve and the gender of the patient.

The growth potential is assessed by the measurement of the Tanner stage and the Risser grade. The Tanner stage reflects the stage of puberty; this is based on items like the growth of pubic hair, the development of the genitalia in boys and breast growth in girls.

Besides the X-ray of the back, also an X-ray of the pelvis is taken. This is done to measure the Risser grade. This grade is based on the degree of bony fusion of the iliac apophysis;[2] no ossification is grade 0 and complete bony fusion is grade 5 (figure 4). The Risser grade and the Tanner stage together give a conception of the growth potential. For example a patient with no signs of pubic hair or breast growth and a Risser grade of zero has a very high growth potential. A boy with lots of pubic hair, very developed genitalia and a Risser grade of 4 has a limited growth potential (Reamy & Slakey, 2001).

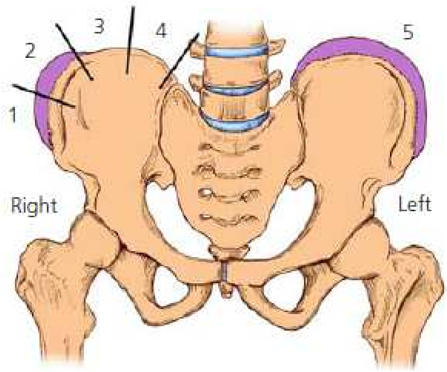

Figure 4 Grade of bony fusion of the iliac apophysis (Greiner, 2002)

The magnitude of the curve is an indicator for progression. Curves of 20° have a chance of 20% to progress; curves of 50° have a chance of 90% to progress. The growth potential is usually expressed in the Risser grade (0 to 5). The Tanner stage is used as indicator for the growth spurt; the period with the maximum progression of the scoliosis. The relation between the magnitude of the curve and the Risser grade gives a good prediction of progression. Table 1 is the result of multiple studies done to assist in predicting the risk of curve progression in adolescents.

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[2] iliac apophysis = bony outgrowth of the ilium, a bone in the pelvis.

Curve (degree)	Growth potential (Risser grade)	Risk
10 to 19	Limited (2 to 4)	Low
10 to 19	High (0 to 1)	Moderate
20 to 29	Limited (2 to 4)	Low/Moderate
20 to 29	High (0 to 1)	High
>29	Limited (2 to 4)	High
>29	High (0 to 1)	Very High

Low = 5 to 15% Moderate= 15 to 40% High= 40 to 70% Very High risk= 70 to 90%

Table 1 Risk of curve progression (Reamy & Slakey, 2001)

The gender of the patients and the place of the curve are also indicators for progression. By a curve of 10°, the ratio of girls to boys is equal. When the curves get bigger than 30° the ratio is changing. For every boy with a curve of 30°, there are 10 girls; Girls have a bigger chance on progression. Double curves are more likely to progress than single curves; 27% of the double curves and 18% of the single curves progress. In single curves, thoracic curves have a bigger chance to progress than lumbar curves (26%:9%) (Lonstein & Carlson, 1984).

Consequences

Most of the time scoliosis is established at young age, before there are symptoms. Without treatment several complications can occur, which all have an impact on the overall enjoyment of life of the patient. The overall enjoyment of life is also called Quality of Life; more specific, the Health Related Quality of Life (HRQoL). The HRQoL is defined as the functioning of people on physical, psychological and social level and their personal evaluation thereof (Hoeymans et al., 2005). Back pain is an example of the physical level. Of adult patients with adolescent idiopathic scoliosis 61% reports chronic back pain, compared to 35% of the people with no scoliosis (Weinstein et al., 1981). Back pain is indicated significantly more by patients with moderate and large curves (≥45°) (Haefeli et al., 2006). Research shows that women with adolescent idiopathic scoliosis report a lower Quality of Life than a norm-sample of individuals with back pain (Freidel et al., 2002). Another complication within this domain is a sudden death due to cor pulmonale[3]. This can be a result of a Cobb angle larger than 100°, but scoliosis with this severity is rare. A cardiovascular problem that occurs more often is shortness of

[3] Cor pulmonale = Hearth failure due to a chronic lung problem

breath. This is also related to the severity of the curve; A larger curve results in a lower vital capacity and more patients with shortness of breath and dyspnoea. Further curve progression is also a symptom of scoliosis.

Weinstein indicates that the cosmetic aspects of the disorder should not be underplayed (Weinstein, 1999). There is lot of change for children in puberty; Physical change like breast growth with girls and change of voice in boys. Mental changes like falling in love and feelings of sexuality. Most children in this period are insecure about themselves. When these adolescents also face scoliosis, it is not easy. Many patients have severe limitations psychosocially, even with minimal curves. They often try to shop clothes which hide their deformity. The self-esteem of scoliosis patients can be low and it is possible that they are worrying of what someone thinks about them. A psychosocial problem can also be a reason for surgery. It appears that middle aged patients tolerate psychosocial problems better than teenagers (Weinstein, 1999) (Welten, 2007).

A problem at one level can be a problem at another level. For example cosmetic problems can also be a problem at the social level instead of the psychosocial level. Sometimes the low self-esteem stops the children to make new friends or be active in a new network. The same for back pain; this can stop patients to go to sports or work. Interesting is that the age and Cobb angle are independent to the impairment of the HRQoL (Freidel et al., 2002).

