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Communication

A new orthotic device in the non-operative treatment of idiopathic scoliosis

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Abstract

A transverse force system, consisting of an anterior progression force counteracted by a posterior force and torque, acts on the vertebrae of a scoliotic spine. The aim of the newly introduced TriaC brace is to reverse this transverse force pattern by externally applied and constantly present orthotic forces. In the frontal plane the force system in the TriaC brace is in accordance with the force system of the conventional braces. However, in the sagittal plane the force system acts only in the thoracic region. As a result, there is no pelvic tilt, and it provides flexibility without affecting the correction forces during body motion. In the current preliminary study it is demonstrated that the brace prevents further progression of the Cobb angle and axial rotation in idiopathic scoliosis. The new brace has the added advantage of comfort for the wearer, and it offers a better cosmetic appearance, as well as, potentially, a better compliance.

Keywords: Scoliosis; Orthosis; Spine biomechanics

1. Introduction

The purpose of this paper is to present the preliminary results of a new orthotic device for the non-operative treatment of idiopathic scoliosis.

Throughout history, external devices have been used to correct deformities and immobilise the spine. Although current scientific analysis has yielded a more thorough understanding of the mechanism of action of those devices, the function has always remained the same.

The development of braces for scoliosis has been empirical, based on trial and error.

Brace designs have changed periodically over the years, but most modifications have been attempts to improve efficacy and failed to acknowledge the importance, especially to teenagers, of physical appearance. This group resists acting or looking different from their peers, which obviously occurs when a visible brace is worn. Modern materials, lower profiles, and reduced wearing times have been tried, in attempts to reduce resistance and the emotional difficulties encountered with brace wear.

Idiopathic scoliosis is a complex three-dimensional deformity of the trunk, characterised by lateral deviation and axial rotation of the spine, usually accompanied by a rib cage deformity.

The aetiology of idiopathic scoliosis is still unknown and therefore its treatment difficult.

Whatever factors underlie the aetiology, they ultimately express themselves in the biomechanical changes that define scoliotic curve progression.

It is generally known that the spine may be regarded as an inherently unstable system that requires support of the musculo-ligamentous structures to maintain its posture and to provide motion [14,27,29,37,38]. The majority of these musculo-ligamentous structures are located at the posterior side of the spine and contribute to the stability of the spine by resisting primarily tension forces. In contrast, the anterior spinal column, which consists of the vertebral bodies and the intervertebral discs, has a special role in transmitting compression forces.

In the normal spine a balance between the compress-

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ive forces of the anterior column and the tension primarily maintains the stability of the physiological sagittal curve, i.e. the thoracic kyphosis and lumbar lordosis, forces in the posterior column. This biomechanical concept was first mentioned by Meyer [19] in 1866.

Nachemson et al measured the in vivo lumbar intradiscal pressure and found large compressive forces in different body positions. They also demonstrated pre-stress in the intervertebral disc, which was mainly preserved by the musculo-ligamentous structures of the posterior column [22,23,25,30,38]. Due to the anatomic structure of a motion segment the direction of the tension and compression forces in a normal spine will mainly follow the kyphotic or lordotic curvature, resulting in transversal components of those forces in the sagittal plane [24].

A similar process occurs in a scoliotic spine where the compression forces (F_c) on the vertebral body and the tension forces (F_t) on the posterior part of the vertebra will follow the scoliotic curvature. These forces result in a lateral shear force ($F_{anterior}$) driving the vertebral body outwards (Fig. 1a) and a lateral shear force ($F_{posterior}$), that will try to keep the vertebra at its place. To achieve equilibrium in the scoliotic spine, these lateral force components have to be counteracted by a torque. This torque may be produced by the musculo-ligamentous structures of the posterior column, as well as bone elements such as the facet joints and ribs (Fig. 1b). Our study on the intrinsic bony vertebral and rib deformities in scoliosis suggests that a force pattern, as explained above, is indeed present. The deformations in the vertebra are caused by bone remodelling process due to forces acting on the vertebra (Fig. 2). A lateral directed force drives the apical vertebral body out of the midline, and forces of the musculo-ligamentous structures of the posterior column, which attempt to minimise the deviations and rotations of the vertebrae [36]. However, should these structures fail to stabilise the scoliotic spine, for example during periods of growth, curve progression will occur [24].

Other authors also stress the importance of "posterior tethering" with regard to geometrical and morphological configuration of the scoliotic deformity [11,15].

When cumulating the progression mechanism as explained in Figs. 1 and 2, on every level in a scoliotic spine, a pattern of laterally directed forces will act as shown in Fig. 3.

The aim of the new orthosis is to reverse this transverse force pattern by externally applied and constantly present orthotic forces (F_l and F_t).

