

Results of a Prospective Cohort Study of the TriaC Brace and its Clinical Effects

In a prospective cohort study it could be proved that it is possible to successfully treat patients suffering from scoliosis with a high risk of progression with the TriaC Brace. To do so an early start of the treatment and a good compliance of the patient are as important as a good primary correction, as only a scoliosis brace that is really used can have an effect. The TriaC Brace is a modular construction system which is adapted individually. It connects constantly working correction forces with the highest possible normal range of motion for the patient. The filigree and non-bulky construction increases the readiness of the patient to wear the orthosis consequently. The TriaC Brace represents a genuine alternative to the conventional brace systems. The article describes briefly the construction of the orthosis and then discusses the study results.

Introduction

We realize again and again that the conservative treatment with scoliosis braces is put off for too long because of the psychological strain for the patient. For this reason there is often a drastic worsening of the scoliosis which cannot be reversed. Even with a successful course of treatment it makes a big difference if treatment has started for example at a Cobb angle of 25 degrees or only of 35 degrees.

Montgomery [8] describes that with an increasing Cobb angle the failures of therapy in the brace increase, too. If the Cobb angle is below 30 degrees we can assume a failure rate of 5 per cent. If the Cobb angle is between 30 degrees and 45 degrees it is already 33 per cent, and with a Cobb angle of

more than 45 degrees the failure rate increases even further to 62 per cent of the scoliosis patients treated with orthoses.

The Cobb angle at the beginning of the therapy plays an important role, but it is not the only factor influencing a treatment. An orthosis which is carefully adapted to the patient's needs, concerning medical requirements as well as personal needs and desires should be self-evident. As the most frequent treatment is a 23-hour-therapy which often lasts for years the patient management during therapy plays an important role. Patient management means a team of therapists who are constantly in contact with each other and act along the same lines in front of the patient and his family and communicate in an understandable language. Thus the young patient can be given the urgently needed support. A close supervision through the medical doctor and the orthopaedic technologist allows a quick reaction in case of fitting problems and a deterioration of the scoliosis in the brace, the aim of a scoliosis treatment with a brace being to prevent the progression of the scoliosis.

Compliance

Compliance also means acting true to the therapy and this is just what is important to carry out a successful therapy. F. Landauer et al. [6] showed that with a good primary correction but a bad compliance of the patient a progression couldn't be prevented. A good primary correction is the first important element but it is by no means a successful therapy yet. The greatest challenge is to keep the young patient in the orthosis

for therapy as long as possible. Only a scoliosis brace which is really used can have an effect. In a study of Houghton et al. [5] 65 per cent of the patients said they wore the brace regularly and as long as prescribed, but only 20 per cent of the patients really wore their orthosis as prescribed.

It is important to include all possibilities which motivate the patient to a consequent cooperation as an orthotic therapy is an enormous strain for the patient. Thus with the TriaC Orthosis the so-called three C's have been consequently integrated into the orthosis to increase the compliance (fig. 1a and b). For the construction of the TriaC Brace attention was paid to an optimal connection of the three C's "Comfort, Compliance and Cosmetics". The aim was to develop an orthosis which permits an early involvement of the patient and makes a lasting correction of the scoliosis possible.

Design

The correction forces were supposed to have a permanent effect onto the spine no matter if the patient is standing up, sitting, lying down or walking (fig. 2) [9]. That means that the correction pads should – independent of the movement – always have enough correction force onto the spine so that a correcting pressure controlling the growth can be exerted. A movement of the trunk between the thoracic and the lumbar pad should always be possible so that the patient can move as normally as possible and everyday life is as little restricted as possible. For this reason a frame was constructed which covers only a small area of the skin so that the strain on the



Fig. 1a and b The joint connection between the thoracic and lumbar part of the TriaC Brace gives the patient free range of motion in all directions, including rotation (Photos: Sporlastic).

skin is minor and a heat accumulation between the orthosis and the body can be avoided. Thus the compliance is improved by the filigree construction which does not bulk under the clothes.

The TriaC Brace consists of single modular parts and is individually adjusted by the orthopaedic technologist in several steps. It must be kept in mind that the modular system needs to be strongly modified according to the position and the type of the scoliosis to reach a good correction result.