Treatment

The way of treating patients with adolescent idiopathic scoliosis depends on the severity of the curve and the remaining growth potential. The various treatment methods are exercise/physiotherapy, bracing and surgery. Patients with remaining growth potential and a small curve (<25°) are placed under observation. An examination by the orthopedic surgeon, including an X-ray, is performed every six months. This is done till the end of growth of the patient. When the orthopedic surgeon observes progress of the curve, he can choose the right treatment.

Exercise

Sometimes the observation is accompanied with exercise. This depends on the patient and a on the country where the patient is living. The goal of exercise is to improve and maintain flexibility and functions at risk for pain, pulmonary dysfunction and progression (Weiss et al., 2006). Weiss (2003) reports that there is almost no clinical research to test the efficacy of proactive, physiotherapy methods in the United Kingdom and the United States of America. A reason mentioned is that small curves often remain stable. The opposite takes place in Continental Europe. Especially in Germany were the Schroth-method seems to be effective in improving pulmonary dysfunction and in reducing the pain. Out-patient physiotherapy following the Schroth method begins at a Cobb angle of 15°. By curves of 20°-30°, scoliosis intensive rehabilitation is recommended. The patient is in the centre for 4-6 weeks and has 6 hours of exercise a day. This treatment can be repeated due to the prognosis (Weiss et al., 2006).

Bracing

Bracing of patients with adolescent idiopathic scoliosis is not a new concept, it is the oldest treatment known for scoliotic spinal deformity. The goal of bracing is to stop progression and prevent the deformity from exceeding a Cobb Angle of 40° by skeletal maturity. So that surgery can be avoided. Below is a description of four bracing methods; a brace used from 1954 till 1979, a brace that is used nowadays, a brace that is used in accompany with exercise and finally a brace that is non-rigid.

Figure 5 Milwaukee Brace (eOrthopod, 2007)

<u>Milwaukee brace</u>

The Milwaukee brace, figure 5, used from 1954 till approximately 1979, was the first widely accepted brace for the treatment of adolescent idiopathic scoliosis. The appearance of the brace is characterized by the neck and chin bracket. Still the efficacy is not completely obvious, because the initial improvements were lost over time. The curve did not progress, but there was no decrease in Cobb angle (Lonstein, J; Winter, R, 1994).

Boston Brace

The company of the Boston race claims that the system is the primary orthopedic solution at the moment. The system is available in different sizes and can be adjusted to the patient. It is suitable for the different locations of the scoliosis. The Boston Brace is a rigid system, completely manufactured of hard plastics, figure 6. In a review, the Boston Brace was associated with the lowest surgical rate (14%) in comparison with other braces. The overall pooled surgical rate was 23%. This implicates that the Boston Brace is effective, because it reduces the rate of surgeries in a group of patients (Dolan & Weinstein, 2007).

Figure 6 Boston Brace (eOrthopod, 2007)

Chêneau Brace

The Chêneau brace, figure 7, is most used in addition to the exercise program of Schroth in Spain, Germany and other parts of central Europe. *It is defined as a thermoplastic brace modeled on a hypercorrected positive plaster mould of the patient* (Rigo, 2003). Rigo (2003) concludes that the prevalence of surgery as found in a study to the Chêneau brace was significantly lower than in the control group. Treatment with the Chêneau brace in combination with Schroth therapy has favourable outcomes.

Figure 7 Chêneau Brace (Ortotika s.r.o.)

TriaC

The TriaC brace, figure 8, is a non-rigid brace and corrects scoliosis using force control. This type of brace is not widely tested yet, there are two preliminary reports. Both conclude that the brace provides increased comfort compared to conventional braces. One research concludes that the curve reduces; the other research concludes the curve is increasing (Veldhuizen et al., 2002) (Zeh et al., 2008).

Figure 8 Triac Brace (Department of Biomechanical Engineering, 2008)

In the Netherlands the Boston brace is considered as the standard for the treatment of adolescent idiopathic scoliosis (Bunge, 2009). In some Dutch hospitals other systems are applied on specific groups of scoliosis patients, for example the TriaC in the University Medical Center of Groningen.

Surgery

Surgery is the next step when the brace does not stop the progression (or a brace was not indicated). The indication for surgery is a curve exceeding the 45-50° by skeletal mature patients. Surgery is also possible when there is a significant cosmetic deformity by patients with a curve exceeding 35°, in skeletal immature and mature patients (Betz et al., 2003). The goals of the surgery are to stop the progression, correct the curve as much as possible, improve the appearance and avoid short-term and long-term complications (Weinstein et al., 2008).

Figure 9 X-ray of a patient treated with posterior and anterior instrumentation (Emory HealthCare)

There are roughly two methods for the surgery of patients with adolescent idiopathic scoliosis. Posterior surgery is most used; about 69% of the cases are performed with this method. The patient is placed on the ventral side of the body and the orthopedic surgeon is operating at the back. An example of this is the Harrington method, this system consist of two rods and multiple screws. Nearly all the other posterior system can be traced back to this system. Operation through the ventral site of the body, is done by the anterior method. A combination of the posterior and anterior methods is also possible, for example if the patient still has a high growth potential. When the surgery is only performed by the posterior method, the patient has a chance on the crankshaft phenomenon. This happens when the dorsal side is fused, but the ventral side is still growing. The spine will become deformed. The anterior method is used in 18% of the cases and the combined method in 13% of the cases (Coe et al., 2006) (Welten, 2007) (Connolly et al., 1995). In Figure 9 an example of a combined operation is presented. The instrumentation in the red circle is placed through the ventral side and the other rod(s) and screws are placed by the operation at the back.