2. The working principle of the TriaC brace

The name TriaC is derived of the three C's of Comfort, Control, and Cosmesis.

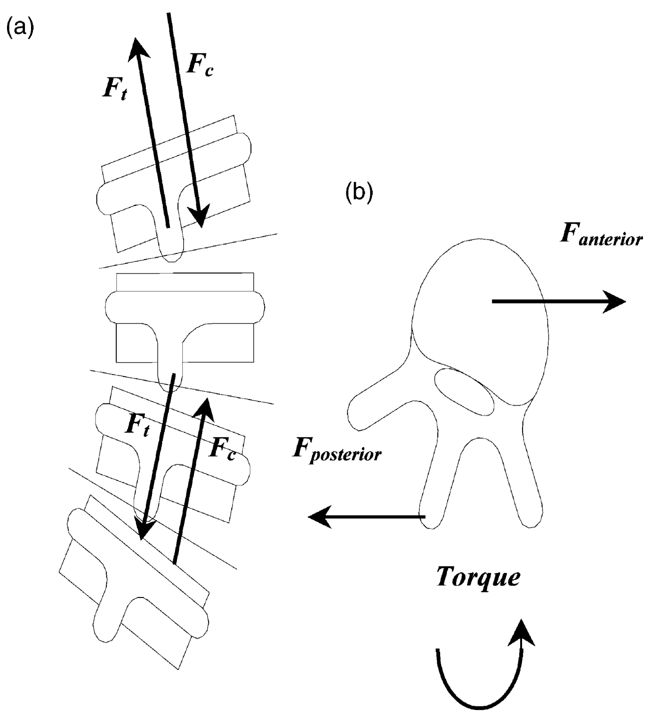

Fig. 1. The force pattern in the scoliotic spine. The compressive forces of the anterior column result in a resultant shear force ($F_{anterior}$) which drives the apical vertebral body out of the midline (a), whereas the torque and a posterior shear force ($F_{posterior}$), provided by the posterior column, attempts to keep the posterior complex in the normal position (b).

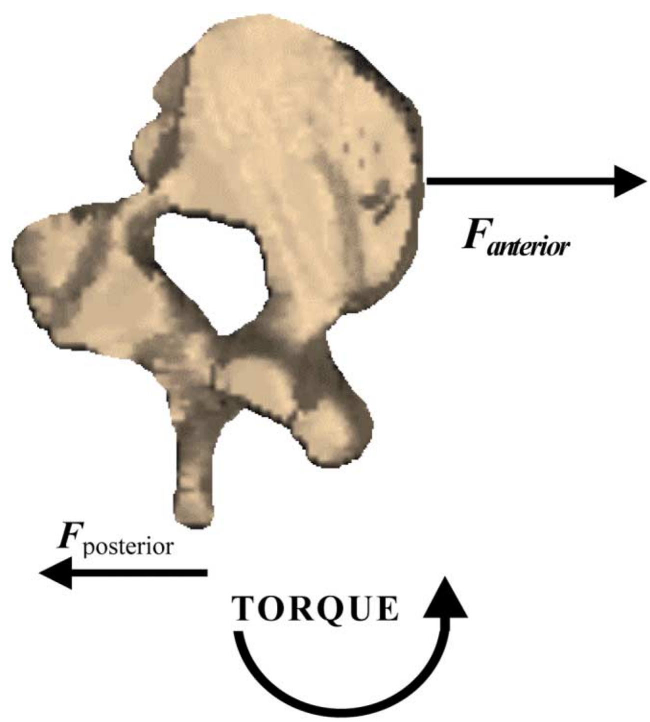

Fig. 2. Top view of a strongly deformed scoliotic vertebra, as a result of the long-term occurrence of a deforming force system. An anterior Force ($F_{anterior}$) and a posterior force ($F_{posterior}$) and torque (M_t) cause the deformation.

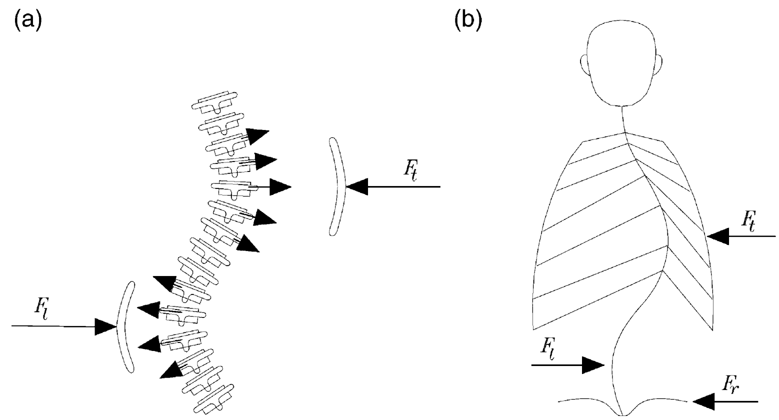

Fig. 3. (a) The aim of the new orthosis is to counteract the progression forces which act on the vertebral bodies of a scoliotic spine. Two forces F_t and F_l are placed near the apex of the curves. F_l acts via the lumbar muscles and F_t acts via the rib cage onto the spine. (b) Generally, a reaction force F_r is needed to obtain equilibrium in the orthosis.