Indication

As with all other scoliosis orthoses, experiences in working with the system and a deep understanding of the scoliosis and its conservative treatment are important (fig. 3). The TriaC Brace should be applied up to a maxi-

mum Cobb angle of 30 degrees in the thoracic section of the spine and up to around 35 degrees in the lumbar section (due to the authors' experiences). Paying attention to the right Cobb angle in the spine sections concerned is a criterium for the choice of patients. Another important aspect is the position of the vertex vertebrae. A vertex vertebra between TH 11 and TH 7 and between TH 12 and L 4 can be treated with the TriaC Brace. For a curvature with a double bow with a vertex at TH 11 a fitting with the TriaC Scoliosis Orthosis is not possible due to its construction. However, for a c-shaped scoliosis also a vertex at TH 11 can be very well corrected with a light modification of the lumbar pad (fig. 4a and b). Basically, due to the construction, lumbar curvatures, thoracic counter-curvatures with a long bow (fig. 5) and c-shaped curva-

tures can very well be corrected and preserved with the TriaC Brace.

As contraindications are regarded vertex vertebrae at TH 7 and above or an isolated thoracic curvature (King III). Children who are smaller than 120 cm cannot be treated with a TriaC Brace either as the single components are too big for these heights and no satisfying correction is reached.

Prospective Cohort Study of the TriaC Brace

A prospective cohort study with the orthosis has been carried out with patients with an immature supporting apparatus and idiopathic scoliosis [1]. We wanted to find out if the TriaC Brace can efficiently prevent a progression of the curvature with an immature

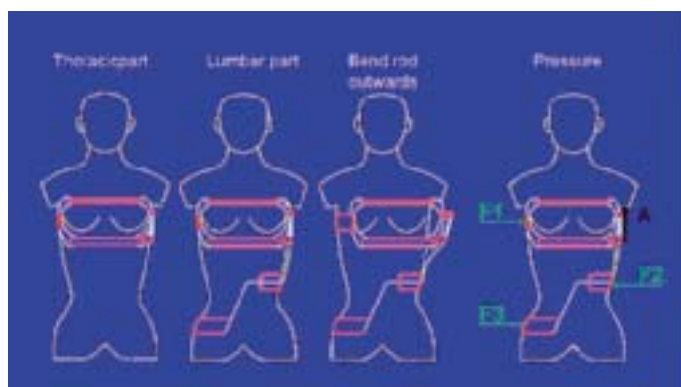


Fig. 2 Thoracic and lumbar pads work in a closed force chain (dynamic), but are movable against each other through a joint connection and allow the patient a nearly normal mobility. Because of the equalizing sliding joint the correction pads remain constantly in the right position (in lying down, sitting, standing up and walking). At the same time the side joint serves the compensation of the elevation of the scapula (fig. 2, A).



Fig. 3 As with any other corset system, you need sufficient experience in using the modular system of the TriaC Brace.



Fig. 4a The open frame construction enables the orthotist to assess easily the clinical value of his work. (Photo: Roland Dötzer, SH Gießler).

Fig. 4b 13-year-old patient (see also fig 4a) with a c-shaped scoliosis, vertex TH 11. TriaC Brace in fitting status with modified lumbar pad (Photo: Roland Dötzer, SH Gießler).

supporting apparatus and idiopathic scoliosis, where a high risk of progression (70 to 100 per cent) of the curvature exists [1, 7]. Burwell studied the natural course of the idiopathic scoliosis with a group of patients with similar parameters with regard to the grade of the curvature and the age (at first presentation) as in the study group presented here. He also found a high risk of progression in the patient group he examined [3].

Material and Method

From 1997 to 2005 all consecutive patients, to whom the following criteria applied, were submitted to a brace treatment with the TriaC Brace and observed prospectively. The indication for a treatment was a progressive curvature with a Cobb angle between 25 and 40 degrees. For all curvatures (except those which were already above 30 degrees) a progression of at least 5 degrees had to be proved. The patients had to have an immature skeleton and have a Risser sign of zero or one for boys and girls. For girls the factor of premenarche or less than one year postmenarche was added. Patients with a systemic illness, which could possibly have influenced the study result were not included in the study. All patients to whom including and excluding criteria applied were treated with a TriaC Brace.

From an overall group of 212 patients, who were treated at the University Clinics of Groningen during the time of the study, all including and excluding criteria

applied to 63 persons or 30 per cent of the patients. These became the study group to be examined. It consisted of 7 patients (11 per cent) with a single curvature and 56 patients (89 per cent) with a double curvature. In the group there were 6 boys and 57 girls.