Regardless of the benefits, a scoliosis surgery has disadvantages. The surgical process is tough for the patient and their parents. It is a very invasive and painful surgery. The patient has to stay at home for at least two weeks after being released from the hospital. It is not allowed to go to school by bike and carrying the schoolbag for another six weeks. After 9 till 12 months after surgery it is admitted for the patient to exercise again (AMC Amsterdam, 2005). The surgery results in a complete stiff part of the spine. Movement (like flexion) has to be realized by a few vertebrae, which are heavily loaded, so also deteriorate earlier.

There is a chance of complication during or after the surgery. The incidence rate in the different reports is not comparable; this is due to a different point of measuring. Coe et al. (2006) is directed at the complication during the time when the patient is hospitalized, Weiss & Goodall (2008) are directed at a longer time after the surgery. Coe et al. (2006) reports an overall complication rate of 5.7%, measured in a population of 6334 patients. Pulmonary problems like pneumonia are the problem in 1.39% of the cases, followed by wound infection (1.14%) and implant related problems (0.82%). Death as a complication of the surgery is also a possibility; in this study there were two patients (0.03%) that died of complications (Coe et al., 2006). Weiss and Goodall (2008) are concluding a complication rate of 20%. Pedicle screw misplacement (15,8%), pseudarthrosis (5%), wound infections (3.1%) and neurologic complications (1.5%) are the main complications mentioned. Pseudoarthrosis is an example of complication that develops after a period of time (Weiss & Goodall, 2008). Back pain, implant failure and further deterioration of the spine are reasons for salvage surgery. Rates of salvage surgery mentioned in literature are 20-22% (Connolly et al., 1995) (Weiss & Goodall, 2008). These rates are from the period 1975-1981; the expectation is that the current rates are lower, due to better techniques.

New developments in surgery

Since the current systems of correction all have major drawbacks, several new scoliosis correction systems are in development. Three recent developments are the vertebral body stapling system, Orthobiom and the non-fusion system of the University of Twente.

In 2003, Betz et al. described a system that uses staples. It is called vertebral body stapling; the vertebrae are connected with a staple. The goal of this minimal invasive surgery is growth modulation and curve stabilization. The preliminary results were promising; in 90% of the patients with at least 1 year follow-up fusion surgery was not necessary. (In this research 50° was the tidemark of fusion-surgery). In the complete first series (n=21) there were no major complications, in 3 cases (14%) there were minor complications. (Betz et al., 2003)

Orthobiom is a non-fusion system that was first implanted in 2007. This system allows the patient to grow; it contains mobile connectors that are able to move along the rod. Orthobiom has two rods, pedicle screws, mobile and fixed connectors and a cross connector. The main difference with other posterior systems is the mobile connector that allows movement and growth. The system is implanted in 7 young patients with different types of scoliosis. The result of this series is a stop in further curve progression, a preservation in movement and the non-fusion of the instruments. A comparison with rigid systems shows that the reduction of the intervertebral rotation is the smallest in the Orthobiom system. Other disadvantages of the system are instrumental problems (breakage and corrosion) and physical complication (Rohlmann et al., 2008) (Geiger & Rauschmann, 2009).

➔ Wegens de vertrouwelijkheid ontbreekt het beschrijvende stuk over het scs van de UT.

Study design

In the introduction the goals of the research have been shortly discussed. In this section the research question and research methodology will be discussed. The research methodology includes the research design, techniques and method of analysis.

Research Question

The research question of this study is:

What are the most important requirements of a scoliosis correction system considered by experts and do they have the opinion that the system of the University of Twente is meeting these requirements better than an alternative correction system?

There are different sub questions accompanying the research question, these are amongst others;

- *Is the social-environment able and willing to implement the technology?*
- *What requirements for a SCS are considered by the experts?*
- *Are these requirements present in the technology of the University of Twente?*
- *Is this new technology better than the current systems?*

The word "experts" refers to the industry of a SCS, the project manager, orthopedic surgeons and hospital managers.

Research method

The research method used is a Constructive Technology Assessment (CTA). CTA is a variation of a Health Technology Assessment (HTA). HTA is defined as "*the comprehensive, multidisciplinary and systematic assessment of the (social) consequences of using health technologies with a broad focus upon societal, economic, ethical, and legal implications using four elements: clinical, economical, patient related and organizational* (Poulsen, 1999). More ordinarily said: HTA evaluates the efficacy, effectiveness and cost-effectiveness of a technology and can be used to assist the decision making process (McIsaac et al., 2007). One of the differences between HTA and CTA is that a CTA is not only focused on the technology, but also on the environment in which the technology is introduced. Another difference is that the results of a CTA can contribute to improvements of the further development process. *The purpose of CTA is to increase the efficiency and effectiveness of the technology, leading to an optimal quality of care and involves an integral assessment of clinical, economic, patient-related and organizational parameters* (Retèl et al., 2008) In table 2 the scheme of Retèl is presented, with the different parameters of a CTA .