In the new orthosis a choice has been made for applying continuous correction forces on the trunk, with the aim to reverse the progression process during the growth period. A basic requirement for such a brace is that the brace force must be able to follow the main body motions of the patient. In order to meet this requirement a flexible coupling, connecting a thoracic and a lumbar part must be incorporated in the orthosis.

Two correction forces F_t and F_l are applied on the thoracic and lumbar apex via pressure pads. These forces are not in equilibrium and so an additional reaction force (F_r) is needed (Fig. 3B).

This reaction force plays only a role in obtaining equilibrium and must be positioned in such a way that it does not influence the correction forces (Fig. 3). The lumbar correction force (F_l) is placed between the pelvis and the lower ribs, and acts via the lumbar muscles on the lumbar vertebral bodies and its reaction force (F_r) is placed on the pelvis. The thoracic correction force (F_t) is positioned near the spine, somewhat posteriorly to avoid overloading of the ribs. Consequently, the thoracic correction force (F_t) has a frontal component (F_{tf}) and a sagittal component (F_{ts}). However, because of the sagittal component (F_{ts}) an additional force (F_v) is needed to obtain equilibrium in the sagittal plane. This force is placed at the anterior side of the trunk.

As it turns out, the working line of this force lies lateral to the sternum. As most of the patients with idiopathic scoliosis are female, this would mean a force F_v would have to be applied onto a breast. To avoid this, the force F_v is split up into two forces, one above (F_{va}) and one below the breast (F_{vb}).

In this way the new orthosis applies a 3-force system (F_{va}, F_{vb}, F_{ts}) in the sagittal plane and a 3-force system (F_r, F_{tf}, F_l) in the frontal plane (Fig. 4). The frontal force system is in accordance with the force system of the conventional braces. However, compared to the conventional brace the sagittal force system acts only in the thoracic region, which has two advantages. Firstly, there are no longer sagittal forces on the pelvis so there will be no pelvic tilt. Secondly, it is possible to provide flexibility in the orthosis without affecting the correction forces during body motions.

Fig. 5 schematically shows the orthosis. To obtain the required flexibility a flexible coupling (1), connecting a thoracic part (2) and a lumbar part (3) has been incorporated in the orthosis. In this version of the orthosis the coupling has been implemented as a sleeve and bar mechanism, enabling the correction forces to follow the main body motions of the patient, like bending (lateral and frontal) and rotation. Therefore, the patient is free to move despite wearing a brace. The correction forces will remain intact regardless of the body motions of the patient. Because of this property the orthosis can be regarded as a force controlled device.

The aim of this preliminary study is to investigate if the force controlled working principle of the TriaC brace will have the same 'holding effects' as the conventional braces.

3. Materials and methods

The study included 35 consecutive patients with idiopathic scoliosis treated since 1996 with the newly introduced brace. The group consisted of 30 female and five male patients with an average age at the initiation of treatment of 12.6 years (range 9.2–16.0 years). All patients were Risser zero to two. Curve pattern was single right thoracic in 21 patients, right thoraco-lumbar in nine, a left lumbar in one and structural double curves in four. All patients had verified progressive curves (an increase of 5 degrees or more Cobb angle). Three parameters were measured: the Cobb angle, lateral deviation and rotation of the apex of the scoliotic curve. The angular parameters measured were expressed in degrees and

