Development and preliminary validation of a new brace appearance questionnaire

A new instrument to investigate, if idiopathic scoliosis patient’s perception of appearance of their Boston corset would influence their compliance and whether it is in a positive or negative way. (A mixed method study).

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**Sammanfattning**

**Syfte:** Att preliminär validera ett frågeformulär som utvecklades i denna studie. Frågeformuläret var utformat för att undersöka om patientens uppfattning om deras Boston korsett påverkar deras compliance på ett positivt eller negativt sätt.

**Bakgrund:** Att genomgå korsettbehandling innebär många känslor för ungdomar med idiopatisk skolios. Att inte ha en ”perfekt kropp” minskar kroppsbilden och självkänslan. Det är högst sannolikt att genom att förändra patienternas perspektiv på deras korsett till att tycka om utseendet på den; så ökar sannolikheten för compliance med positiva känslor.

**Metod:** Mixed Method användes för att utveckla och validera ett nytt frågeformulär. Utvecklingen och validering gjordes med hjälp av litteratur, expert- och patientgrupper. Kvalitativa data utvärderades och kvantitativa data analyserades med användning av Pearsons korrelationskoefficient och Cronbach alpha.

**Resultat:** Ett preliminärt validerat frågeformulär skapades. Gruppen som användes för validering var idiopatiska skoliospatienter, fyra pojkar och fyra tjejer, mellan 6 och 15 år gamla.

**Slutsats:** Ytterligare validering av frågeformuläret krävs före användning i framtida studier. Preliminära resultat indikerar att patienter som tycker om hur de ser ut i deras korsett också följer compliance med positiva känslor.

**Nyckelord:** skolios; korsett; utseende; användande; utveckling; validering; frågeformulär.
Summary

**Aim:** To preliminary validate a questionnaire that was developed in this study. The questionnaire was designed to investigate, if patient’s perception of appearance of their Boston corset influences their compliance, in a positive or negative way.

**Background:** Going through brace treatment brings a lot of feelings for adolescent idiopathic scoliosis patients. Not having a “perfect body” decreases body image and self-esteem. It is highly likely that by changing the patients’ perspective of their brace into liking the appearance of it; the probability of positive compliance will increase in patients.

**Method:** Mixed method approach was used to develop and validate a new questionnaire. The development and validation were done using literature, expert and patient groups. Qualitative data was evaluated, and quantitative data was analyzed using Pearson’s correlation coefficient and Cronbach alpha.

**Result:** Preliminary validated questionnaire was created. The group used for validation were all idiopathic scoliosis patients, four boys and four girls, between the age of 6 and 15 years old.

**Conclusion and outlook:** Further validation of the questionnaire is required before applying on future studies. Preliminary results indicate that patients who like the way they appear in their brace are also compliant.

**Keywords:** scoliosis; brace appearance; compliance; development; validation; questionnaire.
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1.0 Introduction

Scoliosis is a chronic illness that can affect anyone, the most common type is referred to as adolescent idiopathic scoliosis (AIS) (Boden, Freedman, Rhee, Skinner, & Tay, 2014). These patients are commonly treated conservatively with a brace; to prevent curvature of the spine, avoid surgery and hopefully straighten the spine a few degrees (Weppner & Alfano, 2019).

Compliance is crucial and yet varied during orthotic treatment in AIS. Since the corset is removable, the hours of compliance will vary across individuals (Vandal, Rivard, & Bradet, 1999). Previous studies have shown that going through this type of treatment brings a lot of feelings, including not having a “perfect body”. This leads to lowered body image and self-esteem. Patients wanting to hide or not wear their brace leading to feelings of guilt, stress and even suicidal thoughts (Reichel & Schanz, 2003). Patient’s perception of appearance of their body is related to the brace making them feel not attractive, big and wide (Reichel & Schanz, 2003). This then lowers the patients self-esteem and creates negative body appearance, likely leading to patients being non-compliant; where compliance referees to the agreement between recommended treatment hours and the patients behavior (Reichel & Schanz, 2003).

It is likely that by changing the patients’ perspective of their brace into liking the design, looks and the appearance of it; the likelihood of positive compliance will increase where the users can feel more confident and beautiful wearing the brace. The researcher refers to positive compliance as when the brace is worn without negative feelings. Eliminating negative feelings such a stress and guilt around the treatment will also lead to a better quality of life for the patient and their family and support system (Reichel & Schanz, 2003). The prosthetist’s and orthotist’s (P&O) role in their profession is to provide the patient with an aid that helps the treatment and management of their condition (Nilsen & Jorge, 2013). Summarizing these factors, it all comes down to providing the patient with the best evidence-based treatment that fulfills their needs, improves their condition and hopefully increasing their quality of life.

During real clinical practice, the patient’s needs and wishes on brace design can be hard to align with the device that is best for their condition in a professional opinion, making it difficult to provide a device where all parties are satisfied with the results. Previous studies have shown that patients can have a hard time accepting their device due to the looks of it and discomfort wearing it (Reichel & Schanz, 2003). The researchers suggest that this not only leads to the importance of the patient’s acceptance of the device to get good compliance; but also, a positive perception of the brace from the patient, for better wellbeing and psychological health.

To our best knowledge, it remains uncertain whether a patient’s involvement in the design of the device, without affecting the outcomes of the treatment, could 1) provide a better acceptance and perception of their appearance of their scoliosis brace, and 2) lead to a more positive compliance which relates to better treatment outcomes. Preliminary result from a qualitative study interviewing AIS patients on influence of visual aesthetics, user acceptance of the scoliosis brace and compliance indicates that brace appearance, patient’s involvement of the brace design, and increased compliance are related (Law,
Cheung, Yip, Yick, & Wong, 2017). In relation to this, to the best of our knowledge there are no currently validated instruments that have been made to measure this. Therefore a questionnaire was developed and preliminary validated. The aim of the instrument is to investigate if patient’s perception of appearance of their Boston corset influences their compliance, in a positive or negative way. see Figure 1 for process map of thesis.

2.0 Background

2.1 Introduction of the background

In the following chapter scoliosis, conservative treatment and emotions the patient can experience during that time, will be introduced. The prognosis of the disease and the importance of compliance, development and preliminary validation of a questionnaire will be explained. Finally, evidence-based practice and the significance of this study will be addressed.

2.2 What is scoliosis

Scoliosis is a condition where the spine has a curvature in the coronal plane (Skaggs, Storer, & Vitale, 2004). The curvature can be either C-shaped or S-shaped. The curvature in the spine must be greater than 10 degrees to be called scoliosis, curves under 10 degrees are called spinal asymmetry (Skaggs et al., 2004). Scoliosis can be categorized in three different groups: 1) idiopathic, 2) congenital and 3) neuromuscular. The medical term for unknown is idiopathy, meaning that the etiology of the idiopathic
scoliosis is unknown. The idiopathic scoliosis has been divided up into three categories that are based on the patients age. Infantile is from the age of 0-3 years old, juvenile from the age of 4-10 and adolescent older than 10 years old (Skaggs et al., 2004).

Adolescent idiopathic scoliosis (AIS) is the most common type of idiopathic scoliosis (Skaggs et al., 2004). The percentage of children and teens that are affected by AIS is equally spread between two genders, but the risk for the curve to progress during growth is seven times more in girls than boys (Skaggs et al., 2004).

If a scoliosis is detected, an x-ray can confirm the findings and what type of curvatures it is (Skaggs et al., 2004). On a x-ray image, the Cobb technique can be used to measure the degree of the curve, and this angle is called the Cobb angle (Skaggs et al., 2004). When measuring the Cobb angle, one line is drawn at the top of the superior tilted vertebrae (cranial end vertebra) and the other line at the bottom of the inferior tilted vertebrae (caudal and vertebra), another two lines are then drawn from each line with a 90-degree angle making them intersect with each other; and then the angle is measured between them as Figure 2 describes here below.


2.2 How to treat scoliosis

Idiopathic scoliosis is the most common type of spinal deformity which requires treatment. In general, the treatment philosophy is based upon four factors: 1) the risk of progression, 2) the size of the curve when it was first noticed, 3) loss of neurological function, and 4) if it is caused by any other underlying diagnosis (Düppe, Ohlin, Engquist, & Lyons, 2007).
Conservative treatment with a corset has been around since the 1500s (Düppe et al., 2007). The goal with the treatment is to prevent progression of the curvature and prevent the need for surgery (Weppner & Alfano, 2019). The first corset on the market was the Milwaukee-corset, shown in Figure 3 below. By the end of the 1970s the Boston corset was introduced shown in Figure 4 below. It was made in polypropylene and more discreet than the Milwaukee and enabled to be worn under clothes without being visible (Düppe et al., 2007).

Figure 3. Milwaukee brace [picture]. Retrieved 1 May 2019 from http://www.bracingscoliosis.com/milwaukee-brace.html

After the Boston corset, other models have come to the market; such as hyper correction corsets made for use only during the night (Düppe et al., 2007). It has also been proven that wearing the Boston brace for 23 hours a day gives significantly better treatment result compared to wearing it less than 18 hours a day (Düppe et al., 2007).

The indications to start a conservative treatment are the following; the child needs to be growing still, this is evaluated by using the Risser sign which is an indicator for skeletal maturity (Hacquebord & Leopold, 2012). The scale rates from 0-5, the numbers indicate the state of ossification of the iliac apophysis (Hacquebord & Leopold, 2012). The iliac apophysis grows anterolaterally to posteromedially and is an indication for spinal skeletal maturity as shown in Figure 5 (Hacquebord & Leopold, 2012). The number 5 indicates that the child has a complete ossification (fully fused), of the iliac apophysis and has reached full skeletal maturity (Düppe et al., 2007).

Moreover, the Cobb angle must be between the angles of 25-45 degrees. Ideal conditions for corset treatment are Cobb angles between 25-35 degrees and <3 on the Risser scale (Düppe et al., 2007).

The Boston corset is fitted using modules, it is important that the Cobb angle is corrected >50% when wearing the brace or else the treatment won’t be successful, x-rays are used to confirm the correction (Düppe et al., 2007). During the treatment period the skeletal maturity is tracked by x-rays of the iliac apophysis, the treatment fades out for girls when they reach 4 on the Risser scale and for boys when they reach 5 on the Risser scale (Düppe et al., 2007). The corset is then used less and less for about a year (Düppe et al., 2007).

