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The flexible TriacTM-Brace for conservative treatment of idiopathic scoliosis. An alternative treatment option ?

Alexander ZEH, Michael PLANERT, Stefan KLIMA, Werner HEIN, David WOHLRAB

From Martin-Luther-University, Halle-Wittenberg, Germany

The flexible TriacTM-Brace was developed to improve cosmetic appearance and wearing comfort. It was evaluated in this study with respect to primary curve correction in idiopathic scoliosis (IS).

Twenty patients (15 girls, 5 boys, mean age : 12.5) with a diagnosis of IS were treated with the TriacTM-Brace. Lumbar curves showed an initial average Cobb angle of 26° (SD = 9°), thoracic curves of 25° (SD = 7°). After 6.2 weeks the primary curve correction was measured (Cobb). Further radiological follow-up was done every 6 months during the average wearing time of 15 months. Cosmesis and wearing comfort were assessed by a valid scoring system (Quality of Life Profile for Spine Deformities).

We observed a primary correction of 41% in lumbar curves (n = 12) (significant, t-test), and 10% in thoracic curves (n = 17) (not significant, t-test).

An increase in correction over time as reported by Veldhuizen *et al* was not seen. Curve progression was noted in five patients (average 12°). The scores for cosmesis (4.2/5) and flexibility of the back (4.6/5) were high. Ninety percent of the patients reported a wearing time of 22-23 h.

We do not recommend treatment of thoracic or double curves with the Triac[™]-Brace. Larger studies are necessary to assess the effectiveness in lumbar curves. The improved wearing comfort is a potential advantage.

Keywords : TriacTM-Brace ; idiopathic scoliosis ; brace ; primary correction.

INTRODUCTION

The TriacTM-Brace (Sporlastic GmbH, P.O. Nürtingen, Germany) was designed under the direction of Veldhuizen *et al* for conservative treatment of idiopathic scoliosis (IS) (27).

The developers of the TriacTM-Brace see the improved cosmetic effect as leading to greater patient acceptance and flexibility of the device

■ Werner Hein, MD, Professor of Orthopaedic Surgery, Head of Department.

■ David Wohlrab, MD, Attending Orthopaedic Surgeon, Assistant Professor.

Department of Orthopaedic Surgery and Traumatology, Martin-Luther-University of Halle-Wittenberg, Faculty of Medicine, Halle/Saale, Germany.

■ Stefan Klima, MD, Attending Orthopaedic Surgeon and Traumatologist.

Department of Traumatology and Reconstructive Surgery, Plastic Surgery, Leipzig University, Faculty of Medicine, Leipzig, Germany.

Correspondence : Alexander Zeh, MD, Department of Orthopaedic Surgery and Traumatology, Martin-Luther-University of Halle-Wittenberg, Faculty of Medicine, Halle/Saale, Germany.

E-mail : alexander.zeh@medizin.uni-halle.de © 2008, Acta Orthopædica Belgica.

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Alexander Zeh, MD, Attending orthopaedic Surgeon.

[■] Michael Planert, MD, Orthopaedic Surgeon.

without restriction to sporting activity as being major advantages in comparison with conventional devices.

The Boston, Chenau and Bending braces mainly used in Europe, are highly effective and must be regarded as the standard against which a new concept should be measured (8,11,19,28).

This study presents the results of the TriacTM-Brace with regard to the primary correction achieved and with respect to the evaluation by the "Quality of Life Profile for Spine Deformities" (11).

PATIENTS AND METHOD

Basic features of the device are the principle of correction by forces which continuously take effect and its flexibility. Curvature correction is achieved by the three-point principle in the sense of a translation.

The flexibility of the device allows for both a lateral inclination as well as an ante flexion, whereby a constant truss pad pressure is achieved by a spring tension mechanism.

The TriacTM-Brace was developed for the conservative treatment of idiopathic scoliosis. The indication range is determined by a Cobb angle of 15 to 40°. Contraindications are a scoliosis apex higher than Th 7, a scoliosis apex about the thoracic-lumbar transition (Th 11-12), and secondary scoliosis (3,27).

The TriacTM-Brace was used from January 2002 to December 2004 in accordance with the indication criteria for conservative therapy of an IS postulated by Veldhuizen et al (27). Prescription was determined in agreement between the patients and the parents, after they had been informed about the new type of brace system.

Patients with curvature of 15-25° (Cobb) were provided with the TriacTM-Brace if a progression of 5° within 6 months was attested. For curvatures of more than 25° . the TriacTM-Brace was prescribed at the first consultation if a Risser sign of 0-III was present or the menarche had taken place no longer than 12 months previously (23).