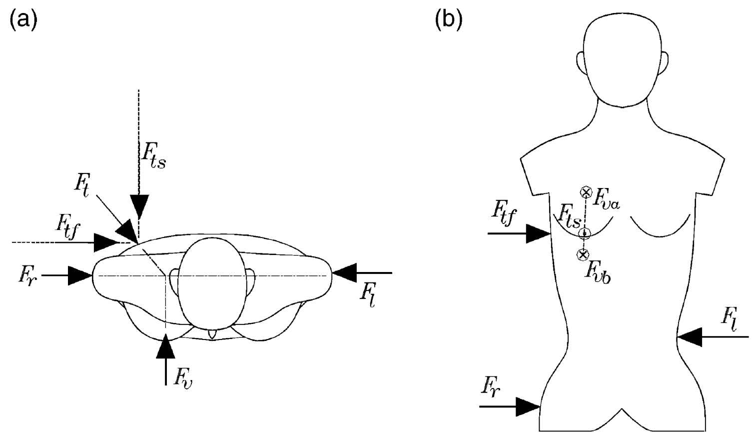

Fig. 4. (a) The force F_t positioned close to the spine to avoid overloading of the ribs will have a frontal F_{tf} and a sagittal F_{ts} component. Consequently, an additional anterior force F_v is needed to obtain equilibrium. (b) This force may be situated near a breast, which should be avoided. Therefore, the construction will be two anterior forces, one above F_{va} and one below the breast F_{vb}. The frontal component F_{tf} of the thoracic correction force together with F_l, F_r forms a 3-force system.

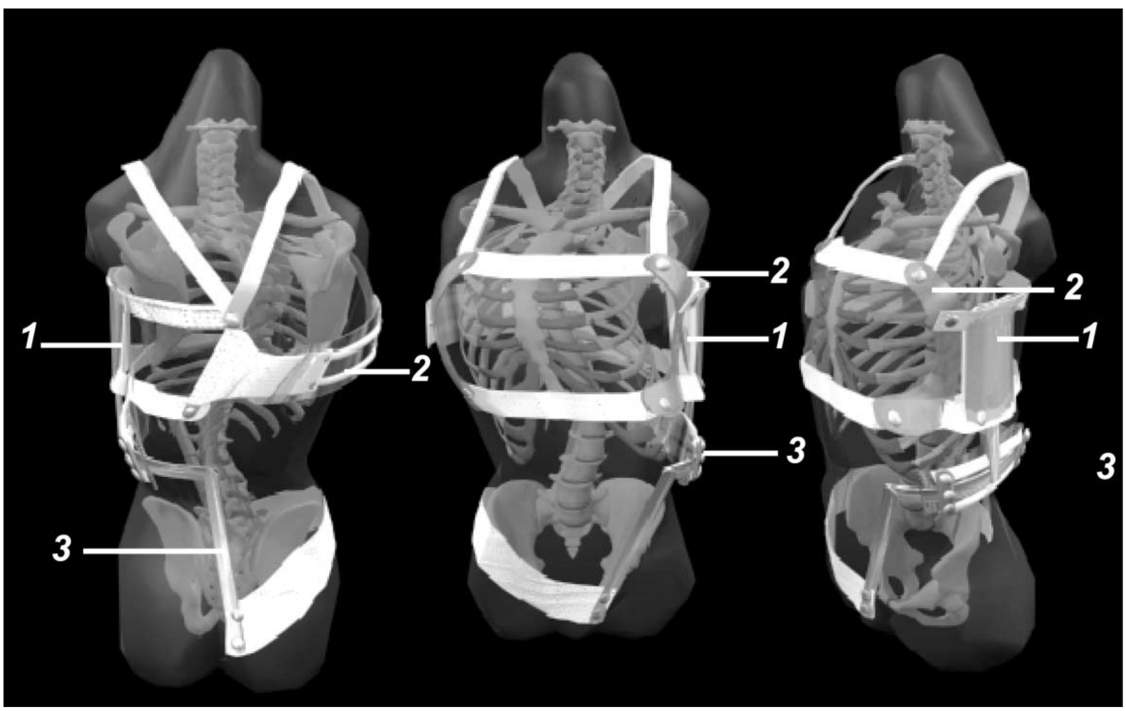

Fig. 5. The TriaC orthosis with the flexible coupling (1) connecting a thoracic (2) and a lumbar part (3).

the lateral deviation in millimetres. Radiographs were taken at six-month intervals in the standing position using Philips Easy Vision Digital Radiographic technique (Philips, Eindhoven the Netherlands). This method is based on radiographic digital reconstruction images. A sequence of overlapping radiographic images of the whole spine is first made from cranial to caudal in the standing position (Fig. 6). These images are then combined via an algorithm into one overview image of the entire spine. For the radiographic measurements, six landmarks per vertebra on each AP radiograph were identified and marked with a cursor by the same observer (Fig. 7).