It is commonly seen that the child is refusing brace treatment. It's therefore important to think of compliance and how to work as a team; prosthetist and orthotist (P&O), physiotherapist, nurse and the orthopedists in order to give the best possible care for the patient; as well as quality of life during the
treatment years for not only the patient but also their family (Düppe et al., 2007). Co-designing the looks of the rigid brace between patient and P&O have been suggested to create a larger likelihood of brace acceptance for the user and result in better compliance (Law et al., 2017).

2.3 Boston Corset
The Boston brace was brought to the market by J. E. Hall and M. E. Miller in 1971 (Katz, 2008). The brace is created and designed based on three principles: 1) prefabricated, symmetric thoracolumbar-pelvic module, 2) applying force on the convexity of the curve, and 3) relieving pressure on the opposite side from where the force is placed (B. Emans, Kaelin, Bancel, E. Hall, & E Miller, 1986). The shape and angles of the curvature of the patient's spine is seen through a full-length radiograph (B. Emans et al., 1986). Location of pressure pads, trim lines and where the pressure relief areas/openings are created, are all based on the radiography of the patient (B. Emans et al., 1986). Once these factors have been decided, they are then moved over to the module, customizing the brace by the P&O for each patient (B. Emans et al., 1986). Single- or double-curved can be treated effectively by the Boston brace (Katz, 2008). It has been shown that the Boston brace is as effective in controlling the progression of the curve as the Milwaukee brace (Katz, 2008). See Figure 4 for example of Boston brace.

The brace creates a lumbar flexion which is done with an abdominal concavity together with flattening posterior in the module at the lumbar area (B. Emans et al., 1986). This together with the low trim lines on the bottom of the corset both anterior (front) and posterior (back) both serve a purpose (B. Emans et al., 1986). The anterior trim lines are shaped for the patient to sit comfortably in the corset and the posterior and inferior (lower in position) trim lines are done for a better pelvic control (B. Emans et al., 1986).

The Boston brace has a good control over the spinal curve progression (B. Emans et al., 1986). Findings support that the Boston bracing system appeared to significantly improve the curve progression in the curves that were between 30 and 45 degrees and there was even results of curve correction of 5 degrees (B. Emans et al., 1986).

2.4 Prognosis and the role of compliance
Unless treated in a timely manner, scoliosis can lead to severe physical, psychological, and social problems. Examples can be, pain, poor body image, limited physical activity, and difficulty of adjusting at school and peer relationships (Hyejung, Jihea, Jin-Ho, & Jung Hyun, 2016). Compliance is defined as the hours the brace should be worn daily as prescribed by a health professional (Vandal et al., 1999). Bracing is an important intervention to prevent the curvature from progression, improve pulmonary function and pain management (Berkowitz, Rivett, Rothberg, & Stewart, 2009). Whether the outcome is successful depends upon if the patient is compliant or not to the bracing treatment (Berkowitz et al., 2009).
Compliance can be hard to measure, and validity and reliability of the results are often questioned. The data often comes from interviews and questions, where the users are asked about their brace wear. The researchers then have to rely on the patient telling the truth (Vandal et al., 1999). However, different measure methods can be used when measuring compliance. Vandal et al. (1999) has used two measurement methods: 1) directly with a sensor and 2) indirectly with questionnaire-interviews. The results of the study showed a 50% difference between the direct and indirect reported compliance (Vandal et al., 1999). This observed difference proves that there is an existing problem between the observed compliance and how much the patient admits to wearing the brace. It’s been argued that self-reported measurement method in compliance is likely to be inaccurate, due to that patient might not be truthful (Climent & Sánchez, 1999). It was stated that patients reported more use then the actual wearing time (Veldhuizen, Cheung, Bulthuis, & Nijenbanning, 2002). Finally, temperature sensors have been used where compliance was measured, giving scientific based evidence as results (Rahman, Bowen, Takemitsu, & Scott, 2005). Participants who complied with their treatment, had significant improvement in curve progression (Rahman et al., 2005).

2.5 Quality of life and emotions during brace treatment

Quality of life (QOL) is often measured by using different types of questionnaires (Danielsson, Hasserius, Ohlin, & Nachemson, 2012). The SRS-22r and the SF-36 are two surveys which have been commonly used throughout studies on QOL, where the SRS-22r is specifically designed for scoliosis patients (Danielsson et al., 2012). The questionnaires are designed to relate to the subject’s physical, emotional and social well-being. For example, rating pain, happiness, body appearance, and daily life activities (Danielsson et al., 2012).

Adolescent idiopathic scoliosis (AIS) has been considered to possibly lead to a social problem, and the brace treatment is thought to influence the patient’s QOL. The condition is not directly connected to pain, but the bracing treatment can cause discomfort for the patient, affecting their daily life and therefore their quality of life (Vasiliadis, Grivas, & Gkoltsiou, 2006). Multiple studies have been done about emotions and quality of life relating to brace treatment. Perceptions of body image, happiness and satisfaction among adolescents undergoing Boston brace treatment, was found to be significantly poorer then within the control group (Sapountzi-Krepi et al., 2001). In addition to this it has been showed that by involving the patient in the design process can have a positive effect on eliminating bad emotions related to brace treatment (Law et al., 2017).

Patients whom are compliant tended to have a higher quality of life then to those who are not compliant (Berkowitz et al., 2009). The patients who had poor compliance were also experiencing absence in vitality, as well as functioning badly physically, emotionally, socially and had weak self-image and self-esteem (Berkowitz et al., 2009). The authors suggest that their result might mean that the quality of life among scoliosis patients also depends on their ability of psychological coping strategies rather than the spinal deformity (Berkowitz et al., 2009).
In addition, another factor that has been proven to affect QOL among AIS patients is their perception of their body image (Danielsson et al., 2012). Patients that were treated with a brace experienced their body as more distorted than the non-braced patients even though the curve type, sizes, and degree of trunk rotation in both groups were similar (Danielsson et al., 2012). In the end, they concluded that patients who experienced their body less distorted were more satisfied with the treatment and had better QOL (Danielsson et al., 2012). It has also been shown that negative self-image and lowered level of activity among AIS patients was related to higher levels of stress (Misterska, Glowacki, Latuszewska, & Adamczyk, 2013). By involving the patient in the process of designing the brace it has been suggested that it not only allows them to eliminate negative feelings, but also includes them in creating their own body image (Law et al., 2017).

2.6 Appearance during brace treatment

The cosmetic of an orthopedic device has been shown to be an important factor to consider when treating patients with scoliosis (Vasiliadis et al., 2006). Self-image is one of the most important aspects affecting development and adaptations for young adults in a social society (Hyejung et al., 2016). It has been stated that it is not enough for a brace to only be successful in outcome measures in a conservative scoliosis treatment (Veldhuizen et al., 2002). The brace also needs to meet the standards of being comfortable in a reasonable way, and the cosmetic of the brace is accepted by the user (Veldhuizen et al., 2002). It has been showed in a pilot study that by including patients in visual aesthetics of the scoliosis brace e.g. color or pattern can help them drive attention from physical discomfort, reduce physical pain and create a more positive view of the brace treatment (Law et al., 2017). Here to the importance of co-design between patient and caregiver is worth bringing up, because it has been presented that patients involved in the design process of their brace are more likely to perceive their brace as a fashionable device, rather than a medical instrument (Law et al., 2017).

2.7 Development of a questionnaire

Before developing a new questionnaire, literature research should be done to see if there is any exciting validated questionnaire that could be used (Safdar, Abbo, Knobloch, & Seo, 2016; Tsang, Royse, & Terkawi, 2017). If no validated questionnaire fits the construct of interest, it is relevant to develop a new one (Tsang et al., 2017).

When developing a new questionnaire, it is important to first identify what construct is intended to be measured (Safdar et al., 2016; Tsang et al., 2017). In relation to this, one should also identify what types of behavior that are related to the construct of interest (Tsang et al., 2017). This can be approached with different methods such as literature and review of research (Tsang et al., 2017). In this thesis the construct of interest would be behavior related with the appearance of the device. For an estimation of the construct of the questionnaire, subscales are often created (Tsang et al., 2017). The subscales of the domains create a total score when combined (Tsang et al., 2017). The subscales are used to estimate the different components of the construct (Tsang et al., 2017). The weight and value of each item depends on their importance (Tsang et al., 2017).
Attaching an information letter for participants that they can keep after finishing the questionnaire is encouraged (Boynton & Greenhalgh, 2004). Questionnaires that are too long might lead to that the respondents lose interest in completing the questionnaire (Boynton & Greenhalgh, 2004; Safdar et al., 2016). Because of this it is important to not include to many questions, but enough to cover the construct wanted to be measured (Tsang et al., 2017). Good explanations and design will increase the likelihood of a good response rate (Boynton & Greenhalgh, 2004).

There are two types of questions for a questionnaire: 1) close-ended questions, give the participant a limited number of options for their answer, and 2) open-ended questions, give the respondent room for more thoughts (Tsang et al., 2017). Close-ended questions are easier for the researcher to analyze, but a downside is that participants can’t develop their answer and they might be biased by the answer options given (Tsang et al., 2017). Scales can be used to scale level of agreement or frequency of event (Tsang et al., 2017). An example for level of agreement scale can be: strongly agree, agree, neither, disagree, strongly degree (Tsang et al., 2017). In relation to this the Likert scale is a valid method to measure and evaluate people’s attitudes, mood and values (Mellor & Moore, 2014). For Likert scales the response scale normally ranges from either three or five options (Mellor & Moore, 2014). If statistical results are to be evaluated researchers need to scale the questions so that acceptable variance among respondents can be collected (Tsang et al., 2017). Moreover, questions should only address one issue, and leading questions are to be avoided because they can lead to biased answers (Tsang et al., 2017).

When developing a new questionnaire it is important to keep in mind to phrase questions appropriately according to the targeted population (Boynton & Greenhalgh, 2004). This is extra important if the questionnaire is self-administered and if the targeted population are children (Tsang et al., 2017). Extra consideration about children’s cognitive levels should be kept in mind by the researchers (Tsang et al., 2017).