This scheme is based on the schemes of Poulsen and Douma (Poulsen, 1999) (Douma et al., 2007). Within these parameters, different aspects can be distinguished. The parameter scenario/roadmap with the aspect diffusion scenario is not applicable, because the technology is at a very early stage. That is why an environmental analysis is performed with the goal to evaluate if the environment is willing and able to implement the technology. The other parameters of the CTA (clinical, economic, patient-related and organizational) are assessed with use of the method Analytical Hierarchical Process (AHP). AHP is developed as an analyzing instrument for complex problems on the field of technological, economical and socio-political problems (Hummel, 2001). More specific to this research; it helps to choose the best treatment method, based on the opinions of the experts on the clinical, economic, patient-related and organizational aspects. AHP works by developing priorities for alternatives and the criteria used to judge the alternatives (Saaty, 2008).

Clinical	Safety, efficacy, effectiveness
Economic	Cost-effectiveness
Patient-related	Ethical/juridical, acceptability, psychosocial reactions, patient centeredness, juridical
Organizational	Diffusion, adoption, implementation, timeliness, equity, skill/routines/logistics/education/training, juridical
Scenario/Roadmap	Diffusion scenario (using Rogers phases)

Table 2 Different parameters of a CTA (left), with in the right column different aspects that can be distinguished (Retèl et al., 2008).

Part 1 – Environmental Stage

In the beginning of the research the assumption was made that the environment of the technology must be willing and able to implement the technology; will the implementation will be successful. Generally in a CTA the environment is studied with the goal to map the diffusion process, now the social-environment is studied to map the implementation. The University Medical Center of Groningen (UMCG) is participating in the development of the technology and will be the first location to use the SCS. Therefore the research is first directed on the UMCG. Different stakeholders were interviewed, concerning the process at hospital level. The stakeholders were (innovation) managers, an orthopedic surgeon, a surgery assistant, a nurse of the department of orthopedics of the UMCG and a Dutch health care expert. The goal of this environmental stage was to map possible bottlenecks that can impede the implementation of the technology. By preceding interviews and the literature review, three possible bottlenecks were selected; effectiveness, costs and complexity. Effectiveness and costs are derived from the parameters ‘clinical’ and ‘economic’. Complexity refers to the ‘skills’, ‘routines’, ‘logistics’, ‘education’, ‘training’ and ‘safety’. All derived from the scheme of Retèl (Retèl et al., 2008). The opinion of the experts was conducted by a scenario analysis based on these three parameters. The goal of a scenario analysis is mapping the different opinions and making an inventory of possible bottlenecks, even when there are different uncertainties (Postma & Liebl, 2005). There were six scenario's with subtle differences. The experts were asked to answer the question 'Implement the technology or not with this scenario?'. In table 3, two examples of the scenarios are given. After the analysis of the answers of the respondents (n=4), an overview can be given of the different parameters (table 4).

Information was also gathered about the reimbursement system in the Netherlands. Methods used are: searching the website of the ministry of Health, Welfare and Sports, the website of the DBC Onderhoud (≈ DRG maintenance), and the website of the Dutch Health Care Authority. For information specified to these treatments there was contact with the Dutch Health Care Authority and an interview with a Health Care expert, a former director of an insurance company.

Scenario 2/6	**Scenario 4/6**
The effectivity is comparable	The effectivity is lower
The complexity is comparable	The technology is less complex
The costs are lower	The costs are lower

Table 3 an example of two scenarios, used by the scenario analysis.

Part 2 – Technology stage

The aim of the technology analysis is to study the opinion of the experts concerning the different parameters and alternatives. The objective was to see if the 'new treatment' is preferred over the 'current treatment'. The method AHP was used with the following steps. The first step was to create a structure of the complex decision. The structure consist of three levels (figure 11); the goal, the criteria (and sub criteria) and the alternatives.