These landmarks were positioned at the corners of the vertebral bodies and the inner edges of both pedicles from T_1 to L_4. L_4 was chosen as the last vertebra because L_5 often is barely visible in standing AP radiographs because of its large lordotic tilt. The corners of the vertebrae were determined by means of tangent lines through the upper and lower end plates and both lateral sides of the vertebrae. The accuracy of identifying the anatomic landmarks was assessed in a previous study

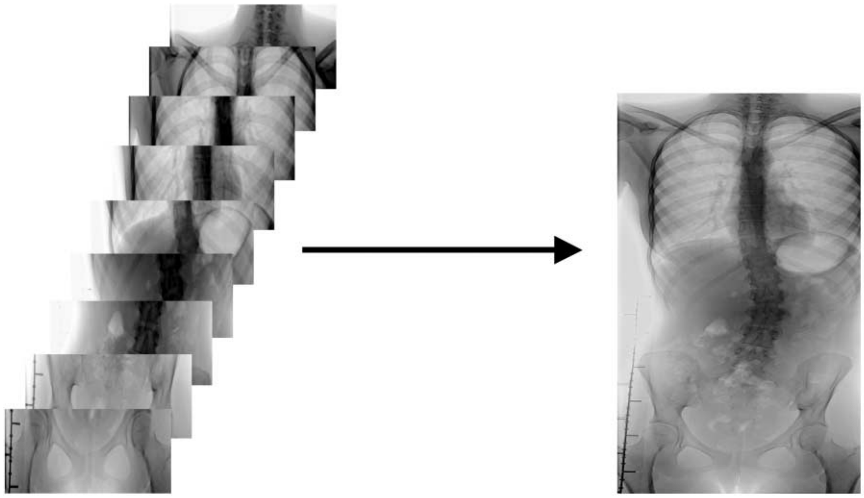

Fig. 6. Translation reconstruction creates overview images of the entire spine.

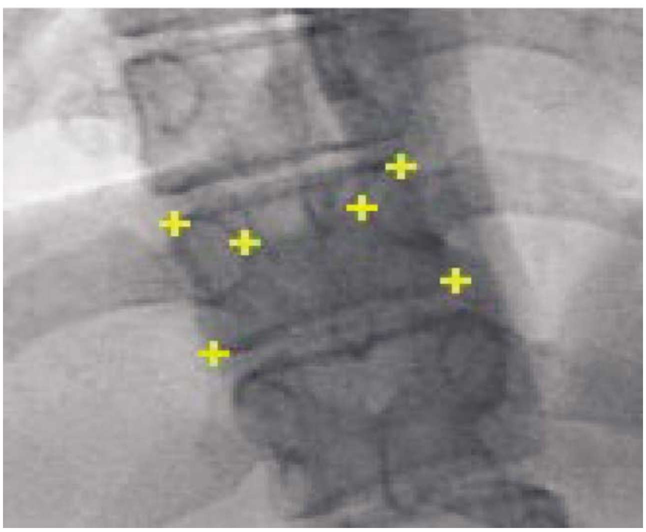

Fig. 7. Positions of the digitised landmarks on the corners of the vertebral bodies and the inner edges of both pedicles on the AP radiograph.

[3,34,35]. With the two-dimensional co-ordinates of the landmarks, the midpoints of the vertebral bodies and the lateral tilt of the upper and lower end plates of each vertebra were calculated by a computer algorithm. The computed Cobb angle consisted of the angle between the upper end plate of the upper, most tilted vertebra and the lower end plate of the lowest, most tilted vertebra in the scoliotic curve, and thus an equivalent of the Cobb angle measured clinically. The axial rotation was determined with a method adapted from Stokes et al. [32], which uses the co-ordinates of both pedicles and the midpoint of the vertebra.

A single observer made all the measurements, and all patients were followed prospectively.

Statistical analysis for differences in time for the three measured parameters was performed using the Friedman's two-way analysis of variance test. Level of significance was reached when the p-value (two-tailed) was less than 0.05.

4. Results

Nineteen patients are still wearing the brace, of which eight patients have passed their rapid growth period but have not yet completed their growth, although further deterioration is not very likely to occur. Seven patients have shown progression of their curves and an operation was indicated.

Nine patients have completed their growth and ended their brace treatment.

In order to determine the change in the three parameters described above, the averages of each parameter measured on each visit were compared. The initial mean Cobb angle, measured with the 'landmarks' method before brace treatment, was 26.5°, the mean lateral displacement at the apex 18.5 mm, and the initial axial rotation of the apex was 12.3°.

The overall results of the 35 patients are shown in Fig. 8A, while Fig. 8B shows the results of the 19 patients still wearing the brace. Nine patients (one male, eight females) have completed their growth, and the results of the post-brace group are shown in Fig. 8C.

Analysis of differences between each successive visit showed that the difference was not statistically significant for the Cobb angle (p=0.71), nor for the other parameters (p=0.24 for the rotation angle of the apex) as shown in Tables 1 and 2.

The new brace has prevented further deterioration of the scoliotic curves, except for the seven patients, who required surgery.