Concerns regarding whether children are a good population to use as survey respondents has been addressed (Bell, 2007). It has been argued that due to children’s social, cognitive and communicative skills they might not be able to provide both valid and reliable answers (Bell, 2007). It has therefore been advised to follow a few key methods when developing and testing questionnaires for children (Bell, 2007). Keep the questions short and simple and include extra explanation to help the children understand the question (Bell, 2007). Here-and now questions are preferable instead of retrospective questions (Bell, 2007). If measuring retrospectively it is important to be clear and using a precise period (Bell, 2007). This will help the child understand e.g. how many times have you “specify activity” in the last six days (Bell, 2007). Avoid option of “do not know”, children that get bored more easily are then more likely to choose an option of “do not know” if it is available (Bell, 2007). It has been suggested that survey studies are possible to conduct with children from approximately the age of 7 years old (Bell, 2007). It has been proven that scaled responses where the child chooses on what level they agree with a statement gives a more trustworthy result if the scales are completely-label. In addition, verbal labels have been suggested to be easier for children to understand than numeric ones (Bell, 2007). The Likert 5-scale have been proven to be an instrument to consider when collecting answers from children (Mellor
Commonly used scales have been tested among children to see which they prefer (van Laerhoven, van der Zaag-Loonen, & Derkx, 2004). This was done between the Visual analog scale (VAS), the numeric VAS, and the Likert scale, the children favored the Likert scale (van Laerhoven et al., 2004). For children between the age of 6-12 years old no differences were detected in response rate for the younger participants in contrast to the older (Mellor & Moore, 2014). It was clear that even the youngest participants understood how to use the scale (Mellor & Moore, 2014).

When the first draft of a questionnaire is done the effectiveness and quality of the questions should be tested (Tsang et al., 2017). This is preferably done by revising the questions and the design of the form (Bell, 2007). A group of qualified experts on the subject should review the questions (Tsang et al., 2017). The expert should to their best capacity review the form and make sure it does not contain any grammar mistakes. Also ensure to their best ability that the content of questions are accurate for the group investigated, as well as look for any possible offensive or biased questions (Tsang et al., 2017).

Preliminary testing of questions is especially important for a group that are extra prone to fall for poor questionnaire design, such as children (Tsang et al., 2017). When a preliminary testing is conducted the questionnaire is pre-tested on a smaller sample group that represent the intended respondents (Tsang et al., 2017). This gives the investigator insight on whether the questions are confusing in any way (Tsang et al., 2017). The response distribution for every question can also be obtained through the preliminary pilot test, which can give an idea if there is enough variation in the response rate (Tsang et al., 2017).

### 2.8 Validation of a questionnaire

Validity refers to the extent of degree of which a test measures what is intended to be measured (Heale & Twycross, 2015). Validity is divided into three categories: 1) content validity, 2) construct validity, and 3) criterion validity (Heale & Twycross, 2015).

The first category, content validity includes whether the instrument covers the whole domain intended to be measured (Heale & Twycross, 2015). Face validity is an addition to the content validity and refers to how well the respondents think the questionnaire is, including questions relevant to the subject of interest. Face validity is the weakest way to create validity of a questionnaire. It more reflects whether the questionnaire contains items that are meaningful for the respondent (Heale & Twycross, 2015).

The second category, construct validity includes if inferences can be drawn between result received from the instrument and what is intended to be investigated (Heale & Twycross, 2015). Hereto there are three types of evidence that can be used to see whether research has good conduct validity: 1) homogeneity, making sure the instrument measures one construct, 2) convergence, if the instrument measures similar concepts as of other instruments, this is not applicable if there are no other similar instruments, and 3) theory evidence, this is applicable when the theoretical construct measured is related to behavior, for
example if anxiety was measured and participants scored high one would assume that they also shows anxious behavior in their everyday life (Heale & Twycross, 2015).

Lastly, criterion validity refers to any other instrument investigating the same variable (Heale & Twycross, 2015). Correlation between instruments to what extent they measure the same variables can be evaluated (Heale & Twycross, 2015). Criterion validity can be measured in three ways: 1) convergent validity, shows that instruments measuring the same construct are highly correlated, 2) divergent validity illustrates that instruments measuring different variables should have poor correlation, and 3) predictive validity includes that an instrument is due to have high correlation with future criterions (Heale & Twycross, 2015).

When validating a new questionnaire there are two main types of validity that should be considered, content validity and construct validity (Tsang et al., 2017). The content validation when developing a new questionnaire is important (Tsang et al., 2017). The content validity refers to the items in the questionnaire and if they represent the theory that is trying to be investigated with the questionnaire (Tsang et al., 2017). Experts that are familiar with the subject evaluate the content of the questionnaire, to see if the questions are essential, accurate and in fact measuring what the questionnaire is intended to measure (Tsang et al., 2017). Examples that are looked into when assessing the content validity are: 1) the questions are clear and easy, 2) the questions cover the whole area intended to be investigated, 3) would they (the experts) like to use the questionnaire in the future, 4) does the questionnaire lack important questions regarding the studied aim, and 5) the questions violate privacy in any way (Tsang et al., 2017).

Construct validity is important when evaluating a questionnaire that is measuring something that is not observable (Tsang et al., 2017). The construct validity of a questionnaire can be estimated by evaluating the correlation between other variables (Tsang et al., 2017). For example, correlation between an existing questionnaire measuring the same constructs as the newly developed questionnaire or correlation between different questions within the questionnaire. In addition to this the correlation coefficient can range between \( r = -1 \) to \( r = 1 \) where they indicate negative/positive perfect correlation, \( r = 0 \) indicates no correlation (Akoglu, 2018; Schober, Boer, & Schwarte, 2018). It has been suggested that the levels of correlation vary between weak \( (r=0.10-0.39) \), moderate \( (r=0.40-0.69) \), strong \( (r=0.7-0.89) \) and very strong \( (r=0.9-1) \) (Akoglu, 2018; Schober et al., 2018).

Another crucial factor when validating a questionnaire is reliability (Tsang et al., 2017). Reliability of a questionnaire can be referred to the consistency of the study result (Tsang et al., 2017). Consistency can be evaluated testing three levels of consistency 1) internal consistency, 2) test-retest reliability, and 3) inter-rater reliability (Tsang et al., 2017).

Internal consistency refers to which extent the questions in the questionnaire are inter-correlated and if the questions are reliable measuring the same construct (Tsang et al., 2017). Internal consistency is normally measured using the Cronbach’s alpha and is ranked from 0-1, it is also possible to have a
negative correlation (Tsang et al., 2017). If alpha = 0 there is no internal consistency, which means none of the questions are correlated with each other (Tsang et al., 2017). If alpha = 1 there is perfect internal consistency, which means all questions are correlated with each other (Tsang et al., 2017). A score of alpha = 0.7 has been suggested acceptable internal consistency (Tsang et al., 2017). A alpha score that is too high > 0.9 suggests that there might be to many questions asking the same thing but in different ways, and the investigators should consider removing questions (Tsang et al., 2017). In addition, it is important to bear in mind that the result from the Cronbach's alpha only refers to the sample group that answered the questionnaire when the correlation was investigated (Tsang et al., 2017). It is not an estimate correlation for reliability of the questionnaire under all circumstances (Tsang et al., 2017). In other words, a questionnaire might have excellent reliability with one sample but not with another.

Test-retest reliability refers to what extent the respondents answer relatively the same, provided the same individuals where given the same questionnaire twice or more (Tsang et al., 2017). This is applicable to questionnaires measuring traits such as anxiety, personal traits and pain (Tsang et al., 2017). Investigators should be careful when doing retest on traits that will change over time since it will not give a trustworthy result (Tsang et al., 2017).

Inter-rater reliability is applicable when multiple investigators are evaluating a result using the same instrument (Tsang et al., 2017). For example, two clinicians rating range of motion on a patient after surgery (Tsang et al., 2017).

2.9 Evidence Based Practice

The importance of evidence based practice (EBP) in the healthcare field is necessary not only to provide the patient with the best possible care; but also to work safely as a professional (Socialstyrelsen). Our own experience has given us a picture of that the P&O field in Sweden lacked the structural ways of implementing an EBP on a clinical level. Lack of time to stay updated on research, relying most on experience, and attitudes such as “it has always been like this” are defining the way clinicians seem to work.

Evidence based practice is about finding prosthetic and orthotic solutions based upon three sources of knowledge: 1) best available knowledge from the P&O as a professional, 2) P&O professional’s expertise in his/her field of work, and 3) patient’s own wishes, experiences, and situation. These three factors are then weight together in a discussion with the P&O and the patient receiving the care, to come to a patient centered solution (Socialstyrelsen).

EBP can hereto be applied to our current study and the field of conservative idiopathic scoliosis treatment. Patient should according to EBP be a part of their choice of care, without it affecting the function or biomechanical factors of the device. The Boston Corset is a well-recognized brace, it's been around since the 1970s, and many braces have come to the market post the Boston (Dippe et al., 2007). Still the lack of EBP makes it hard to provide patients with a new solution. We believe that with new
technology and different manufacturing processes/techniques, the field of P&O is growing rapidly. A trend possibly towards a more customized brace; that is not only doing its biomechanical purpose but also appears nicer to the user. It’s therefore important for the P&O to stay updated and have an EBP to improve and develop scoliosis braces in the future.

2.10 Significance of this study

Patient-reported perspectives can provide information and insight on what impact the treatment has on their day to day life as well as potential burdens with the intervention (Marquis, Arnould, Acquadro, & Roberts, 2006). The term patient reported outcome (PRO) stands for health data reported by the patient and can be applied in any healthcare field (Marquis et al., 2006). PRO provides information capturing the patient’s perspective, that cannot be collected using objective clinical measures (Marquis et al., 2006). For example, the impact the treatment has on the patient’s overall health status and quality of life (Marquis et al., 2006).

PRO can focus on either generic or disease (Marquis et al., 2006). Generic allows for comparison of results between different diseases and domains (Marquis et al., 2006; Vasiliadis et al., 2006). One example is the short form SF-36, which can be used to rank quality of life among different disease conditions (Marquis et al., 2006). Disease targeted instruments can instead provide specific focus for a particular condition and its health-related outcomes (Marquis et al., 2006; Vasiliadis et al., 2006). This means a questionnaire can be targeting health related qualities around a particular condition, and information gathered will also be more specified (Marquis et al., 2006; Vasiliadis et al., 2006).