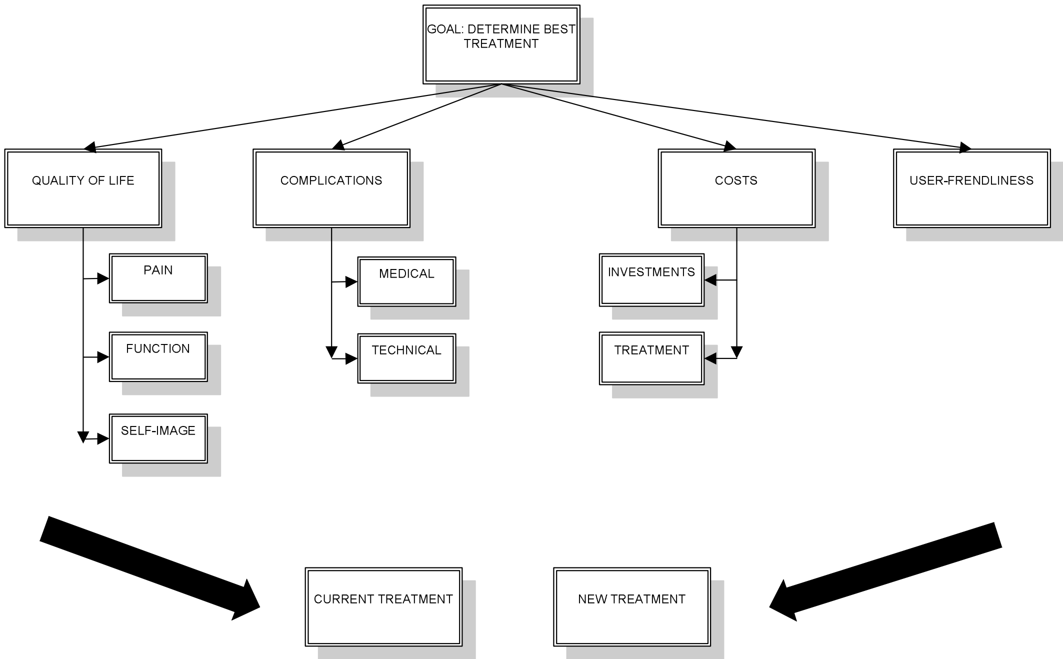

Figure 10 AHP structure of the goals, the (sub) criteria and alternatives

The second step is dividing the problem into subunits, which simplify the focus on a smaller set of the decision (Hummel, 2001). This is realized by making pair wise comparisons on a nine-point scale by the participants (figure 12). Finally all the answers were analysed. The software package Expert Choice is used because it is suitable in combination with the AHP[4]. An advantage of this software is the user friendliness. There were 6 participants included; the project leader of the non-fusion scoliosis correction system, a manager from the UMCG, two orthopedic surgeons and two manufacturers of scoliosis correction systems. The manager of the UMCG has only answered the first part (parameters) of the survey, because she was not a member of the project group of the University of Twente.

Figure 11 An example of a pair wise comparison on a nine-points scale

[4] Expert Choice 11, 2006

Results

The results are divided into two parts. In part 1 the results of the social-environmental analysis are described and in part 2 the results of the technology analysis, with the use of AHP.

Part 1 – Environmental Stage

Parameter	Of interest?	Implemented when?
Effectiveness	Yes	Equal or larger
Costs	Yes	Lower, Equal or larger*
Complexity	No	-

Table 4 Scenario analysis of parameters
The * means that by higher costs the technology is implemented on the condition that there is budget left in the innovation budget of the UMCG.

In the scenario-analysis the following parameters were used; effectiveness, costs and complexity. The results of the scenario analysis are presented in table 4. The results show that the effectivity is of major importance. When the technology is ineffective, it will not be implemented. The scenario-analysis indicates that the complexity is of no bearing on the implementation. The management of the UMCG does not take the complexity into consideration. Also the orthopedic surgeon and the surgery assistant see beyond the complexity if the advantages of the patient are great. The third parameter 'costs' is of interest and can be a bottleneck. The technology is only implemented with higher costs when there is budget left or if there are other possibilities for financing. To get these possibilities clear the reimbursements system of the Dutch health care was studied. In this study a division was made between further development, and implementation costs and structural costs.

After the project of the SCS is finished, a prototype is developed. When the technology is ready for use, the orthopedic surgeon and other stakeholders need to be trained. The study showed that there are three possibilities to finance these and other implementation costs:

- ➔ Innovation fund of the UMCG: Every department can file an application for a budget. Important for remuneration is that the effectivity of the system is proven in earlier studies. Because of a yearly budget, the remunerations also depend on the applications of other departments. When there is no budget left, remuneration is not possible.
- ➔ Funding of the Government: The government provides funding for research every year, by the ministries or specialized organizations. An example is the Technology Foundation STW, an organization that realises the transfer of knowledge between technical sciences and users of technology.

- Sponsoring by health insurance companies: When health insurance companies are convinced that the technology can have advantages, they sometimes are willing to sponsor. This is mainly the case after the development, for example for the costs of the implementation.

After the implementation of the technology the costs of the new treatment can be lower or higher than the current treatment. For lower costs there is no problem. When the costs are higher the treatment is not fully covered and there will be a deficit. The study showed that there are two options to solve these deficits;

- Relocate scoliosis treatment from the A-section to the B-section. Reimbursements for health care treatment are determined by the DBC system, the Diagnosis Treatment System (Diagnose Behandel Combinatie). The A-section of this system exists of national agreements, negotiation is not possible. Scoliosis treatment is placed in this section. There is also a B-section where negotiation with insurance companies is possible. Requirements for this B-section are that the treatment must follow a protocol and the treatment must be evidence based. Also in this case there is the possibility that when health insurance companies are convinced of the possible advantages, they are sometimes willing to pay more for the new treatment.
- Request for a new DBC. Because the treatment with the non-fusion scoliosis device is a new treatment method (non-fusion/fusion) a request for a new DBC can be made. There are requirements for new DBCs: The treatment needs to be performed in 10 hospitals and the turnover would be 3.5 million EUR. So it is necessary that 9 other hospitals are convinced of the effectivity of the treatment and implement the system too.

Part 2 – Technology stage

The results of the AHP analysis regarding the priority are all normalized, to make a comparison between the parameters more clear. In table 5, for example, the Quality of Life (1,000) has a five time higher priority than costs (0,197). The goal referred to in the tables is 'determine the best scoliosis correction treatment'. The tables mention also the inconsistency; this represents in which degree each pair wise comparison is consistent with the remainder of the comparisons. The number by the inconsistency is also mentioned as the consistency ratio (CR). A CR of 0.1 of lower is preferred, but in general a CR lower than 0.2 is also seen as tolerable (Byun, 2001) (Chang et al., 2007) (Hummel, 2001). The CR of prioritizing the criteria is 0.06 and the CR of the sub criteria pain, function and self image is 0.18 and therefore tolerable. The other two tables do not have a CR, because there are only two (sub) criteria and only one comparison; inconsistency is not possible.