The upper limit for brace prescription was a Cobb of 40°.

In one case (No. 11, table I), the device was provided at Risser IV, in a female patient for whom, because the menarche had taken place less than a year earlier, there was reason to assume there was adequate growth to come, with correction potential.

As a departure from the Cobb angle limit, in case 7 (King II with 48° Cobb thoracic) because of the decisive

Case number	b Gender	Age (years)	King Classific	Range thoraci	Range lumbar	o Risser	Wearing time (months)
1	I C	15.91	I	17-112	112-L4	3	0.0
2	f	15.11	1	T5-L1	LI-L4	3	10.0
3	t	12.39	1	16-112	T12-L4	2	49.0
4	m	11.38	Ι	T4-T10	T10-L4	2	28.0
5	m	15.17	Ι	T5-T12	T12-L4	3	6.0
6	m	13.51	Ι	T6-T12	T11-L4	2	31.0
7	f	12.99	II	T5-T11	T12-L4	3	5.0
8	f	13.89	II	TT7-TL1	L1-L4	3	24.0
9	f	8.34	II	T5-L1	T12-L4	2	28.0
10	m	10.59	II	T1-T8	T9-L3	2	19.0
11	f	16.03	III	T5-T11		4	9.0
12	f	6.80	III	T5-T11		2	8.0
13	m	15.10	III	T6-T12		3	8.0
14	f	13.17	III	T7-L3		3	2.0
15	f	14.45	III	T6-T12		3	6.0
16	f	11.51	III	T5-T11		3	5.0
17	f	12.33	III	T6-L1		3	2.0
18	f	11.81	III	T5-L1		2	2.0
19	f	7.41	IV	T4-L4		2	36.0
20	f	13.25	LS		T12-L4	3	9.0
Μ		12.5				2.6	14.7
SD		2.6					13.4

Table I. — Patients Demographics (m = male, f = female, M = mean, SD = standard deviation, LS = lumbar scoliosis)

noracic curves

assification

umbar curves

rejection of a rigid device by the parents and the patient, the TriacTM-Brace was provided. In addition, despite extensive explanation of the presence of an indication for surgery, a conservative therapy attempt was preferred.

Weaning began with Risser sign IV and a growth < 1 cm within the last 6 months. Among girls, an additional requirement criterion was the presence of menarche for at least 24 months (22).

All the patients received a Schroth's 3-dimensional exercise therapy during the entire follow-up once a week, with instruction for daily individual exercises. Partial exemption from sport was prescribed (no jumping exercises and no sustained running).

At the first follow-up examination, which was carried out on average after 6.2 weeks, the AP radiograph of the spinal column was taken with the device in place, standing upright in order to determine the primary correction.

In cases with a primary main curvature correction of less than 30%, a correction of the spring tension was carried out, or a change in the pad location if appropriate, on the basis of the X-ray image.

In these cases a further X-ray examination was carried out after 4 weeks in order to check on the effect of these measures.

Otherwise, a repetition of the X-ray examination of the spinal column was carried out with the device in place every 6 months, during an average follow-up period of 15 months.

All the Cobb angle measurements were conducted by the first author (6). The primary correction was defined as the difference between the initial Cobb angle and the Cobb angle measured at the first X-ray examination or at the X-ray examination carried out after possible correction of the spring tension or the pad position.

An increase of 5 degrees or more in the Cobb angle was determined as a significant progression.

Wearing time, comfort, and leisure activity were investigated with the "Quality of Life Profile for Spine Deformities" at the last follow-up examination. The score was translated into German by the first author. There was no trans-cultural adaptation or validation (4).

RESULTS

From January 2002 to December 2004, 20 patients (15 girls, 5 boys, average age 12.5 years) were treated with the Triac[™]-Brace for conservative treatment of an IS at the Department of Orthopedics of Martin Luther University, Halle/Wittenberg.

At the start of treatment an average Risser sign of 2.6 was noted, with 10 girls being an average of 5 (1-12) months post-menarche, and with 5 premenarchal girls.

The total average wearing time of the TriacTM-Brace was 15 months (SD 13 months).

The patient numbers given hereafter relate to tables I and II

In 2 cases (Nos. 2 & 9) there was a switch from a Chêneau brace to a TriacTM-Brace after an average of 15.3 months of treatment, when the patient grew out of the rigid device.

At the start of the treatment an average Cobb angle of 26° of thoracic curvature was measured (SD 9°) and 25° for the lumbar curvature (SD 7°). For thoracic curves, the apex lay at an average height of Th9 and for lumbar curves at L2.