The average Cobb angle for the primary curvatures before the brace treatment was $30.2 \text{ degrees} \pm 7.5 \text{ degrees}$, the average Cobb angle for secondary curvatures was $22.3 \text{ degrees} \pm 6.4 \text{ degrees}$. The average age of the patients at the beginning of the treatment was 11.3 ± 3.1 years. The treatment was finished when the patient reached a Risser sign of four (average age of 15.6 ± 1.1 years). All patients were observed after the end of the brace treatment in a check-up programme.

Radiological Analysis

All x-rays were taken with the patient standing up. The postero-anterior projection was used because there the radiation dose working on the chest could be minimized. All x-rays were taken in accordance with the standard x-ray protocol. Anatomic vertebral measuring points were determined and marked by hand on a high-resolution 21-inch monitor using a pointer marker [10]. After the marking the Cobb angle was calcu-

lated by using an automatic recognition of the vertex and the final vertebra [4]. All measuring dates were taken by one single observer who accompanied the patients up to their skeletal maturity.

Results

The patient group was divided into a success group and a failure group, the "failure" being defined as a progression of more than 5 degrees (as compared to the initial value). In the success group the



Fig. 5 12-year-old girl with a double-bow scoliosis. The x-rays were taken directly after the application of the TriaC Brace.

primary correction of the primary curvature was $34 \text{ per cent} \pm 17 \text{ per cent}$, in the failure group it was $-16 \text{ per cent} \pm 17 \text{ per cent}$. The success rate in all the study cohort is 76 per cent (48 successful treatments) and the failure rate is 24 per cent (15 unsuccessful treatments).

In the group of single curvatures the average Cobb angle at the

beginning of the treatment was 35 degrees \pm 11 degrees. The average primary correction in this group was 23 per cent \pm 9 per cent. There were no failures in this group. Although, as compared with the cohort with double curvature, the difference is significant it is still too small to allow conclusions. It was evident that it was not possible to hold the primary correction during the whole course of the treatment.

At the end of the treatment the average correction of the Cobb angle of the successfully treated patients had decreased to 19 per cent \pm 13 per cent. The average correction status reached at the first check-up after the end of the brace treatment was 20 per cent \pm 15 per cent. All patients with whom the brace treatment had been successful were observed during an average period of 1.6 years after the end of the brace treatment. The latest check-up was carried out six years after the end of the treatment (fig. 6).

Discussion

The present study shows that the TriaC Brace reduces scoliosis (also after the end of the treatment) and that the single corrections are preserved during the brace treatment. In addition it prevents a further progression of the Cobb angle with idiopathic scoliosis. As compared with studies published on the natural course of idiopathic scoliosis the use of the TriaC Brace obvi-

ously had a significant influence on the improvement of curvatures of patients with an immature skeleton (with a very high risk of progression [2]).

For 76 per cent of the patients a progression could be prevented or a

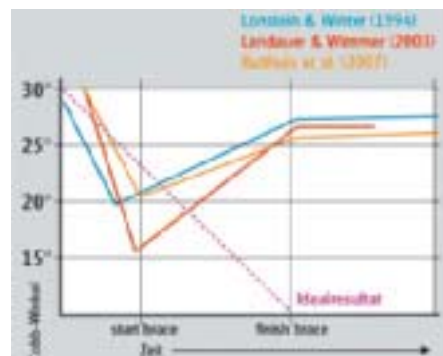


Fig. 6 The success group treated with TriaC shows a lasting correction after the end of the treatment with the TriaC Brace (Bulthuis et al.). The other studies carried out with the Chêneau (F. Landauer et al.) and Boston Brace (Lonstein et al.) show comparable results.

correction of the scoliotic curvature could be reached. In their study Lonstein and Carlson found a risk of progression of 70 to 100 per cent with the same target group [7].

Including the experiences we made, the study results related to the primary correction would probably be even better. At the beginning of the study the therapists had put on only very low correction pressures being afraid the patients wouldn't tolerate the pressure. These fears turned out to be unfounded in the course of time as also higher correction pressures

were and still are very well tolerated by the patients.

As to its efficiency the TriaC Brace is not different from conventional brace systems [1], its application is, however, limited by the restricted indication. The TriaC Brace represents a genuine alternative to the conventional brace systems for patients with the given indications. This is particularly true for the treatment of patients with a primary lumbar scoliosis. Because of the higher comfort it offers and the improved outer appearance the TriaC Brace has a positive influence on the patient compliance and thus on the overall success of the treatment.

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