Aspects of bracing in adolescent idiopathic scoliosis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational non invasive

Summary

ID

NL-OMON47894

Source
ToetsingOnline

Brief title
Brace treatment of adolescent idiopathic scoliosis

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
curved spine, scoliosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brace, Motion analysis, Pulmonary, Scoliosis

Outcome measures

Primary outcome

Primary Objective: The primary objective of the study is determining the contributing factors in bracing for AIS. The contributing factors are determined as factors of influence in the corrective possibilities and therefore end term results of the M-brace, which are currently unknown. The contributing factors are listed as secondary - fifth objective together with patient characteristics such as length and weight. The effect of contributing factors is quantified in changes of Cobb*s angle over time. The changes of Cobb*s angle over time are measured every six months on anteroposterior and lateral full spine radiographs until full bone maturation.

Secondary outcome

Secondary objective:

• Compliance of brace wear

o An incorporated thermal sensor (Orthotimer, Appendix 2) is used to quantify ours of brace wear per day. Sensor data is monitored every outpatient clinic visit through a wireless read-out system.

Third objective

• Pulmonary function and relation of brace wearing

o Pulmonary function over time is measured once a year with use of dynamic and static spirometry. The measurements are with and without (very short term)

brace wearing. The increased wearability and comfort of the Maastricht brace is expected to optimise pulmonary function and therefore support any form of activity whilst brace wearing.

Fourth objective

• Pressure distribution and development in brace wearing

o Incorporated pressure sensors (Pressure Guardian) are used to quantify force and force distribution in the M-brace. Sensor data is monitored every outpatient clinic visit. It is still unclear how the force changes over time, whether there is a wear effect or if the brace applies the same force in different situations (sitting, standing ea.).

Fifth objective

• Motion analysis in brace (CAREN)

o Motion analysis with and without brace, before, during and after treatment with M-brace. Analysis of gait and development of posture and balance before, during and after brace wear. An over- and or under correction can result in an imbalance in the coronal and or sagittal plane, and therefore a change in motion analysis. As we expect the brace to be optimally fitted, the hypotheses is that the kinematics of the walking pattern, the spaciotemporal parameters (such as walking speed, step length, ao) and measures of stability will be better comparable to short term non-brace wearing.

Study description

Background summary

Scoliosis is a three dimensional deformity of the spine, characterized by lateral deviation in the coronal plane. As growth sets in this deformity can increase. The amount of curvature is objectified on anteroposterior full spine radiographs, by measuring Cobb*s angle. Cobb*s angle is defined as the angle formed between a line drawn parallel to the superior endplate of one vertebra above the curvature and a line drawn parallel to the inferior endplate of the vertebra one level below the curvature. The Soliosis Research Society defines adolescent idiopathic scoliosis (AIS) as a curve > 11 degrees. Curves of a lesser magnitude have little potential for progression.

Once the curvature shows progression and exceeds a Cobb angle of about 20 degrees, chances are small that this curvature will disappear spontaneously. Weinstein and Ponseti concluded in 1983 that curves between 40 and 50 degrees progress after skeletal maturity. Non-operative measures therefore aimed at preventing curves progressing to this magnitude. The risk of progression is inversely proportional to the Risser grade or the age of the patient, and proportional to the size of the curve. There is little epidemiological data of the Netherlands available, but it is estimated that about 600 adolescents with AIS are treated with a brace yearly, and around 5-10 percent are treated surgically. Only 11 hospitals include the surgical treatment of scoliosis, including Maastricht UMC+.