PRO instruments are especially good to use when patient’s perception is of greater interest than the objective measures (Marquis et al., 2006). Health related quality of life (HRQL) also includes both patients positive and negative feedback on a particular treatment, and in contrast with objective measure methods it might be a better predictor of treatment outcome (Marquis et al., 2006).

To the best of our knowledge there are no previous studies apart from a qualitative pilot study interviewing AIS patients on the matter of visual brace aesthetics related to user acceptance and compliance (Law et al., 2017). This leaves a gap in the research field, to the authors best knowledge no validated instrument exists that can measure if the involvement of the patients in the visual design of the brace, can lead to a more positive treatment outcome for idiopathic scoliosis patients. Design factors that can be changed to create a more visually accepted brace without affecting the biomechanical purposes.

The outcome of the current study will hopefully provide a preliminary validated instrument that can be applied in the field of P&O. A questionnaire that can measure a factor we so far haven’t seen measured. Does the appearance of the brace have importance to the patient and is it related to/ affecting compliance, in a positive or negative way. With hope this questionnaire can be an additional instrument
for future studies and for better evidence-based practice (EBP) in the field of P&O for idiopathic scoliosis patients.

3.0 Aim
The aim of this thesis was to preliminary validate the questionnaire that was created for this study. The questionnaire was designed to investigate, if patient’s perception of appearance of their Boston corset influences their compliance, in a positive or negative way. The hypothesis of the preliminary results is that if the patients’ perception of the brace appearance is positive, it then leads to positive influence on compliance.

4.0 Research methodology
4.1 Introduction to the research methodology
The following chapter contains information on the study design, the process of how the questionnaire was created and preliminary validated. Information regarding the participants within the study, and ethical considerations when including people in a study. Finally, outcome measures, data collection and data analyses are presented.

4.2 Study design
Mixed methods research is where the investigator uses both qualitative and quantitative approach in one study, when collecting data, analyzing data and integrating the findings and drawing inferences (Borglin, 2012). The aim of mixed methods is to receive the most optimal answer to the research question (Borglin, 2012). This thesis is a mixed method study were exploratory sequential- and convergent- design was used. The exploratory sequential design was used during the development of the quantitative questionnaire and a convergent design were the developed questionnaire was validated (Borglin, 2012).

4.3 Questionnaire
The Questionnaire was designed, specifically for this thesis. The purpose of the questionnaire was to get a better understanding on what the patients’ perception is on the brace appearance, if the brace design matters to them, and effects their compliance in a positive or negative way (see Appendix 1 for final questionnaire).

4.4 Participants
4.4.1 Prosthetists and orthotists
The Prosthetists and orthotists included in the study where professionals working at clinics in Sweden. They were chosen with the inclusion criteria that they needed to be familiar with scoliosis patients and conservative treatment. Two different expert groups were required for this study: 1) for development of
the questionnaire, and 2) for validation of the questionnaire. They were recruited via email, information regarding the study was attached in the email and it was made clear that it was their free choice to be a part of the study. Depending on what group they were recruited to, additional information was attached regarding development of the questionnaire or validation of the questionnaire.

4.4.2 Patient group

The patient participants included in the study were juvenile and adolescents that had been diagnosed with idiopathic scoliosis. They were undergoing a scoliosis treatment with a Boston day corset during the period the study was conducted, this as well as being able to understand and answer the questionnaire was the inclusion criteria. The participants were encouraged to ask and discuss the questions with an adult if something was unclear. The recruitment of the participants went through prosthetic and orthotic clinics in Sweden. The clinics contacted their patients that fulfilled the inclusion criteria. Once a selection had been made, the participants received an information letter about the study, the questionnaire and a consent form that both participants and their guardians had to sign to be able to participate in the study. The information letter and the consent form are based on ethical principles to inform the participants about their freedom and choice of participation (Kjellström, 2012).

4.5 Ethical considerations

The researchers were aware of ethical challenges when involving people in a study. For protection of the participants human rights the fundamental ethical principles were considered. The beneficence principle, the principle regarding participants justice, autonomy and the informed consent principle (Patten & Newhart, 2018). Researchers need to make sure that, participants do not get harmed physically or psychologically, avoid that the participants are used in any way, informed that their participation is of free will, and that they can withdraw from the study at any given moment without consequences (Kjellström, 2012). In addition to this the researcher needs to be professional when collecting data making sure that the care of the patient remains as good as possible while aiming to answer the research question (Kjellström, 2012).

Ethical consideration regarding studies including children were also considered by the researchers. It is recommended to be sure that the study can’t be done on grown-ups before using children for participants (Kjellström, 2012). Sometimes it can’t be avoided that children are needed for participation, it is then important that the research leads to improved situations for children (Kjellström, 2012). If the child is under the age of fifteen a guardians consent needs to be received before asking the child if they want to participate in the study (Kjellström, 2012). An information letter was sent to the participants with the questionnaire where they were informed that the participation in the study was optional, and that their identities would be kept hidden. Within the information letter a consent form was included for both the parent and the participant to sign (see Appendices 2 and 3 for information letter and consent form).

In Sweden two laws regulate research ethics. The first law (SFS 2003:460) “law of ethical research regarding humans”, includes that any research including sensitive personal data needs to be ethically
evaluated by a Swedish ethics review board (Kjellström, 2012). The second law (SFS 2018:218) “the General Data Protection Regulation”, includes to protect people's personal data, insults against one's integrity, and consent from participants. The laws imply that a research project can only be accepted if it can respect the humanitarian grounds (Kjellström, 2012).

Finally, a thesis on Bachelor level normally does not need an ethical approval from an ethics review board, it is more common that the supervisor has the main responsibility. However, many universities have created their own local ethical review boards (Kjellström, 2012). For this thesis the ethical committee at the school of health and welfare reviewed the study plan before data was collected for the thesis.

4.6 Protocol

4.6.1 Development of the questionnaire

The development of the questionnaire was initiated by a literature review of existing questionnaires. The SRS-22r was discovered, it specifically measures quality of life among scoliosis patients (Tsang et al., 2017). However, the SRS-22r doesn’t cover the construct of interest for this thesis. When it had been established that no existing questionnaires regarding brace appearance for scoliosis patients existed, the development of the new one started. The SRS-22r was used as guidelines.

The SRS-22 takes into account both brace treatment, surgery and evaluates QOL (Tsang et al., 2017). However, it does not evaluate the factor if the brace design itself affects QOL (Tsang et al., 2017). The new disease-specific questionnaire could provide clinicians in the field of prosthetics and orthotics with a preliminary validated instrument to assess a factor that to our best knowledge has only been investigated with a small pilot study (Law et al., 2017).

For this new questionnaire five domains were created: 1) appearance, 2) brace appearance, 3) emotions 4) socializing, and 5) compliance. The questionnaire included three parts: 1) collection information regarding patients’ perception on all five domains, 2) participants thoughts on brace appearance after seeing pictures of different brace designs, and 3) the participants were given a short text to read regarding the brace function and its biomechanical aspects. This was done to try and give them a better understanding of what features of the brace can be changed without affecting its biomechanical purposes. Questions to follow the text were regarding brace appearance and compliance. The picture document and inspiration to what specific design features to focus on in part two was chosen after reading a pilot study regarding brace appearance (Law et al., 2017). The result from their study provided us with information on what features of the brace design that seems to influence how the user perceive the brace, without affecting the three-point pressure system. Some of those features were: 1) color, 2) shape, 2) size, and 4) trimlines (Law et al., 2017). The pictures are therefore different colored braces and 3D printed braces. To follow are specific questions regarding those four features in part two.

The questionnaire was created to be self-administered and appropriate for children from the age of 6 years young and older. The items in the questionnaire are written accordingly, clear and easy to
understand (Tsang et al., 2017). The items are closed questions with a five-option choice, e.g. “very much”, “much”, “either or”, “a little” and “not at all”. This was done according to the Likert scale method recommended for children from the age of 6 years young (Mellor & Moore, 2014; van Laerhoven et al., 2004). A few questions had additional space for written text for the respondents to further comment on their choice of answer. These questions were picked out by the researches when thought to be appropriate and contribute better understanding for the researchers. All questions carry the same value and therefore have the same scores. The scores of the items were rated from five to one, five being the highest score and meaning more positive and low scoring more negative. Giving that, high scoring means positive brace appearance. The total scoring was scaled according to 40% and lower being a low score, 41-60% as moderate and 61% and higher as a high score. Description of the question scoring are shown in Table 1 and Table 2.

Table 1

**Scoring of the questions in the questionnaire**

<table>
<thead>
<tr>
<th>Questions: 1, 2, 7, 9, 21, 22, 23, 24, 25, 26, 31, 32, 33</th>
<th>Questions: 4, 5, 6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Choice of answer</strong></td>
<td><strong>Scoring</strong></td>
</tr>
<tr>
<td>“Very much”</td>
<td>5</td>
</tr>
<tr>
<td>“Much”</td>
<td>4</td>
</tr>
<tr>
<td>“Either or”</td>
<td>3</td>
</tr>
<tr>
<td>“A little”</td>
<td>2</td>
</tr>
<tr>
<td>“Not at all”</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 2
Scoring of the questions in the questionnaire

<table>
<thead>
<tr>
<th>Question: 8</th>
<th>Question: 10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Choice of answer</strong></td>
<td><strong>Scoring</strong></td>
</tr>
<tr>
<td>“Very gladly”</td>
<td>5</td>
</tr>
<tr>
<td>“Gladly”</td>
<td>4</td>
</tr>
<tr>
<td>“Either or”</td>
<td>3</td>
</tr>
<tr>
<td>“A little”</td>
<td>2</td>
</tr>
<tr>
<td>“Not at all”</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question: 11</th>
<th>Question: 12, 3.3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Choice of answer</strong></td>
<td><strong>Scoring</strong></td>
</tr>
<tr>
<td>“0 occasions”</td>
<td>5</td>
</tr>
<tr>
<td>“1-3 occasions”</td>
<td>4</td>
</tr>
<tr>
<td>“4-6 occasions”</td>
<td>3</td>
</tr>
<tr>
<td>“7-9 occasions”</td>
<td>2</td>
</tr>
<tr>
<td>“10 or more occasions”</td>
<td>1</td>
</tr>
</tbody>
</table>

4.6.1.1 Prosthetists and orthotists involvement

During the development of a new questionnaire, the items should be evaluated by a professional to make sure that the questions are accurate, properly structured and grammatically correct (Tsang et al., 2017). Two P&O professionals from Sweden, that work with scoliosis patients were asked to review and give comments on the items of the questionnaire. From their notes the items where altered with the intention to create a better questionnaire.