At the first follow-up examination after 6.2 weeks, a primary average correction of 10° was measured in the lumbar curves (n = 12, with inclusion of King IV scolioses). This corresponds to 41% of the initial average Cobb angle (SD 6°; t-test, p = 0.01)).

The primary correction for thoracic curvatures (n = 18) was 3°, which corresponds to 10% of the initial average Cobb angle (SD 4°; t-test, p = 0.43).

For King III scoliosis in particular (n = 8; 7 girls, 1 boy, average age 13) no statistically significant correction could be measured at the first follow-up examination (t-test, p = 1.0). This finding remained unchanged after case No. 13, which for the reasons given was prescribed the TriacTM-Brace outside the indication framework postulated by Veldhuizen *et al*, was excluded from the statistical calculation (t-test, p = 1.0) (27).

An increase in correction at the second or third follow-up examination, and also in the further course of the study was observed with 2 patients or 3 curves (Nos. 1 and 2) respectively. This increase in correction amounted to 3° on average and therefore lay within the error range of the Cobb angle measurement of 5° . On the basis of this minimal measured improvement in only 2 patients, we could not conclude that the dynamic correction postulated by Veldhuizen *et al* is achieved with the TriacTM-Brace (27).

We found an unsatisfactory primary correction (< 30% of the initial value of the main curvature) for thoracic curvatures in a total of 16 out of 18 cases (89%). For lumbar curvatures we recorded an unsatisfactory primary correction in four out of 12 cases (33%).

In five patients a progression of the curve of more than 5° was noted, in relation to the primary correction. This was seen in three thoracic and four lumbar curves and amounted to an average of 12° (table II).

In 5 cases the application of a CBW achieved a substantially better correction. Patient No. 17 did



Fig. 1. — TriacTM-Brace front and back view (Source : Fa. Sporlastic GmbH, Postfach 1448, D-72604 Nürtingen, Germany).

not further attend after the prescription of a CBW and was lost to follow-up (table III) (fig 4).

The evaluation by means of the "Quality of Life for Spine Deformities" (participation by 17 patients (85%)) showed a high value for cosmetic considerations (score value 4.2 out of 5) and mobility of the back (score value 4.6 out of 5).

An objective method of measuring wearing time was not applied. Eighteen patients (90%) indicated a wearing time of 22-23 hours daily.

Continuation of the brace treatment was rejected in 3 cases (Nos. 1, 5, 19) by the patients and parents due to cosmetic objections and frequent defects in the spring mechanism and the thoracic pad, after an average of 16 months (6-36 months).

In two cases (Nos. 7, 13), due to the absence of correction with the TriacTM-Brace 5 and 8 months respectively after the start of this treatment, surgical treatment was carried.

In 8 cases the treatment with the TriacTM-Brace was regularly terminated by weaning.

DISCUSSION

This study focuses on the primary correction observed with the TriacTM-Brace. This is a major prerequisite for a successful bracing for IS. It was not possible to carry out long-term observation and discussion of the curve development after weaning the brace, because of the numerous cases of change of treatment because of unsatisfactory correction (change to the Chêneau brace).



Fig. 2a & b. — TriacTM-Brace in ante- and retro flexion (Source : Fa. Sporlastic GmbH, Postfach 1448, D-72604 Nürtingen, Germany)

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Case number	Initial Cobb angle of thoracic spine	Cobb angle of thoracic spine 1. Follow-up	Cobb angle of thoracic spine 2. Follow-up	Primary correction (degrees) (initial Cobb – 1. follow-up)	Primary correction (%) (initial Cobb – 1. follow-up)	Insufficient correction of thoracic spine (< 30% initial Cobb angle)	Initial Cobb angle of lumbar spine	Cobb angle of lumbar spine 1. Follow-up	Cobb angle of lumbar spine 2. Follow-up	Primary correction (degrees) (initial Cobb – 1. follow-up)	Primary correction (%) (initial Cobb – 1. follow-up)	Insufficient correction of lumbar spine spine (< 30% initial Cobb angle)	Progress	Change to Cheneau-Brace	Brace weaned
1	22	22	18	0	0	x	25	25	22	0	0	х			
2	28	28	28	0	0	Х	32	28	25	4	12	Х			Х
3	22	20	29	0	0	х	22	14	30	8	36		Х		Х
4	20	10	28	10	50		30	10	24	20	67		х		
5	20	20	20	0	0	х	30	20	20	10	33				
6	15	8	8	6	43		16	0	0	16	100				
7	48	38	21*	10	21	х	36	30	20*	6	17	х		Х	
8	20	20	23	0	0	х	20	16	16	4	20	х			Х
9	20	15	15	5	25	х	16	6	6	10	37				Х
10	35	28	32	7	20	х	24	14	20	10	42		х		х
11	24	24	24	0	0	Х									Х
12	20	20	10*	0	0	х								Х	
13	40	40	48	0	0	х									
14	30	30	17*	0	0	х								Х	
15	35	29	29	6	17	х									х
16	28	28	20	0	0	X								Х	
17	20	26				х							х	Х	
18	24	24	12*	0	0	X								Х	
19							27	6	2	21	78				
20							20	10	38	10	50		Х		х
Total						16						4	5	6	8
М	26	24	24	3	10		25	15	18	10	41				
SD	9	8	10	4			7	9	10	6					