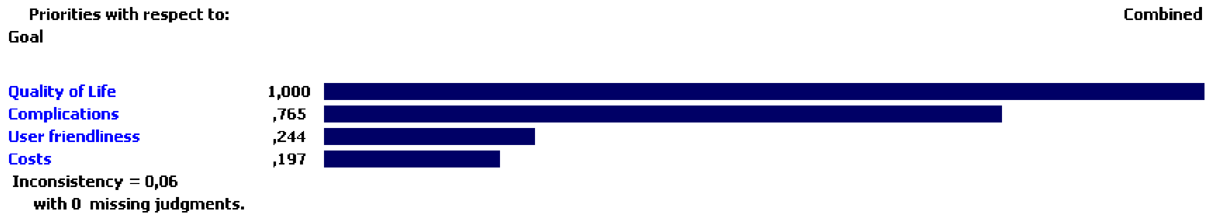

Table 5 Prioritizing of the criteria

The Quality of Life and complications are the main criteria. User friendliness and costs are of less importance as seen by the experts.

Table 6 Prioritizing of the sub criteria of the criteria Quality of Life

The Quality of live has tree sub criteria; pain, function and self-image. There are slight differences; pain is seen as the most important sub criteria, followed by self-image and function.

Table 7 Prioritizing of the sub criteria of the criteria Complications

The criteria “complications” is also divided into two sub criteria; medical complications and technical complications. The experts are rating this sub criteria almost equally.

Table 8 Prioritizing of the sub criteria of the criteria Costs

There are large differences within the results of the sub criteria of the costs; the experts are prioritizing the treatment costs over the investment costs. The treatment costs (the cost for each treatment) are clearly seen as the main sub criteria in the criteria costs. But the overall criteria “costs” has not a high priority.

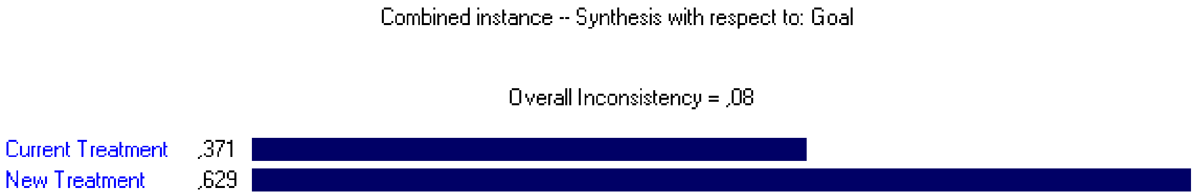

Table 9 AHP results of the alternatives

The next step in the AHP is evaluating the alternatives. In table 9 the results concerning the opinions about the alternatives are given. The performance graph shows the weights of the parameters as the vertical bars. The relative scores of the alternatives (the coloured lines) are presented on the right axis (figure 13). A table with all weighing factors can be found in the appendix.

For the needs of the experts, the new treatment contributes the best to the goal “Find the best treatment”. Only on costs the experts prefer the current treatment above the new treatment. On Quality of Life, complications and user friendliness there is a high preference for the new treatment.

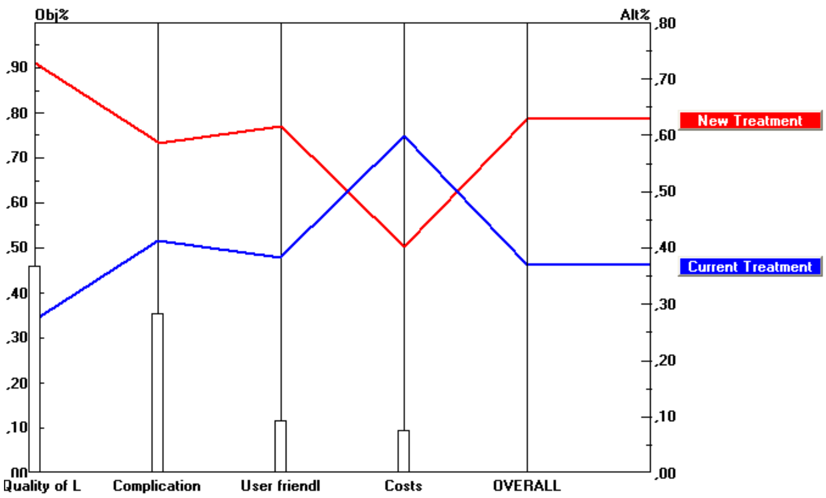

Figure 12 Performance sensitivity Graph of the alternatives divided by criteria

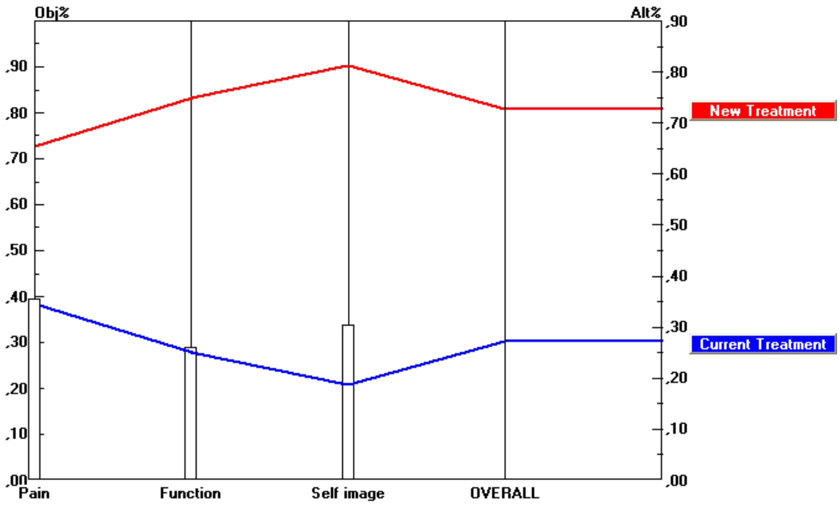

Figure 13 Performance sensitivity graph of the alternative for the criteria Quality of Life

The Quality of Life is divided in pain, function and self image. On all sub criteria the new treatment is preferred above the current treatment. The performance sensitivity graph shows the weights of the parameters as the vertical bars. The relative scores of the alternatives (the coloured lines) are presented on the right axis (figure 14).