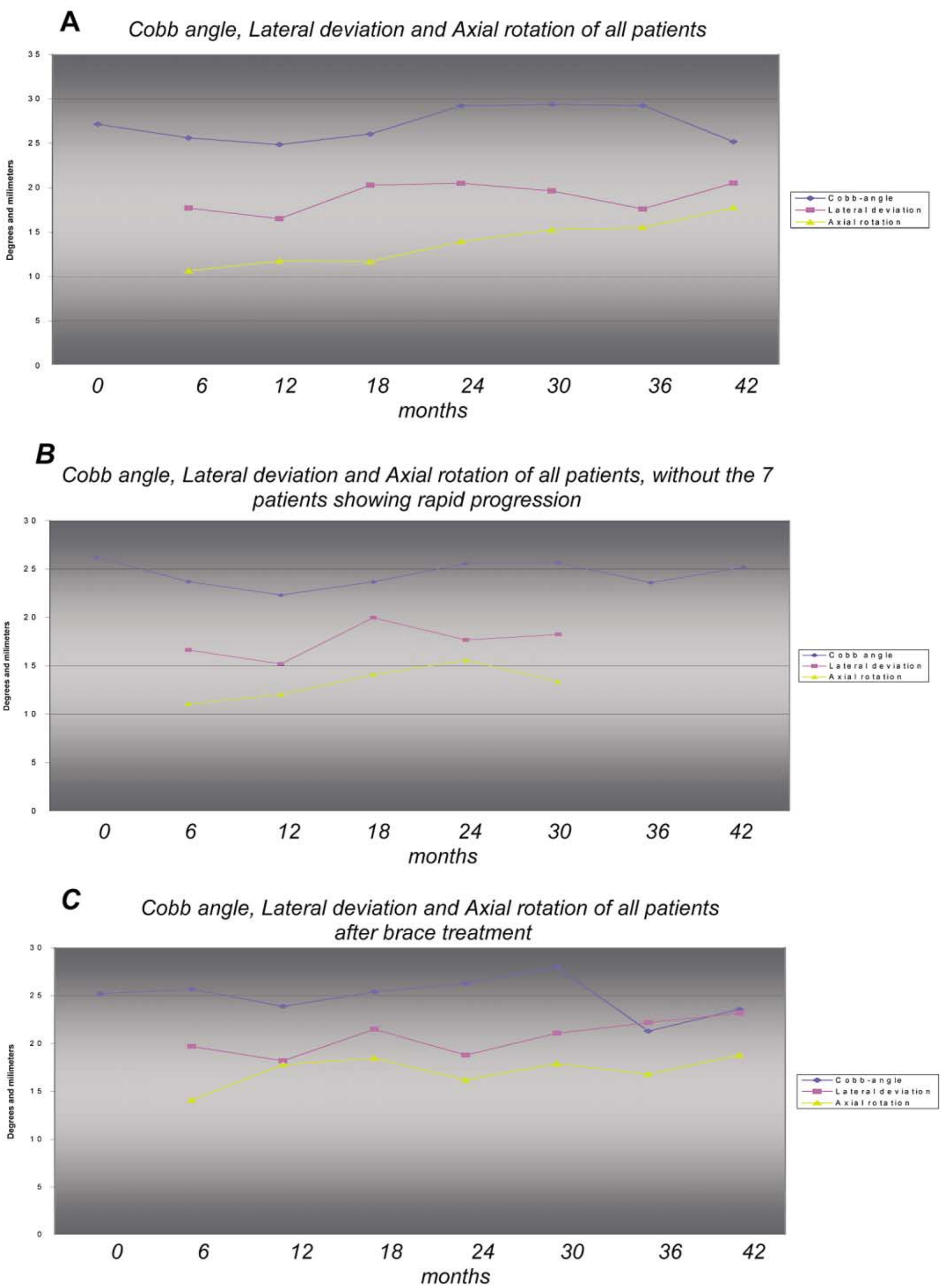

Fig. 8. The results of 35 patients are shown in A, including the seven brace-failures, while in B those failures are removed. Nine patients have ended their brace-treatment and their post-brace results are shown in C, showing stable curves.

5. Discussion

Braces are the oldest recorded method of treatment of spinal injury and deformity. The primary goal in treating a patient with a scoliosis deformity is to stabilise the curves to prevent further progression of the deformity. Closely related to this is the goal of achieving correction of spinal deformity, although this is not part of the therapeutic regimen for every patient. Although there is a wide variety of braces, all the commonly used really have the same working principle. The purpose of these braces is to obtain correction by applying forces in the frontal plane. The correction forces induce a bending moment on the spine in order to correct the lateral curves. However, these bending moments not only correct the curves but they also induce a horizontal dis-

Table 1
Cobb angle during six follow-up visits measured with the landmark method (Friedman χ^2=1.4; *df*=3; *p*=0.71)

Visit	Mean Cobb (°)	95% CI (°)[a]
1	26.5	(19.9–28.3)
2	21.5	(15.9–28.3)
3	20.0	(15.9–30.3)
4	21.5	(15.9–30.3)
5	24.2	(19.9–28.3)
6	23.4	(22.7–30.3)

[a] 95% CI=confidence interval.