Brace treatment is intensive for the patient, as a minimum wear of 20 to 23 hours a day is mostly prescribed. There are several disadvantages of a brace. Problems with clothing in summer and winter, sore skin, decreased mobility, depressed pulmonary function (causing restrictions in the necessary physical therapy) are the foremost problems of brace wearing. Since the brace corrects the stature of the child, optimal fitting is of outmost importance. An over- and or undercorrection can result in an imbalance in the coronal and or sagittal plane. If the brace treatment is ineffective, and the curve magnitude progresses above 50 degrees, operative approach is contemplated. Such an operation, in which the vertebrae are anteriorly and or posteriorly fused over a large distance, is substantial. There is a long postoperative course, with several operative complications which may occur.6 Therefore optimal brace treatment is of outmost importance to prevent progression to an extent that an operation cannot be avoided.

The only treatment to prevent the -rather radical- surgery in AIS is also intrusive. Brace treatment is intensive for the patient, as a minimum wear of 20 to 23 hours a day is mostly prescribed. In an age in which appearance is everything, most patients in their puberty consider brace treatment as unpleasant. Problems with clothing in summer and winter, sore skin, decreased

mobility, are all unpleasant for the patient. Until 2014, when Weinstein published his results in the New England Journal of Medicine, there was no proof of bracing being an effective intervention. Since evidence has been provided, the quality of bracing is of outmost importance for the outcome of brace treatment.

Study objective

• AIS is a chronic condition of the back. Once the curvature shows progression and exceeds a Cobb angle of about 20 degrees, chances are small that this curvature will disappear spontaneously.2 There is little epidemiological data of the Netherlands available, but it is estimated that about 600 adolescents with AIS are treated with a brace yearly, and around 5-10 percent are treated surgically. Only 11 hospitals include the surgical treatment of scoliosis, including Maastricht UMC+.

The only treatment to prevent the -rather radical- surgery in AIS is also intrusive. Brace treatment is intensive for the patient, as a minimum wear of 20 to 23 hours a day is mostly prescribed. In an age in which appearance is everything, most patients in their puberty consider brace treatment as unpleasant. Problems with clothing in summer and winter, sore skin, decreased mobility, are all unpleasant for the patient. Until 2014, when Weinstein published his results in the New England Journal of Medicine, there was no proof of bracing being an effective intervention.3 Since evidence has been provided, the quality of bracing is of outmost importance for the outcome of brace treatment.

Our rationale for the study is multi-layered. Brace treatment is only effective if the patient is compliant; an optimally constructed brace is not effective if only worn for two hours a week. The Maastricht brace was developed to increase compliance by optimizing wearability and therefore more comfort, while obtaining the same pressure and therefore effect as the current golden standard, the Boston brace. Initial results are promising and further effects need to be objectified. There are many contributing factors in obtaining good results in bracing. The contributing factors are determined as factors of influence in the corrective possibilities and therefore end term results of the M-brace. Because of small patient populations current literature does not impart on these factors. There are many unknowns, and therefore different types of braces, brace regimes, and sport (or physiotherapeutical) regimes aside the different brace regimes. There is a differentiation between night braces, day braces, 23 hour a day braces and thoracolumbar or lumbar braces. There is a differentiation between brace renewal each year or only on indication (non-optimal fitment). There is a differentiation between static and dynamic bracing. There is no current proof which of the above is better. There are several aspects of bracing which are only partly known or scarcely described in current literature; motion analysis in patients with AIS with or without brace is only investigated in small groups using older techniques. Pulmonary function

in brace has only been published with use of rigid braces, with no correlation made to correction of brace or end term bracing results.4,5 If force distribution changes before the usual time of brace renewal there might be an indication to renew the brace before the normal time of renewal. If force distribution is non-optimal during the night or during schooltime (sitting position), there might even be an indication to reduce brace time in such situations.

As thoracic parts of the Maastricht brace are flexible (semi-rigid) and custom made, our hypothesis is that pulmonary function will be influenced by the brace in a predictable manner. With an optimal fitment the pulmonary function should approach normal population. If the pulmonary function decreases or changes there might be an indication to change the brace regime or increase radiological follow-up with the reasoning of increase of Cobb*s angle. The pulmonary function in brace is not only important for comfort and wearability, but also for training purposes in physical therapy and daily activities.