To determine the objectivity of the study it is interesting to evaluate the differences between the opinions of the experts. The experts are divided in three groups for this analysis; industry (n=2), orthopedic surgeons (n=2) and project management (n=1). In the figures 15 - 17 the opinion about the criteria and the alternatives are represented. All three groups prefer the new treatment over the current treatment. The industry has the opinion that the new treatment is only preferred with respect to the Quality of Life, but because the Quality of Life is the most important criteria the new treatment is relatively preferred over the current treatment. The opinions of the project management and the orthopedic surgeons are equal, except for the costs. The orthopedic surgeons are more negative concerning the costs, but still they prefer the new treatment over the current treatment.

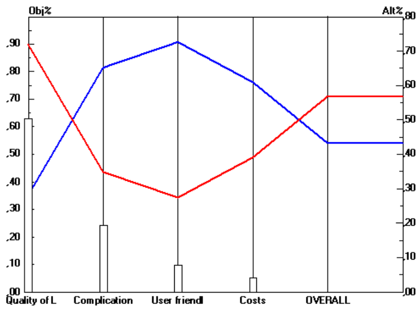

Figure 16 Alternatives: Industry

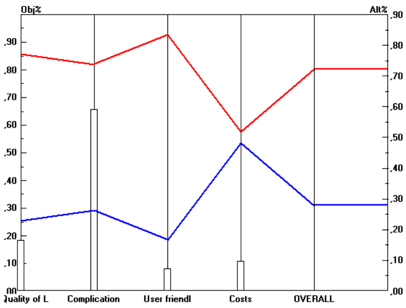

Figure 15 Alternatives: Orthopedic Surgeons

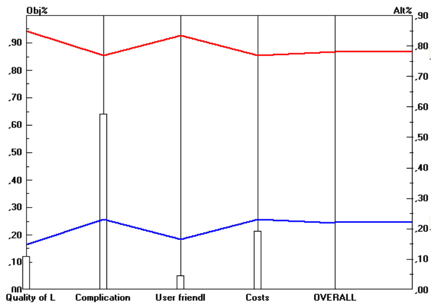

Figure 14 Alternatives: Project Management

Figures 15-17 represent the opinions of the experts divided in groups about the criteria and the alternatives. The red line represents the new treatment and the blue line represents the current treatment.

After closer analysis, large differences are found in the criteria 'complications' (figures 18-20); the industry prefers the current treatment above the new treatment, in contrary to the orthopedic surgeons and the project management. There is also no consensus which sub criteria is more important.

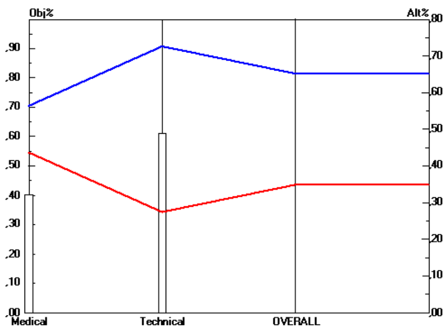

Figure 17 Complications: Industry

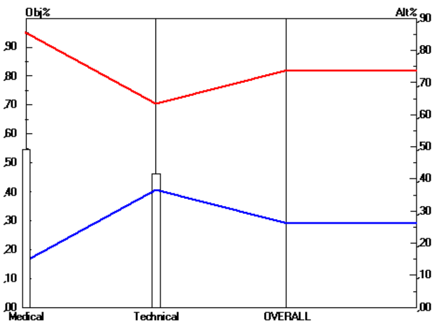

Figure 19 Complications: Orthopedic Surgeons

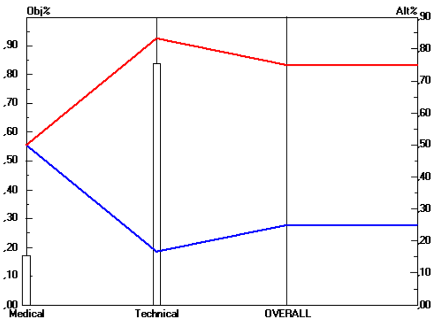

Figure 18 Complications: Project Management

Figures 18-20 represent the opinions of the experts divided in groups about the criteria "complications" and the alternatives. The red line represents the new treatment and the blue line represents the current treatment.

Discussion

In this section different aspects of the study will be discussed. First a conclusion of the results is given, followed by the relevancy of this study. After that, the shortcomings of the study will be discussed and finally recommendations for further research will be discussed.

Conclusion

The prospects of implementation of the new technology are bright, if the effectivity will be proven in the in-vivo tests. The results of the environmental analysis reflect that there is only one bottleneck to be overcome; the costs. This bottleneck can be overcome by different possibilities of financing that can be claimed, mentioned on page 18-19. The technology analysis shows which aspects of the new technology are the most important as seen by experts. Two aspects (Quality of Life & Complications) are seen as most important. By just these aspects the new technology is preferred over the current technology. The costs of the current treatment are preferred over the costs of the SCS. It has no large effect on the ration new technology / current technology, because the priority of costs is low.