Table 2
Rotation of the apex vertebra during six follow-up visits measured with the landmark method (Friedman χ^2=4.23; *df*=3; *p*=0.24)

Visit	Mean Cobb (°)	95% CI (°)[a]
1	12.3	(8.8–15.8)
2	8.9	(8.0–15.8)
3	8.0	(7.1–15.8)
4	12.3	(8.1–18.5)
5	13.4	(8.7–18.6)
6	9.4	(8.3–19.9)

[a] 95% CI=confidence interval.

placement of the head, resulting in a response from back muscles to maintain the head vertically above the pelvis (righting reflex). Therefore, the correction obtained by the brace is not only the result of external forces but also of internal muscle forces. It has been suggested in the literature that the largest amount of correction from a brace be obtained via these muscle contractions [26,33]. Besides affecting the lateral curve most common braces reduce the sagittal lordosis and kyphosis by tilting the pelvis. The purpose of pelvic tilt is to move the lumbar spine closer to the correction pads within the brace. Furthermore, reducing the lumbar lordosis may automatically lead to a reduction of the scoliosis [16] as a result of a coupling mechanism between sagittal and lateral motions of the vertebra [26]. However, reduction of lumbar lordosis will also reduce thoracic kyphosis and this is not really wanted, because a reduced thoracic kyphosis is already an integral component of the scoliosis deformity [39].

Schaal et al., therefore, emphasise the necessity of a system to diminish the effect of pelvic tilt on the thoracic kyphosis [31].

There is a contradiction in the two-fold working principle of conventional braces. On one hand the brace has to apply bending forces to straighten the spine, and at the same time the patient is supposed to move away from these forces in order to provide self-correction.

In the new brace a choice has been made for applying continuous correcting forces with the aim of reversing the deforming forces [24].

A transverse force system, consisting of an anterior progression force counteracted by a posterior force and torque, acts on the vertebrae of a scoliotic spine. The posterior reactions are provided by the musculo-ligamentous structures, which show viscous behaviour during growth. Failure of these structures will result in slowly deviating of the vertebrae towards the convex side of the curve.

The aim of the new brace is to reverse this transverse force pattern by externally applied and constantly present orthotic forces. Growth is a continuous process and therefore, the correction forces must be applied continually, even during normal body motions of the patient.

In order to meet this requirement a flexible coupling, connecting a thoracic and lumbar part of the brace must be incorporated in the device. Furthermore, the forces in the brace must be applied in such a way that they can be maintained during the body motions of the patient.

The new brace consists of three different functional elements: frame, elastic elements and pelottes. The elastic elements induce the orthotic forces, which are distributed by the frame and transmitted to the skin by pelottes. Moreover, a flexible coupling unites the thoracic and lumbar frame parts.

In the first group of patients the above-described elastic elements were used. However, due to perspiration, the elastic elements lost their elasticity quite soon. Moreover, patients could alter the amount of forces applied themselves. A change in the design, therefore, was made; the elastic elements have been replaced by springs, resulting in the application of constant forces that cannot be altered by the patients themselves. (Figs. 9 and 10). The amount of externally applied forces has been chosen from the literature [4,8,15].

Brace treatments do not generally correct the scoliosis, but prevent further progression, i.e. bracing has a 'holding effect' [40]. In the published studies, the brace treatment has been considered a failure if the patient subsequently had operative stabilisation or if the curve progressed five degrees or more compared with the curve before the bracing [1,2,5,7,9,18,20,21,28].

The current preliminary study demonstrates seven brace failures (20%). However, the rate of failure in the patients for the same level of skeletal maturity as measured by the Risser sign and an initial curve of between 20 and 29 degrees Cobb angle was 40% in the Lonstein [18] and 36% in the Bassett study [1], while the expected rate of failure in the natural history study [17] was 68%.

The TriaC-brace allows a good primary correction of idiopathic scoliosis (Fig. 1). The average correction within the brace was 20%, less than reported in the literature [1,18,20,21].

In the beginning, we have not been certain how patients will respond to the application of constant

Fig. 9. TriaC brace.