4.6.1.2 Patient group involvement

Preliminary pilot testing was done of the questionnaire during the development. The test was laid out for a sample of respondents. This preliminary testing helped the researchers understand if there is any confusion about the items among the respondents and if improvements can be done on the items (Tsang et al., 2017).

4.6.2 Preliminary validation of the questionnaire

Psychometric evaluation are properties referring to the reliability and validity of a new instrument. A challenge when creating a new questionnaire is to make it psychometrically sound. However, it is important to accomplish that for it to be applicable in research and clinical settings (Vasiliadis et al., 2006).
4.6.2.1 Prosthetists and orthotists validation
Moreover, a crucial part of validating a questionnaire is the process of content validation (Tsang et al., 2017). For this questionnaire, two P&O professionals evaluated the content validity by looking into different aspects of the questionnaire. The P&O's took into consideration whether the questionnaire achieves measuring what was intended to measure, whether the questions were clear and easy to understand, did the questions cover the area of domain and if this questionnaire would be something they could think to themselves using in the future (Tsang et al., 2017).

4.6.2.2 Patient group
After a preliminary pilot testing had been done on the new developed questionnaire a pilot test was conducted for initial validation (Tsang et al., 2017). The pilot test was conducted on a group of respondents that are intended for the questionnaire, idiopathic scoliosis patients. The final draft of this new questionnaire was sent out to 11 patients here in Sweden for the initial validation.

The consistency of the questionnaire results provides the reliability (Tsang et al., 2017). The internal consistency was assessed by using the coefficient alpha, allowing access of the reliability this questionnaire has for this specific patient group (Cronbach’s alpha). Test-retest was initiated by sending the same group of respondents the same questionnaire twice.

Construct validity was assessed by looking into correlations between questions within the questionnaire between the participants answers (Tsang et al., 2017). The Pearson’s r correlations test was used to gather the results.

4.6.3 Preliminary results
Preliminary results were assessed using the answers from the final questionnaire, that the second patient group received.

4.7 Outcome measures
4.7.1 Qualitative data
The qualitative data provided the data for development of the questionnaire as well as the validation.

4.7.2 Quantitative data
The quantitative data provided the data for the validation, reliability and preliminary results.

4.8 Data collection
The data was collected in two steps: 1) the development of the new questionnaire, qualitative data was collected from two P&O’s working with scoliosis patients as well as answers from the first group of
participants and, 2) the validation of the finished questionnaire, another two P&O’s validated the questionnaire and the second group of participants answered the finished questionnaire.

4.9 Data analysis

4.9.1 Qualitative data

The data received via email from the first and second P&O groups regarding the development of the questionnaire and the preliminary validation was analyzed and considered. The data from the comments in the questionnaire from the patient group did not add any value to the scoring of the questionnaire but were used to give the researchers better understanding of the preliminary result.

4.9.2 Quantitative data

Data from answered questionnaires was analyzed using Cronbach’s alpha and the Pearson’s r correlation test. The strength of the correlation was interpreted with the use of Table 3. The significance level was set at p <0.05 (Schober et al., 2018).

Table 3

Interpretation strength of correlation coefficient

<table>
<thead>
<tr>
<th>Absolute Magnitude of the Observed Correlation Coefficient</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00–0.10</td>
<td>Negligible correlation</td>
</tr>
<tr>
<td>0.10–0.39</td>
<td>Weak correlation</td>
</tr>
<tr>
<td>0.40–0.69</td>
<td>Moderate correlation</td>
</tr>
<tr>
<td>0.70–0.89</td>
<td>Strong correlation</td>
</tr>
<tr>
<td>0.90–1.00</td>
<td>Very strong correlation</td>
</tr>
</tbody>
</table>

(Schober et al., 2018)

5.0 Result

5.1 Introduction of the results

To follow are results of the development and preliminary validation of the questionnaire. Finally, preliminary results gathered from the second patient group.

5.2 Development of questionnaire

The response rate for the P&O’s was 100%. Below is the result from the email correspondence with P&O 1 and 2. The feedback from the P&O’s are to follow. The researchers have divided the comments
according to 3 different categories 1) grammar, 2) structure, 3) clarity and, 4) relevance, shown in Table 4, 5, 6 and 7 (see Appendix 1 for final questionnaire).

<table>
<thead>
<tr>
<th>1) Comments regarding the grammar and how the questions were written in the questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Do you believe that your corset prevents you from school activity? Suggestions to change to: prevents you in your school-activities.”</td>
</tr>
<tr>
<td>“Question 7 is verbally incorrect: have you been a part of designing your corset? Should be: have you participated in designing your corset.”</td>
</tr>
<tr>
<td>“Really good and really ugly- can be changes to very good…”</td>
</tr>
<tr>
<td>“Change very much to very gladly and much to gladly - the answer alternative shall match the question.”</td>
</tr>
<tr>
<td>“How come you have chosen specifically nervous/worried as mood? I do not mean that it is wrong but e.g. down/angry might have been as relevant?”</td>
</tr>
</tbody>
</table>
Table 5
Result category 2)

<table>
<thead>
<tr>
<th align="left">2) For a better structure of the questionnaire it was suggested to adjust the order of questions.</th>
</tr>
</thead>
<tbody>
<tr>
<td align="left">&quot;Here I think that you could swap places on question 3 and 4, since question four is about appearance which you have introduced in question 1 and 2.&quot;</td>
</tr>
</tbody>
</table>

Table 6
Result category 3)

<table>
<thead>
<tr>
<th align="left">3) Further explanations regarding questions and specific wording were recommended to create a clearer questionnaire.</th>
</tr>
</thead>
<tbody>
<tr>
<td align="left">&quot;Do you like the appearance of corset 1, 2 and 3? If you look at the trimlines? (do you believe that the patient understands the word trimline and know what to answer?)&quot;</td>
</tr>
<tr>
<td align="left">&quot;Part 2 (I believe that it could be good to include extra lines in the end of these questions where they can leave comments.&quot;</td>
</tr>
</tbody>
</table>
The answers from the questionnaires received back from patient 1-6 was evaluated. Questionnaires were sent out to eight respondents and six answers were received, giving the researchers the response rate of 75%. The results were that a few questions had been left unanswered. The researcher believes this is because: 1) they did not understand the meaning of the question, 2) they were bored/not willing to answer the question.

The results from the development of the questionnaire provided the researchers with a complete questionnaire ready for preliminary validation.

### 5.3 Preliminary validation of questionnaire

#### 5.3.1 Results from qualitative data

The emails from the P&O 3 and 4 regarding the content validity of the questionnaire was evaluated and content validity results drawn from that. The response rate from the P&O’s was 100%. Below are the comments from the experts used for validation of the questionnaire, shown in Table 8.

| “Part 1: Relevant questions in relation to the issue, but with few remarks.” | Professional 2 |
| “I must admit that I don’t quite understand why you have mixed pictures of day- and night corsets. Basically, all colors and prints can be put on both day- and night corset.” | Professional 2 |
| “It is the same type of bands on all pictures where the bands are visible and on corset three there is no band visible, what information will you get from that?” | Professional 2 |
| “A day corset like corset 2 would have given the questions a greater relevance.” | Professional 2 |
According to the comments from P&O 3 and 4, the researchers came to conclude that they had created a questionnaire with moderate content validity. Meaning the questions represent the construct of interest.

### 5.3.2 Results from quantitative data

The questionnaire was sent out to 11 patients and 8 received giving a response rate of 72%. Strong positive correlations were between three sets of questions: 1) question 3 and 11, 2) question 4 and 6 and, 3) question 8 and 12. Moderate negative correlations was between question 6 and 11 and mild positive correlations was between four sets of questions: 1) question 4 and 10, 2) question 6 and 10, 3) question 9 and 10 and, 4) questions 9 and 11. The correlation coefficient results between these questions is shown in Table 9.
Beside from these results, the researchers noticed that when looking into correlation between two domains, the strength differed depending on questions from each domain. The placement of the questions that were used for correlation are categorized into domains in Table 10.

Table 9
The Pearson’s and p values

<table>
<thead>
<tr>
<th>Correlation between questions:</th>
<th>Pearson’s value (r)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance (3) and Compliance (11)</td>
<td>0.760</td>
<td>0.028</td>
</tr>
<tr>
<td>Emotions (4) and Socializing (6)</td>
<td>0.789</td>
<td>0.020</td>
</tr>
<tr>
<td>Emotions (4) and Compliance (10)</td>
<td>0.343</td>
<td>0.406</td>
</tr>
<tr>
<td>Socializing (6) and Compliance (10)</td>
<td>0.104</td>
<td>0.807</td>
</tr>
<tr>
<td>Socializing (6) and Compliance (11)</td>
<td>-0.520</td>
<td>0.186</td>
</tr>
<tr>
<td>Brace appearance (8) and Compliance (12)</td>
<td>0.801</td>
<td>0.017</td>
</tr>
<tr>
<td>Brace appearance (9) and Compliance (10)</td>
<td>0.218</td>
<td>0.604</td>
</tr>
<tr>
<td>Brace appearance (9) and Compliance (11)</td>
<td>0.288</td>
<td>0.489</td>
</tr>
</tbody>
</table>

In the column “Correlation between question:” indicates questions within a domain that were correlated. For example, question number 3 from the domain appearance and question number 11 from the domain compliance were correlated. Level of significance p<0.05

Table 10
Questions categorized into domains

<table>
<thead>
<tr>
<th>Domains</th>
<th>Question number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>(3)</td>
</tr>
<tr>
<td>Brace appearance</td>
<td>(3), (8), (9)</td>
</tr>
<tr>
<td>Emotions</td>
<td>(4)</td>
</tr>
<tr>
<td>Socializing</td>
<td>(6)</td>
</tr>
<tr>
<td>Compliance</td>
<td>(10), (11), (12)</td>
</tr>
</tbody>
</table>

The numbers in the column “Question number” indicate the question number. For example, question number 8 and 9 are categorized in the brace appearance domain.