Table II. — Primary correction.(1. Follow-up = 6.2 weeks after the start of treatment ; 2. Follow-up = 5.7 months postoperatively on average 1. Follow-up ;* = Cobb angle after change to CBW)

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The evaluation of the indication criteria, values of skeleton maturity, and the basic data from the patients shows that our investigation does not differ from other studies with respect to these parameters (6).



Fig. 3a & b. — Sufficient curve correction (Patient Nr. 4 King I) a : initial radiograph (Th3-Th10 Cobb 26°; Th10-L4 Cobb

30°), b : radiograph at first follow-up (Th3-Th10 Cobb 16° ; Th10-L4 Cobb 16° ; Th10-L4 Cobb 13°).

Independently of the medical necessity, the decision to carry out brace treatment is to be regarded as a substantial intervention into the personal development of an adolescent. The low acceptance of the rigid trunk orthotic device, deriving from the restriction of movement caused and the cosmetic impairment, represents a problem for the conservative treatment of IS (10,18,26).

The development of a cosmetically more favourable brace with greater wearing comfort appears to be a good idea, in view of the fact that the effective wearing time measured objectively in different studies lies well below that prescribed, and in one study amounted to only 20 percent (*12,17*). The significance of the wearing time is underlined



Fig. 4a-c. — Insufficient curve correction followed by switch to a Chêneau brace (Patient Nr. 2 King I). a : initial radiograph (Th5-Th11 Cobb 35°; Th12-L4 Cobb 30°), b : insufficient correction in the TriacTM-brace, c : effective correction after prescription of a Chênau brace (Th5-Th11 Cobb 16°; Th12-L4 Cobb 20°).

by the finding of other study groups that a deterioration in the correction result was demonstrated, with deficient compliance levels (*16,20,21*).

In addition to this, impairment in quality of life must be weighed as an important argument against the brace treatment of IS, in particular inasmuch as the efficacy of brace therapy is not undisputed (9).

For example, Climent and Sanchez in their investigations into the impairment of quality of life were able to determine a statistically significant difference between the Boston brace, thoracolumbosacral orthosis, the Charleston-Bending brace, and the Milwaukee brace, whereby the most severe impairment of quality of life was determined for the Milwaukee brace (4).

Coillard *et al* presented their concept of a flexible orthotic device (SpineCor) for the conservative treatment of idiopathic scoliosis to counteract the cosmetic impairment due to rigid braces as well as

the disadvantage of muscle weakening. The authors postulate that dynamic forces in flexible orthotic devices could achieve a sustained correction (6).

Results from the extensive study showed a primary correction of 38% overall, and 35% in thoracic curvatures in particular (6). The effective-ness of the SpineCor was recently confirmed in a further study which included 170 patients (7).

The recent study by Bulthuis *et al* presents the results of conservative treatment with the TriacTM-Brace in 63 patients with idiopathic scoliosis from 1997 to 2005 (*3*). The indication for treatment was a progressive curve with a Cobb angle between 25 and 40° in skeletally immature patients (Risser 0 or I). Interestingly the range of Cobb angle which was considered to be appropriate for the treatment with the TriacTM-Brace was enhanced from 15-35° (25,27) to 25-40° (*3*). Unfortunately the authors give no information about which consideration led to the significant change regarding this indication.

Case number	King Classification	Primary correction in the Triac TM -Brace (%)	Correction in the CBW Brace (%)		
7	II	lumbar 17	lumbar 44		
		thoracal 21	thoracal 56		
12	III	0	50		
14	III	0	43		
16	III	0	29		
18	III	0	50		

Table III. — Primary correction after switch from the Triac[™]-Brace to a Chêneau-Brace

Table IV. — Literature data on primary correction of idiopathic scoliosis by treatment with rigid braces

Type of scoliosis (King-Moe)	Number of cases	Type of Brace	Percent Primary Correction	Reference
King IV King I,II,III,lumbar King I-V King I-IV King I-V King I,II,III,IV	18 (f) 52 52 (38f,14m) 64 295 79 (76f,3m)	Chenau Chenau Wilmington Boston Boston Wilmington	64% 41% 41% 64% 50% 50%	(14) (11) (28) (19) (8) (1)
King I-V	71 (59f,12m)	Rosenberger	30%	(24)

In 2002 Veldhuizen *et al* reported the results of 35 patients with the diagnosis of idiopathic scoliosis and a Risser sign of 0-2 who were treated with the new TriacTM- Brace at the University Hospital of Groningen since 1996 (27).