As the braces are worn for longer periods of time, 23 hours a day, usually several years, we want wo objectify the pressure applied by the brace. The wear effect or habituation on pressure is unclear, as is the pressure in different situations. If the pressure in the brace is absent or minimal in full rest (sleeping), there might be an indication to shorten the brace wearing time at night. Furthermore if there is a change in pressure as the brace ages, this might be indicative for fitting a new brace. Currently this is evaluated at the outpatient clinic by the treating physician by means of assessment of fit. This information could be objectified by pressure measurements in brace.

Optimal fitment of a brace should also result in better in-brace movement. Our hypothesis is that an optimal fitted brace should result in motion analysis without noticeable imbalance in the sagittal and or coronal plane, and therefore comparable to healthy subjects (not in this study) as defined in literature.7 Since the brace corrects the stature of the child, optimal fitting is of outmost importance. An over- and or under correction can result in an imbalance in the coronal and or sagittal plane, and therefore a change in motion analysis. As we expect the brace to be optimally fitted, the hypotheses is that the kinematics of the walking pattern, the spaciotemporal parameters (such as walking speed, step length, ao) and measures of stability will be better comparable to short term non-brace wearing (this study).

With this study we would like to develop an optimal conservative treatment plan for AIS with use of the Maastricht brace, and more insight in the pathophysiology of AIS and the effects (or effectiveness) of bracing. Optimal brace treatment will result in a better success rate of bracing and therefore prevent surgery in the adolescent child. The Maastricht brace has been in use since 2011. Initial results are promising, however long- term results and contributing factors are unclear. In developing an excellent brace and bracing protocol we hope to optimize the results of conservative AIS treatment.

Study design

The study design is a prospective longitudinal cohort study.

We would like to include twenty-two patients. As there are approximately 10 patients per year with AIS treated conservatively with a thoracolumbar brace in the MUMC+, the minimum inclusion period would be two years, and an average of four years of brace treatment, in which we can collect the requested data and measurements. The duration therefore is estimated at a six years total.

The setting of the study is in the outpatient clinic of the MUMC+. There will be no clinical admission necessary as in line with current normal practice.

Included in appendix 1, table 1, is a flowchart to demonstrate the study design (C1 formulier)

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden associated with participation is as follows (Table 1, Appendix 1):
1. An increase of time in every outpatient clinical visit to evaluate brace compliance with use of the Orthotimer and Pressure Guardian (Appendix 2).
a. Reading the sensors (both the Orthotimer and Pressure Guardian) will take place at the outpatient clinic and lasts about five minutes.
2. After an adequate brace placement of the initial brace there is an additional pulmonary test (+-2 hours) and an additional motion analysis (+-2 hours). These tests are non-invasive, but they do however consume half a day in total. These tests are to be repeated every year until endpoint of bracing at full bone maturity.
a. In summary both the pulmonary tests and the motion analysis will be taken every year and at start- and endpoint of brace treatment.
3. There is only one group of patients subject for these tests, there is no control group. There are no risks of attending. Treatment with the Maastricht brace and outpatient clinical controls are identical to current clinical practice in adolescent idiopathic scoliosis.
4. Additional questionnaires (two) are filled in every three months at the outpatient clinic. The average time investment is 15 minutes per visit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

1. AIS
2. Indication for conservative treatment
3. Minimum age of 12 years old
4. Eligible for follow up
5. Ability to read and write in the Dutch language
6. Patient who are physically and mentally willing and able to comply with the functional evaluation
7. Informed consent signed by both one of the parents and the patient
8. Male and female patients

Exclusion criteria

1. Prior surgery to the spine
2. Morbid obesity (BMI>35)
3. Any musculoskeletal or neurological (congenital) disorder
4. Patients who are unwilling to cooperate with the study protocol and follow-

up schedule.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	21-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL53296.068.15
Other	NTR 22186