The Cronbach’s alpha coefficients for the new developed questionnaire overall score was 0.67, being within the minimal acceptability. Unfortunately, no data was received regarding the test-retest reliability before the thesis was handed in.
5.4 Preliminary results

The preliminary results are based on two sets of data: 1) the Pearson’s correlation test shown in Table 3 and, 2) total score of the questionnaire shown in table 11, 12 and 13. There is a strong positive correlation between how the subjects think they look with the corset on and if they have chosen not to wear the brace due to the appearance of it, this was seen in a statistical significant correlation between question 3 and 11, \( r=0.760, p=0.028 \). The result also indicates that the more positive emotions they feel while wearing the brace the less it affects their social life, this was detected in a statistically significant correlation between question 4 and 6, \( 0.789, p=0.020 \). There was another strong correlation between question 8 and 12, see Table 3 question 8 and 12, \( r=0.801, p=0.017 \). There is a moderate negative correlation between if the subject thinks the brace appearance affect their social life and if they have chosen to avoid social activity due to the brace appearance this is seen between question 6 and 11, \( r=-0.520, p=0.186 \). Our preliminary results present an indication that there is a relationship between compliance and patients’ perspective of their brace appearance.

The result from the total score of the questionnaire indicates how the participants perceive the look of their brace. Higher total score indicates that the patient perceives their brace appearance as more positive. This is shown in Table 5, 6 and 7.

Table 11
Scoring of questions from part 1

<table>
<thead>
<tr>
<th>Questions:</th>
<th>Subjects</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) “Is appearance important for you?”</td>
<td></td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>(2) “Are you in charge of your appearance?”</td>
<td></td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>(3) “How do you think you look with the corset and clothes on?”</td>
<td></td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>(4) “Do you feel down/worried from using the corset?”</td>
<td></td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>(5) “Do you believe that your corset prevents you in your school-activities?”</td>
<td></td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>(6) “Do you think that the brace appearance effects your relations with your friends and other people?”</td>
<td></td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>(7) “Have you participated in designing your corset?”</td>
<td></td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>(8) “Would you want to participate in designing your corset?”</td>
<td></td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>(9) “Do you like the appearance of your brace?”</td>
<td></td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>(10) “How many days over the past 3 months have you skipped activities because of the brace appearance?”</td>
<td></td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>(11) “Have you over the past 3 months for one or more occasions chosen not to wear the corset due to the appearance of it?”</td>
<td></td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>(12) “Would you wear the corset more hours a day if you could decide the appearance of it?”</td>
<td></td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
Table 12
Scoring of question from part 2

<table>
<thead>
<tr>
<th>Questions:</th>
<th>Subjects</th>
<th>1 (M)</th>
<th>2 (M)</th>
<th>3 (M)</th>
<th>4 (F)</th>
<th>5 (F)</th>
<th>6 (F)</th>
<th>7 (M)</th>
<th>8 (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Score: 60</td>
<td></td>
<td>34</td>
<td>30</td>
<td>15</td>
<td>6</td>
<td>33</td>
<td>39</td>
<td>24</td>
<td>31</td>
</tr>
<tr>
<td>(2.1) “Do you like the appearance of corset 1 &amp; 2? If you look at the color”</td>
<td>10</td>
<td>7</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>(2.2) “Do you like the appearance of corset 1 &amp; 2? If you look at the band”</td>
<td>10</td>
<td>7</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>(2.3) “Do you like the appearance of corset 1 &amp; 2? If you look at the size”</td>
<td>10</td>
<td>5</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>(2.4) “Do you like the appearance of corset 1 &amp; 2? If you look at the form”</td>
<td>10</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>6</td>
<td>6</td>
<td>8</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(2.5) “Do you like the appearance of corset 1 &amp; 2? If you look at the trimlines”</td>
<td>10</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>6</td>
<td>6</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>(2.6) “Do you like the appearance of corset 1 &amp; 2? If you look at the openings”</td>
<td>10</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>4</td>
<td>8</td>
<td>5</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 13
Scoring of questions from part 3

<table>
<thead>
<tr>
<th>Questions:</th>
<th>Subjects</th>
<th>1 (M)</th>
<th>2 (M)</th>
<th>3 (M)</th>
<th>4 (F)</th>
<th>5 (F)</th>
<th>6 (F)</th>
<th>7 (M)</th>
<th>8 (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total score: 15</td>
<td></td>
<td>7</td>
<td>6</td>
<td>10</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>(3.1) “Have you participated in designing your corset?”</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>(3.2) “Would you want to participate in designing your corset?”</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>(3.3) “Would you wear the corset more hours a day if you could decide the appearance of it?”</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>
6.0 Discussion

6.1 Introduction to discussion
To follow is a discussion regarding the development and validation of the questionnaire. Discussions regarding results from the preliminary validation and preliminary results. Limitations and the researchers own thoughts are included.

6.2 Development of questionnaire
The PRO approach used with this disease-specific questionnaire allowed the researchers to investigate a specific population and get answers from a patient perspective (Marquis et al., 2006). This questionnaire was developed with close-ended questions, this made it easier to analyze the results. It has been suggested that close-ended questions can lead to biased answers due to certain answer options are given (Tsang et al., 2017). To avoid this, respondents were able to leave comments under certain questions where they could explain their chosen answers.

General questions regarding demographic characteristics were added in the final draft, to be able to see differences between age and gender if required. The number of answer options for the respondents were changed from six to five because of the inspiration from the SRS-22r questionnaire. The investigators also learnt that it is recommended to use a Likert five-scale for children because they understand and prefer that over other scale types (van Laerhoven et al., 2004).

The researchers initially wanted to include as many brace designs as possible, however the picture document was changed by taking out the night brace due to the population investigated, based on experts’ opinions.

Furthermore, one of the five domains were regarding compliance because it was believed by the researcher that the patients view regarding their brace appearance could affect compliance, positively or negatively. The researchers wanted to establish that brace appearance could possibly influence compliance in two ways: 1) the hours the brace was worn, and 2) the way the patient feel during the hours wearing the brace. Hereto the value of the other domains are also worth discussing. As previously mentioned it has been proven that strong emotions are connected to the conservative treatment. It is therefore relevant to include domains such as emotions and socializing (for revision of the changes made in the questionnaire, see appendices 1 and 4).

6.2.1 Limitations
Additional experts could have been used for the development of the questionnaire to get more inputs on the questions and design. Interviewing experts from different professions that work with scoliosis patient could also have been a strong input during creation of the instrument, where the questions and design could have been discussed, for example in a group setting. In relation to the interviews, a group
of patients could have been interviewed as well. The researchers could only assume why participants 1-6 did not fill out certain questions. With a group interview including children of different age and gender the researchers could have asked specifically what is unclear or if questions upset them etc. Time was a factor that made this hard to accomplish, it also limited the times the questionnaire was able to be sent out to patients and experts for revision. When analyzing the comments, we had to translate it from Swedish to English, this might alter the meaning of the original text.

The investigators had prior to this study never developed a questionnaire before, literature review was used to gain understanding on how to create a valid and reliable questionnaire. Additional sources of knowledge might have improved the development even further, e.g. expert opinions specifically on how to create a survey. This questionnaire was created to be a mail-survey, one can argue that a quicker correspondence would have been to prefer, e.g. an online survey.

6.3 Process of preliminary validation of the questionnaire

While creating the questionnaire we learnt that it is crucial to create a valid and reliable instrument. Three different tests were able to be carried out for measuring and evaluating validity and reliability. We believe this makes the psychometric evaluation better than if less tests would have been made. The qualities of the tests are however limited due to time and sample size. The experts included for the content validity were made sure to be familiar with idiopathic scoliosis and if possible also familiar with surveys such as the SRS-22r, for appropriate feedback on the validation. The pilot test conducted had a response rate enough to draw assumptions regarding correlation and connect that to level of validity. In addition to this we were able to begin a test-retest for reliability, the second patient group was sent the questionnaire one week after they had received the first one.

6.3.1 Limitations

Due to the time frame, the test-retest were not received back in time. This resulted in a lack of reliability of the questionnaire. Ideal would have been if the test-retest was sent out later to prevent respondents from remembering what they answered. A further limitation is that the patient group for the pilot test was small, a bigger sample would have been ideal to receive reliable statistical measurements. Lack of participants was because it was hard to recruit patients meeting the inclusion criteria. Prior to starting the validity process, different tests for reliability and validity were looked over. Appropriate tests for this questionnaire were hoped to be included for the evaluation of this questionnaire. Three tests were carried out, however only two were completed. The expert group only gave feedback on the questions as a whole questionnaire, we later learnt that it is good to have them investigate each question separately to create stronger content validity. We learnt that we could have calculated the content validity ratio if the experts would have validated each question separately. In addition to this we also discussed doing a face validity with the same group that helped develop the questionnaire, though this is the weakest type of validity testing we believe it could have been a good addition to the rest of the tests. To make sure the instrument is trustworthy and that it measures the construct of interest we propose further validation of the instrument before conducting future studies.
6.4 Preliminary validation results

The qualitative data from the preliminary validation gave us a preliminary validated questionnaire. The professionals did a validation of the whole questionnaire in general and said that we had captured the essential parts. From their comments we gathered that we had been able to develop a questionnaire with moderate content validity.

The quantitative data from the Pearson’s coefficient indicated that there were some strong positive correlations with a statistical significance (p <0.05) within the items in the questionnaire (Akoglu, 2018; Schober et al., 2018). This relates to our thoughts of the correlation between brace appearance and compliance as well as how the subjects feel during their brace treatment. The strong correlation between question 3 and 11 shows that if their feelings regarding their looks wearing the brace is positive (Akoglu, 2018; Schober et al., 2018) The occasions the subjects decide not to wear the brace due to its appearance decrease, when they are satisfied with how they look with the brace. The strong correlation between question 4 and 6 also shine a light on our thoughts regarding the less nervous the subject felt because of the brace appearance the less it affects their social life (Akoglu, 2018; Schober et al., 2018). Also, worth bringing up is the detected strong correlation between question 8 and 12. The result is based on low scoring in both questions creating a strong correlation. However, the subjects often stated that they were already wearing the brace all the time meaning they cannot choose an option of wearing it more. This affects the evaluation of the validity, because a strong correlation was detected but it does not add any value to the level of validity due to how the question is phrased. But by adding an extra question or changing question 12 into e.g. “would you wear the brace feeling happier if you were a part of the design” might have given us a better understanding of the factor if patient involvement matters.