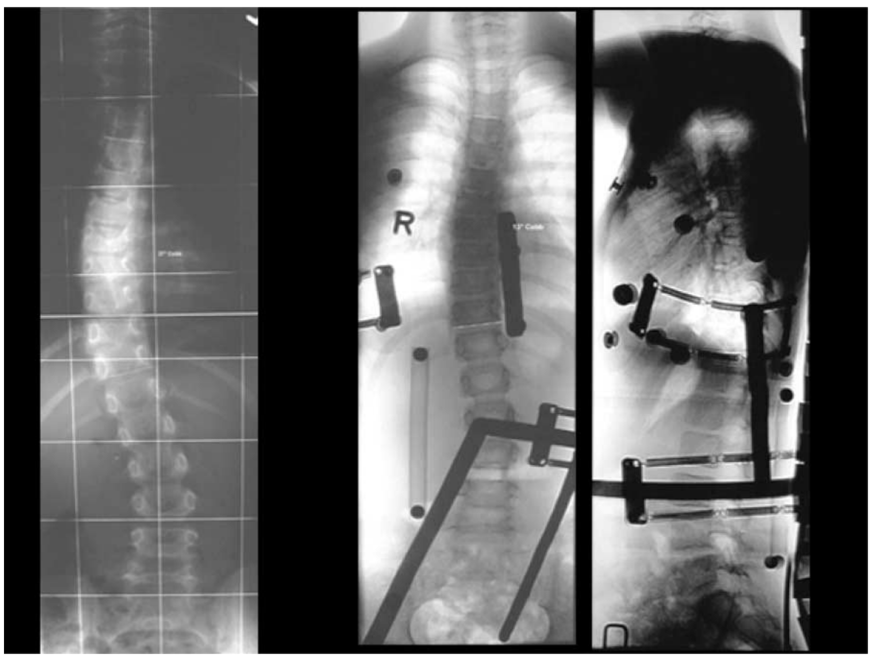

Fig. 10. Pre-brace Cobb-angle: 30° and 19° apical axial rotation. In the brace Cobb-angle: 17° and 9° apical axial rotation.

forces. Therefore, we have started very carefully with low forces, but patients tolerate these forces very well and we have increased the amount of forces resulting in dramatically improved corrections. According to the literature, the achieved corrections will gradually disappear after the ending of the brace treatment [2,10,18,21,40]. The main correction loss will take place within two years after cessation of the brace treatment [10,21].

In our study nine patients have ended their brace treatment and have maintained their achieved correction for nearly two years. Correction in the conventional braces is based on elastic behaviour of the spine while the constant forces in the TriaC braces may effect viscous behaviour. Naturally, the number of patients is too small and the follow-up period too short to make definite claims, but at least it is promising. Although every treating physician and every patient would like to have a permanent correction of the curve, the main purpose of treatment will be preventing of further progression of the deformity. There is no correlation between best correction achieved with the use of the brace and brace failure [18].

However, being efficacious is not enough; a brace must be reasonably comfortable and cosmetically acceptable so that the teenagers who require this treatment will use it.

The brace non-acceptance of a brace by the patient is a serious problem. Houghton et al. [12] placed a hidden transducer in their braces and found that true compliance was considerably less than was reported by the patient; only 20% wore the brace as prescribed.

Modern materials, lower profiles and reduced wearing times have all been tried to improve acceptance and reduce the emotional difficulties encountered with brace wear.

According to some authors, there is little difference in effect between part-time (12–16 h) and full-time (23 h) wearing of a brace [6,9]. Kahanowitz [13] reported similar findings but only if the pre-brace Cobb-angle were less than 35 degrees; if larger than this, then more than 50% would progress to such an extent that surgery became necessary.

Bio-mechanically, small forces with the right properties and long enough duration of application will have the same effect as large forces applied for a short period of time. The lack of difference between part-time and full-time wearing may reflect brace compliance: wearing the brace part-time is always better than not wearing the brace at all.

The new brace is extra effective as a result of the greatly increased comfort. There are no restrictions in daily or sporting activities and it can be worn with all types of clothing.

The simplicity of application and the low production costs are also positive attributes.

The current preliminary study demonstrates that the TriaC brace reduces the scoliosis, and the achieved correction is maintained after cessation of the brace and it also prevents further progression of the Cobb angle and the vertebral rotation in idiopathic scoliosis. The new brace does not differ from the conventional braces as far as maintaining the deformity is concerned. This is not surprising, because the force system of the TriaC brace in the frontal plane is in accordance with the force system in the conventional braces. However, the new brace offers more comfort to the patient, a better cosmetic appearance and, potentially, a better compliance. Theoretically, it is to be expected that, if the treatment starts early, the constantly applied orthotic forces will result in viscous recovery of the musculo-ligamentous structures, and in permanent reduction of the scoliosis. This, of course, has to be proven in a long-term prospective study.

Furthermore, it must be mentioned that our results are short-term. The present study is being continued, and a European multi-centre long-term prospective study will be started this year.

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