Relevancy

The system has the goal to interfere already in the brace period, at the adolescent age. In this period the self-image of patients is very important. The curve of the spine and also the brace have an influence on the self-image of the patient. The intention of the new system is to reduce the Cobb Angle and the intervertebral curve, to decrease the deformation of the spine. The experts have a clear preference for the new system, with respect to the self-image of the patients (figure 14). Self-image is in the technology analysis a sub criteria of Quality of Life, and is rated as the most important criteria. The new system has the goal to increase the self image of the patients and the experts are expecting this is likely to happen.

The comparison between Orthobiom and SCS shows us that the SCS had advantages over Orthobiom. A characteristic of the Orthobiom system is that the intervertebral rotation is just minimally corrected, with the result that patients still have humps. Exactly these humps are severely affecting the self-image of the patients. Orthobiom deals also with medical and technical complications. In this research the experts are choosing the SCS above current systems. Literature shows that current systems are more effective than Orthobiom (Rohlmann et al., 2008). It can be concluded that the expectancy of the experts is that the SCS is better than Orthobiom on the domain of complications.

The results of the environmental analysis are promising. Even though the costs seem relatively high, there are strategies to overcome this bottleneck. In the analysis an option was mentioned to solve the deficits by relocating the scoliosis treatment from the A-section to the B-section of the DBC system. The B-section has the advantage that negotiation with insurance companies is possible. By the improved effectivity of the treatment, the negotiation position is also improved. The chances to get more financial compensation are higher. During the evaluation of the preliminary research results with some experts, information came up that scoliosis treatment can be relocated in 2 till 5 years from the A-section to the B-section. With this information the chance that costs can be a bottleneck, seems to be getting smaller.

The relevance of this research can be found in the fact that already in an early stage it is being reviewed whether the technology is meeting the demands and desires of the stakeholders. A regular HTA is performed after implementation. In this study there is already in an early stage analysed if there are possible bottlenecks in the social-environment and possible strategies to overcome this bottlenecks are considered. Especially since the technology is currently in the phase of development, there is time to adjust the technology. The goal of this study is to draft possible further scenarios, even when there is no certainty yet. That is why assumptions have to be made.
The technology analysis is based on the assumption that the technology is effective in the in-vivo tests. When this is not the case, this part of the research is redundant. On the other hand it is possible to say that the results of the social-environmental analysis can stop further development and therefore save money and time if there was no place in the environment for the technology of trust by the experts.

<u>Shortcomings</u>
In the figures 15 – 17 it can be seen that there are different opinions about the costs. This can be the result of a lack of clarity or information asymmetry. The definition of 'costs' was not explained to the experts, a goal of the system is for instance to reduce the chance on re-operation and other problems. Because of this lack of explanation, it is possible that the results are not completely valid. Other aspects that can affect the reliability and validity of the outcomes are a difference in agreement and consistency of experts. The consistency ratios were all acceptable, but one was higher then the common norm of 0.1. The results also showed that there was difference in agreement on some subjects. Especially the industry is more negative concerning the complications, user friendliness and costs. It is possible that they are more realistic with respect to their experience with product development.

The development of the new technology was during this research in a very early stage. Pending for a patent was not possible yet. A consequence of this was that the research was confidential, respondents needed to be derived from the development group of the new technology. This resulted in a small number of respondents. There is a chance on subjectivity of the experts, due to the information asymmetry and different interest, even though the best available panel was used for the study. As a result of this, it is recommended that another CTA is performed. The advised moment for this is after the first tests and after receiving a patent. Then there is more certainty about the effectivity and less subjectivity because of the fact that more respondents can be approached. The timing of this study makes it possible to adjust the technology before the first in-vivo tests and implementation. A bridge between the users and the developers is made.

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Appendix

☑ Show Totals ☐ Outline ☑ By Alternatives

Alts	Level 1	Level 2	Prty
Percent Current Treatment			37,1
Current Treatment	Percent Complications (L: ,347)		15,8
	Complications (L: ,347)	Medical (L: ,493)	,060
		Technical (L: ,507)	,098
	Percent Costs (L: ,089)		5,8
	Costs (L: ,089)	Investments costs (L: ,271)	,016
		Treatment costs (L: ,729)	,042
	Percent Quality of Life (L: ,453)		11,0
	Quality of Life (L: ,453)	Pain (L: ,388)	,060
		Function (L: ,282)	,028
		Self image (L: ,331)	,022
	Percent User friendliness (L: ,110)		4,5
	User friendliness (L: ,110)		,045
Percent New Treatment			62,9
New Treatment	Percent Complications (L: ,347)		22,5
	Complications (L: ,347)	Medical (L: ,493)	,111
		Technical (L: ,507)	,114
	Percent Costs (L: ,089)		3,9
	Costs (L: ,089)	Investments costs (L: ,271)	,008
		Treatment costs (L: ,729)	,031
	Percent Quality of Life (L: ,453)		29,4
	Quality of Life (L: ,453)	Pain (L: ,388)	,114
		Function (L: ,282)	,083
		Self image (L: ,331)	,097
	Percent User friendliness (L: ,110)		7,2
	User friendliness (L: ,110)		,072