6.4.1. Limitations

The sample group for the preliminary validation for the content validity was small. The authors see that as a limitation for the content validity. The two P&O’s both said that the authors had captured the essential parts and fulfilled the validation criteria, however the authors only estimated the content validation as moderate due to the small sample group and how the content validation was done. The content validity result of the questionnaire was accessed from an overview of the whole questionnaire. Without each question being validated the authors were not able to calculate the content validity ratio and therefore estimated the validation only being moderate. The authors would have preferred an even bigger sample group of subjects for the construct validation and internal consistency. The Cronbach’s alpha value was on the edge of being acceptable which is another limitation of the study or limitation for the use of the questionnaire.

Based on these results from the correlation coefficient of the questions, we evaluate the construct validity of this questions is moderate. However due to limited sample size we evaluated the construct validity of the questionnaire as low. We advise that another validation of the questionnaire should be done before the use of the questionnaire in bigger research.
6.5 Preliminary results on patients’ perception of the brace appearance

Based on the pilot test we were able to gather a preliminary result. Prior to investigating the construct of interest, we hypothesized that the preliminary result would result in that; if the patients’ perception of the brace appearance is positive, it then leads to positive influence on compliance. By relating this to the outcome of the correlation coefficient we can see a trend towards that participants who likes the way they appear in their brace also complied to the treatment. This supports our hypothesis. In addition to this a small pilot study came to conclude that by involving patients in the surface design e.g. choice of color, of their scoliosis brace negative emotions where reduced, leading to higher compliance and better treatment outcome (Law et al., 2017). This can also be related to previous studies that have proven that patients whom are compliant also have higher quality of life (Berkowitz et al., 2009). We also believe that it is likely that there is a correlation between high quality of life, compliance and likening the appearance of their brace. In relation to this Danielsson et al. (2012) concluded that patients who are going trough brace treatment experience their bodies as more distorted than patients who underwent non-braced treatment. Like this current study they also used questionnaires, the SRS-22r and the SF-36 to evaluate their result (Danielsson et al., 2012). In relation to this Law et al. (2017) came to conclude that by involving patients in the design process they create a more positive body image. We believe that this questionnaire can support the factor of increased positive body image by involving patients in the design process. We believe that the design of the brace can affect the user in a way so that negative emotions are decreased during brace wear. A patient can be compliant in a negative way, meaning they wear their device the hours recommended but deal with emotional plague. Then there is positive compliance, that is when the patient has accepted their device and wear their device the recommended hours but without the emotional plague leading to a more positive treatment outcome.

The total score was that five subjects scored high and three subjects scored moderate. The total score does not give us any information on whether the respondent was complaint or not. The total scoring gives us an indication on how the participant feels during the treatment based on brace appearance.

6.5.1 Limitations

The researchers suggest further studies with a larger sample to further investigate the role of brace appearance in relation to compliance. We recognize that the sample size affects the strengths of the result, similarly to Law et al. (2017) that only included 10 subjects in their study. A future study could be done using this questionnaire in combination with an objective measure method, such as sensor. It has been proven that the use of a sensor is reliable when it comes to measuring compliance (Vandal et al., 1999). We believe that a combined result from a sensor regarding hours of compliance, and the questionnaire results regarding how the subject perceive the appearance of their brace. Could further explain if design is a factor that future professionals should consider when treating idiopathic scoliosis.
7.0 Conclusion and outlook
In conclusion our findings can only represent a preliminary understanding of a possible correlation between brace appearance and compliance for idiopathic scoliosis patients. The very small number of subjects makes it hard to come to a final conclusion. However, we believe that this questionnaire can give us a better understanding if small design adjustments on scoliosis braces can provide the patient with a successful treatment. Not only successful in outcomes of compliance but also where the patient can accept the brace and deal with less emotional stress.
8.0 References


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Boston brace [photograph]. (n.d.). Retrieved 14 April 2019, from http://medicom.az/en/product/9/?fbclid=IwAR2bV2pzht4u2QlQOYjz0i8tOgvH0Pr9FsLTtkS624RM8eiEiUjzoVBJg_s


Charleston bending brace [photograph]. (n.d.). Retrieved 14 April 2019, from https://sunshinepando.com/spinal-orthotics-pediatric/?fbclid=IwAR3v3_cVO25NL4XwQ8B5eJiyk5ZSB_BWnJZSy7ma71OswOtbBUWOReRaY_4

Charleston brace [photograph]. (n.d.). Retrieved 14 April 2019, from https://www.researchgate.net/figure/The-Charleston-nighttime-brace-relies-on-side-bending-for-curve-correction-Photo_fig5_24446297?fbclid=IwAR1hll3wQaA8oMSG3BvigQ52cSF9wkgxml4lZmM8xPsfLkvg243X4p518


Danielsson, A. J., Hasserius, R., Ohlin, A., & Nachemson, A. L. (2012). Body appearance and quality of life in adult patients with adolescent idiopathic scoliosis treated with a brace or under...


Appendix

Appendix 1

Final draft of the questionnaire


Kön: _______
Ålder: ______

Vilket år fick du din första korsett: _______________
Hur många korsetter har du haft sen din första: _______________

Del 1

1. Är utseende viktigt för dig? (exempelvis bryr du dig om klädmode, hårstil? Är det viktigt för dig hur du ser ut?)

☐ väldigt mycket ☐ lite
☐ mycket ☐ inte alls
☐ varken eller

2. Tycker du att du bestämmer över ditt utseende? (exempelvis bestämmer du vad du har på dig eller hur ditt hår ser ut?)

☐ väldigt mycket ☐ lite
☐ mycket ☐ inte alls
☐ varken eller

3. *Hur anser du att du ser ut med korsett och kläder på?

☐ mycket bra ☐ oattraktiv
☐ bra ☐ mycket oattraktiv
☐ varken eller
4. *Bör du nedsättad/orolig av att använda korsetten?
   ☐ aldrig        ☐ ofta
   ☐ sällan        ☐ väldigt ofta
   ☐ varken eller  ☐

   Är det något du vill tillägga, ett exempel?

   ____________________________________________________________
   ____________________________________________________________

5. *Anser du att din korsett hindrar dig i dina skol-aktiviteter?
   ☐ aldrig        ☐ ofta
   ☐ sällan        ☐ väldigt ofta
   ☐ varken eller  ☐

   Är det något du vill tillägga?

   ____________________________________________________________
   ____________________________________________________________

6. *Anser du att korsettens utseende påverkar dina relationer till kompisar och andra personer?
   ☐ aldrig        ☐ ofta
   ☐ sällan        ☐ väldigt ofta
   ☐ varken eller  ☐

7. Har du varit delaktig i att designa din korsett?
   ☐ väldigt mycket    ☐ lite
   ☐ mycket          ☐ inte alls
   ☐ varken eller

   Vad var du en del av?

   ____________________________________________________________
   ____________________________________________________________

8. Skulle du vilja vara med och designa din korsett?
   ☐ mycket gärna    ☐ lite
   ☐ gärna          ☐ inte alls
   ☐ varken eller  ☐

   ____________________________________________________________
Varför, vad skulle du vilja göra?

___________________________________________________________________________________
___________________________________________________________________________________

9. *Gillar du utseendet på din korsett?

☐ väldigt mycket ☐ lite
☐ mycket ☐ inte alls
☐ varken eller

Är det något du vill tillägga (vad är det du gillar/inte gillar)?
___________________________________________________________________________________
___________________________________________________________________________________

10. *Hur många dagar under de senaste 3 månaderna har du undvikit aktivitet på grund av korsettens utseende? (exempelvis vara med kompisar, skola, sport?)

☐ 0 dagar ☐ 7-9 dagar
☐ 1-3 dagar ☐ 10 eller fler dagar
☐ 4-6 dagar

11. Har du under de senaste 3 månaderna vid ett eller flera tillfällen valt att inte använda korsetten på grund av dess utseende? (exempelvis idrott, skolan, under natten, födelsedagsfest?)

☐ 0 tillfällen ☐ 7-9 tillfällen
☐ 1-3 tillfällen ☐ 10 eller fler tillfällen
☐ 4-6 tillfällen

När väljer du att inte använda korsetten? Varför? Är det något du vill tillägga?
___________________________________________________________________________________
___________________________________________________________________________________

12. Skulle du använda korsetten fler timmar per dygn om du kunde bestämma dess utseende?

☐ Ja verkligen ☐ troligen inte
☐ troligen ☐ verkligt inte
☐ varken eller

Varför? Är det något du vill tillägga?
___________________________________________________________________________________
Del 2

1. Gillar du utseendet av korsett 1, 2? Om du tittar på färg?

Korsett 1
- [ ] väldigt mycket
- [ ] mycket
- [ ] varken eller

Korsett 2
- [ ] väldigt mycket
- [ ] mycket
- [ ] varken eller

Varför? Är det något du vill tillägga?
___________________________________________________________________________________
___________________________________________________________________________________

2. Gillar du utseendet av korsett 1, 2? Om du tittar på banden?

Korsett 1
- [ ] väldigt mycket
- [ ] mycket
- [ ] varken eller

Korsett 2
- [ ] väldigt mycket
- [ ] mycket
- [ ] varken eller

Varför? Är det något du vill tillägga?
___________________________________________________________________________________
___________________________________________________________________________________
3. Gillar du utseendet av korsett 1, 2? Om du tittar på storlek?

Korsett 1

☐ väldigt mycket  ☐ lite
☐ mycket  ☐ inte alls
☐ varken eller

Korsett 2

☐ väldigt mycket  ☐ lite
☐ mycket  ☐ inte alls
☐ varken eller

Varför? Är det något du vill tillägga?
________________________________________________________

4. Gillar du utseendet av korsett 1, 2? Om du tittar på form?

Korsett 1

☐ väldigt mycket  ☐ lite
☐ mycket  ☐ inte alls
☐ varken eller

Korsett 2

☐ väldigt mycket  ☐ lite
☐ mycket  ☐ inte alls
☐ varken eller

Varför? Är det något du vill tillägga?
________________________________________________________
5. Gillar du utseendet av korsett 1, 2? Om du tittar på trimlinjer?