In contrast to this investigation, for the recent study of the University Hospital of Groningen which was carried out from 1997 to 2005, a Risser sign of 0 or I was defined as an inclusion criterion (3).

It is unclear if there is a relation in between both study groups and for what reasons the inclusion criteria regarding the Cobb angle and the skeletal maturity were changed.

Both study groups showed a relatively high primary correction of both lumbar and thoracic curves which are lower but comparable with those reported with rigid orthoses (3,27).

In their preliminary study, Veldhuizen *et al* (27) reported a primary correction of 20% whereas Bulthuis *et al* (3) found the primary correction to be 22% for primary and 28% for secondary curves. Bulthuis *et al* observed a primary correction of 34% in their success group (n = 48 ; 76%) and -17% for the failure group (n = 15 ; 24%) (3).

Furthermore, the results after a brace switch show in all cases that a greater curvature correction can be achieved with the rigid Chêneau brace used (table III).

Literature review also reveals that, without exception, higher correction values can be achieved with rigid braces than were observed in this investigation (table IV).

It must also be critically noted that in one case there were a deviation from the indication range. The reason for this has been indicated. It was however demonstrated that, if these cases are excluded, the basic statistical outcome of the study with regard to the primary correction and the lack of progressive correction due to the TriacTM-Brace still remains.

Furthermore is should be stated that the study group is relatively small and that we cannot show a follow-up of our patients comparable to that presented by Bulthuis *et al* (3). The small study group is a result of a limitation of the use of the TriacTM-Brace for the conservative treatment in our department. Also because of the change of brace type in a considerable number of patients owing to insufficient primary correction, we are not able to present follow-up results after brace weaning as in other studies. In contrast we have to consider the correction results achieved with the Cheneau-Brace which have been observed to be superior to those achieved with the TriacTM-Brace.

How should the inadequate primary correction observed in this study in the lumbar and more even in the thoracic region be evaluated ?

Strempel recommends that a primary correction of 30-50% should be achieved as a requisite for a successful brace therapy (26). Buhlman *et al* state that the risk of a progression is higher if no more substantial correction can be achieved with the brace (2).

This observation was confirmed by Landauer *et al*, who were able to show a statistically significant correlation with regard to a successful brace therapy, with a primary correction of > 40% and a high compliance rate (15).

Katz *et al* postulated, on the basis of their retrospective analysis of the treatment of IS by means of the Boston device, that for double-curvature scoliosis cases, as well as a wearing time of 18 hours, a correction of at least 25% is a requisite for a successful brace therapy (*13*).

On the basis of these findings and of our own investigation results, we are of the view that the unsatisfactory primary correction with the TriacTM-Brace represents a clear disadvantage for successful brace therapy for IS.

Of course one has to note the main observation of Bulthuis *et al* that the natural history of idiopathic scoliosis appeared to significantly improve with the use of the TriacTM-Brace (3). Also, there is no doubt about the advantage of an improved cosmetic appearance and comfort of this dynamic brace.

In our investigation, in the survey according to the "Quality of Life Profile for Spine Deformities", very high values were noted for cosmetic effects and mobility of the back. Even though no direct comparison was established with the Cheneau brace, which is used as standard in our department, the very high assessments point to an advantage of the TriacTM-Brace. The wearing time was also very high, an important factor in successful brace treatment.

However, it is known from studies of the objective wearing time measurements, that patients are inclined to over-estimate the wearing time (13).

On the basis of these results, it is therefore the authors' view that the TriacTM-Brace represents an alternative exclusively for the correction of lumbar curves. What indication range can be recommended in relation to the Cobb angle cannot be derived from these results, and more extensive investigations are required. According to the results by Bulthuis *et al* one could assume that in lumbar curves also, a Risser sign between 0 and I and a high flexibility of the curves are prerequisites for the treatment with the TriacTM-Brace (*3*).

Considering the poor primary corrections achieved in this study with the TriacTM-Brace, and the existence of alternatives in bracing, the TriacTM-Brace is not recommended for the treatment of thoracic curves and double curves.

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