Korsett 1

☐ väldigt mycket
☐ mycket
☐ varken eller
☐ lite
☐ inte alls

Korsett 2

☐ väldigt mycket
☐ mycket
☐ varken eller
☐ lite
☐ inte alls

Varför? Är det något du vill tillägga?
_______________________________________________________________________________________
_______________________________________________________________________________________

6. Gillar du utseendet av korsett 1, 2? Om du tittar på öppningar?

Korsett 1

☐ väldigt mycket
☐ mycket
☐ varken eller
☐ lite
☐ inte alls

Korsett 2

☐ väldigt mycket
☐ mycket
☐ varken eller
☐ lite
☐ inte alls

Varför? Är det något du vill tillägga?
_______________________________________________________________________________________
_______________________________________________________________________________________


När du nu har läst ovan text om varför korsetten behöver ha vissa egenskaper och kanske förstår lite mer varför den ser ut som den gör vill vi återigen att du tar ställning till nedanstående frågor?

1. **Har du varit delaktig i att designa din korsett?**

   - [ ] väldigt mycket
   - [ ] mycket
   - [ ] varken eller
   - [ ] lite
   - [ ] inte alls

   **Är det något du vill tillägga?**

   ____________________________________________________________

2. **Skulle du vilja vara med och designa din korsett?**

   - [ ] väldigt mycket
   - [ ] mycket
   - [ ] varken eller
   - [ ] lite
   - [ ] inte alls

   **Är det något du vill tillägga?**

   ____________________________________________________________

3. **Skulle du använda korsetten fler timmar per dygn om du kunde bestämma dess utseende?**

   - [ ] Ja verkligen
   - [ ] troligen
   - [ ] varken eller
   - [ ] troligen inte
   - [ ] verkligt inte

   **Är det något du vill tillägga?**

   ____________________________________________________________
Informationsblankett till deltagare

Introduktion

Om studien
Vårt examensarbete handlar om hur skoliospatienter uppfattar utseendet av korsetten och om det i sin tur påverkar användandet av hjälpmedlet. Vi vill ta reda på detta genom att göra en enkätundersökning med patienter som genomgår skoliosbehandling.

Typ av studie
Vår studie bygger på svaren från enkätundersökningen. Du kommer att vara helt anonym det vill säga du personligen kommer inte kunna spåras till svaren du ger.

Deltagare
Du är inbjuden att delta i vår studie för att du är en skoliospatient som just nu genomgår en korsettbehandling och kan därför bidra med information till oss. Och vi kan med hjälp av informationen du ger via svar på frågorna, skapa en förståelse för hur skoliospatienter uppfattar utseendet av korsetten och om det påverkar behandlingen.

Frivilligt deltagande
Det är helt frivilligt att delta i vår studie, du kan när som helst avsluta ditt deltagande. Om du väljer att hoppa av studien kommer inget att hända. Alla deltagare i vår studie är helt anonyma.

Genomförande

☐ instämmer helt
☐ håller delvis inte med

☒ instämmer
☐ håller inte med

☐ instämmer delvis
☐ håller inte med alls
Det är frivilligt att svara på frågorna och om det är någon fråga du inte vill svara på är det ok. Vi har försökt vara tydliga med frågorna men är det något du inte förstår kan du be en vuxen förklara. Det finns inga fördelar för dig att delta i vår studie, det är bara till hjälp för oss.

**Konfidentialitet**
För att hålla dig som deltagare anonym under studien kommer du att få ett nummer, skriv inte ditt namn på frågeformuläret. Det kommer på så vis inte gå att spåra någon specifik person till frågeformuläret.

**Kontaktpersoner**
Sofi Karlsson kasol1621@student.ju.se ; Thorkatla Thorarinsdottir oror1619@student.ju.se

**Viktigt!** Efter du läst och förstått instruktionerna. Signera medföljande samtyckesformulär tillsammans med din vårdnadshavare och lägg i svars kuvert tillsammans med frågeformuläret. Posta enkäten i svars kuvert så snart som möjligt!

**TACK!**
Samtyckes formulär

Jag har läst och förstått informationsbladet och förstår vad det är som förväntas av mig genom att delta i studien. Genom att signera deltar frivilligt i studien.

Namn på deltagare, textat: ________________________________

Namn på deltagare, signatur: ________________________________

Datum: __________________________

Jag som vårdnadshavare godkänner härmed och förstår innebörden av studien som mitt barn deltar i. Jag styrker genom underskrift att mitt barns deltagande är helt frivilligt.

Namn på vårdnadshavare, textat: __________________________

Namn på vårdnadshavare, signatur: ____________________________

Datum: _______________________

Vi som ansvariga för studien lovar härmed att förstöra detta dokument, då samtycke från deltagare och vårdnadshavare säkerhetsställts. För att säkerhetsställa konfidentialitet för alla deltagare.

Namn ansvarig student 1: _____________________

Namn ansvarig student 2: _____________________

Datum: ________________

**Del 1**

1. Är utseende viktigt för dig? (exempelvis bryr du dig om klädmode, hår stil? Är det viktigt för dig hur du ser ut?)

   - [ ] instämmer helt  [ ] håller delvis inte med
   - [ ] instämmer  [ ] håller inte med
   - [ ] instämmer delvis  [ ] håller inte med alls

   Är det något du vill tillägga?

   __________________________________________________________
   __________________________________________________________

2. Tycker du att du bestämmer över ditt utseende? (exempelvis bestämmer du vad du har på dig, hur ditt hår ser ut?)

   - [ ] instämmer helt  [ ] håller delvis inte med
   - [ ] instämmer  [ ] håller inte med
   - [ ] instämmer delvis  [ ] håller inte med alls

   Är det något du vill tillägga?

   __________________________________________________________
   __________________________________________________________
3. Har du varit en del av att designa din korsett?

☐ instämmer helt  ☐ håller delvis inte med
☐ instämmer  ☐ håller inte med
☐ instämmer delvis  ☐ håller inte med alls

Är det något du vill tillägga?
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4. Skulle du vilja vara med och designa din korsett?

☐ instämmer helt  ☐ håller delvis inte med
☐ instämmer  ☐ håller inte med
☐ instämmer delvis  ☐ håller inte med alls

Är det något du vill tillägga?
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5. Gillar du din korsett?

☐ instämmer helt  ☐ håller delvis inte med
☐ instämmer  ☐ håller inte med
☐ instämmer delvis  ☐ håller inte med alls

Är det något du vill tillägga (vad är det du gillar /inte gillar)?
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6. Har du någon gång vid ett tillfälle/tillfällen valt att inte använda korsetten? (Exempelvis idrott, skolan, under natten, födelsedagsfest?)

☐ instämmer helt
☐ håller delvis inte med
☐ instämmer
☐ håller inte med
☐ instämmer delvis
☐ håller inte med alls

När väljer du att inte använda korsetten? Varför? Är det något du vill tillägga?

_____________________________________________________________________
_____________________________________________________________________

7. Skulle du använda korsetten fler timmar per dygn om du kunde bestämma dess utseende?

☐ instämmer helt
☐ håller delvis inte med
☐ instämmer
☐ håller inte med
☐ instämmer delvis
☐ håller inte med alls

Är det något du vill tillägga?

_____________________________________________________________________
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**Del 2**


7. Gillar du utseendet av korsett 1, 2 och 3? Om du tittar på färg, kardborreband?

### Korsett 1

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### Korsett 3

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Är det något du vill tillägga?

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8. Gillar du utseendet av korsett 1, 2 och 3? Om du tittar på storlek, form, pelotter ("tryck-kudde"), trimlinjer, öppningar?

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Är det något du vill tillägga?

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Innan du påbörjar denna del är det viktigt att du tittar på bilderna tillhörande del 3, personer som har korsetternå på sig. Var noga med att titta på rätt korsett till respektive fråga. Om du tycker du har något att tillägga använd raderna efter varje fråga, tack!

1. Gillar du utseendet av korsett 1, 2 och 3? Om du tittar på färg, kardborreband?

   **Korsett 1**
   
   ■ instämmer helt  ■ håller delvis inte med
   ■ instämmer  ■ håller inte med
   ■ instämmer delvis  ■ håller inte med alls

   **Korsett 2**
   
   ■ instämmer helt  ■ håller delvis inte med
   ■ instämmer  ■ håller inte med
   ■ instämmer delvis  ■ håller inte med alls

   **Korsett 3**
   
   ■ instämmer helt  ■ håller delvis inte med
   ■ instämmer  ■ håller inte med
   ■ instämmer delvis  ■ håller inte med alls

   Är det något du vill tillägga?

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2. Gillar du utseendet av korsett 1, 2 och 3? Om du tittar på storlek, form, pelotter ("tryck-kudde"), trimlinjer, öppningar?

**Korsett 1**

☐ instämmer helt
☐ instämmer
☐ instämmer delvis
☐ håller delvis inte med
☐ håller inte med
do
☐ håller inte med alls

**Korsett 2**

☐ instämmer helt
☐ instämmer
☐ instämmer delvis
☐ håller delvis inte med
☐ håller inte med
do
☐ håller inte med alls

**Korsett 3**

☐ instämmer helt
☐ instämmer
☐ instämmer delvis
☐ håller delvis inte med
☐ håller inte med
do
☐ håller inte med alls

Är det något du vill tillägga?

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Del 4


När du nu har läst ovan text om varför korsetten behöver ha vissa egenskaper, och kanske förstår lite mer varför den ser ut som den gör. Hur ställer du dig då till nedanfrågor?

3. Har du varit en del av att designa din korsett?

☐ instämmer helt ☐ håller delvis inte med
☐ instämmer ☐ håller inte med
☐ instämmer delvis ☐ håller inte med alls

Är det något du vill tillägga?

______________________________________________________________________
______________________________________________________________________

4. Skulle du vilja vara med och designa din korsett?

☐ instämmer helt ☐ håller delvis inte med
☐ instämmer ☐ håller inte med
☐ instämmer delvis ☐ håller inte med alls

Är det något du vill tillägga?

______________________________________________________________________
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4. Skulle du använda korsetten fler timmar per dygn om du kunde bestämma dess utseende?

☐ instämmer helt  ☐ håller delvis inte med
☐ instämmer  ☐ håller inte med
☐ instämmer delvis  ☐ håller inte med alls

Är det något du vill tillägga?

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_________________________________________________________________________
Korsett 1 - Del 2

Korsett 2 - Del 2

Korsett 3 – Del 2