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Original Research Article

Rate of surgery in patients treated with a Chêneau light brace using the SRS inclusion criteria

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ABSTRACT

Introduction: Studies investigating the outcome of conservative scoliosis treatment differ widely with respect to the inclusion criteria used. Prospective cohort studies are available using the Scoliosis Research Society (SRS) inclusion criteria for studies on bracing. These seem to provide a great advantage in comparing different strategies of bracing against each other. Because we had gathered all data pertaining to patients treated with a Chêneau light brace between June 2005 and November 2007, it was possible to identify that sample of patients fulfilling the SRS inclusion criteria from the entire sample.

Aim: The aim of this study was to investigate treatment outcomes in patients treated with Chêneau light brace, who met the SRS inclusion criteria for studies on bracing.

Materials and methods: In total, 34 patients (of 152) fulfilled the SRS inclusion criteria having an average age of 12.06 years (10–13 years), an average Cobb angle of 31° (25–40°), an average Risser stage of 0.35, an average in-brace Cobb angle of 13° (i.e., 59% of in-brace correction). There were 17 thoracic, 10 double major, 6 lumbar and 2 thoracolumbar curve patterns. After a change of workplace concerning the first author, patients could not be followed up on as originally planned. Therefore, telephone interviews were performed by the second author.

Results: In total, 28 patients (average age of 16.5 years) have been contacted, 9 of them still undergoing their treatment. No patient has been operated on (rate of surgery is 0%) and only 1 was not satisfied with the cosmetic outcome of the treatment.

Discussion: The rate of surgery was far less than reported in recent studies using the same inclusion criteria even when all drop outs were rated as failures.

Conclusions: The rate of surgery can be reduced with the help of Chêneau braces of the latest standard and satisfactory in-brace correction. Brace treatment employing the Chêneau brace seems to be effective and, therefore, is clearly recommended. Clinical outcomes may be more important for a patient than radiological outcomes.

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1. Introduction

According to the latest review of literature, brace treatment in patients with scoliosis has to be regarded as being an evidence based treatment.¹⁵ Several bracing concepts are utilized today for the treatment of scoliosis and the in-brace corrections accepted as sufficient vary widely. The plaster cast method of brace construction seems to be the most practiced technique worldwide for the construction of hard braces at the moment. Computer aided design (CAD) systems are available, which allow for brace adjustments without plaster. Another development, however, is the ScoliOlogiC off the shelf system enabling the certified prosthetist and orthotist (CPO) to construct a light brace for scoliosis correction from a variety of pattern specific shells to be connected to an anterior and a posterior upright.²⁷ This Chêneau light brace, constructed according to the Chêneau principles, promises a reduced impediment to the quality of life in this brace. The correction effects for the first 81 patients (main diagnosis: adolescent idiopathic scoliosis (AIS) – 64 cases or early onset scoliosis (EOS) – 15 cases), treated

according to the principles of the Chêneau light brace have shown a satisfactory in-brace correction exceeding 50% of the initial Cobb angle.²⁹

Although the effectiveness of brace treatment has been questioned,⁹ there is evidence that brace treatment can stop the curvature progression^{5,8,12,13,15,16,21,23,26,32,40,41} (Fig. 1), reduce the frequency of surgery^{7,14,20,24} and improve cosmetic appearance.^{17,18,19,28,38} Poor cosmetic appearance may be the most important problem for the patient. This problem can be solved or at least reduced through the use of advanced bracing techniques including the best possible correction principles available to date.³⁸

The Chêneau light brace was developed to make the brace lighter, finer, easier to wear, and through this, to allow for a better quality of life for scoliosis patients under brace treatment. This is accomplished by using less material in comparison to traditional bracing systems intended for scoliosis treatment (Fig. 2).

Many 3-point pressure systems are applied on the frontal, the coronal and the sagittal plane. An expansion void is implemented opposite every pressure area. This enables the desired

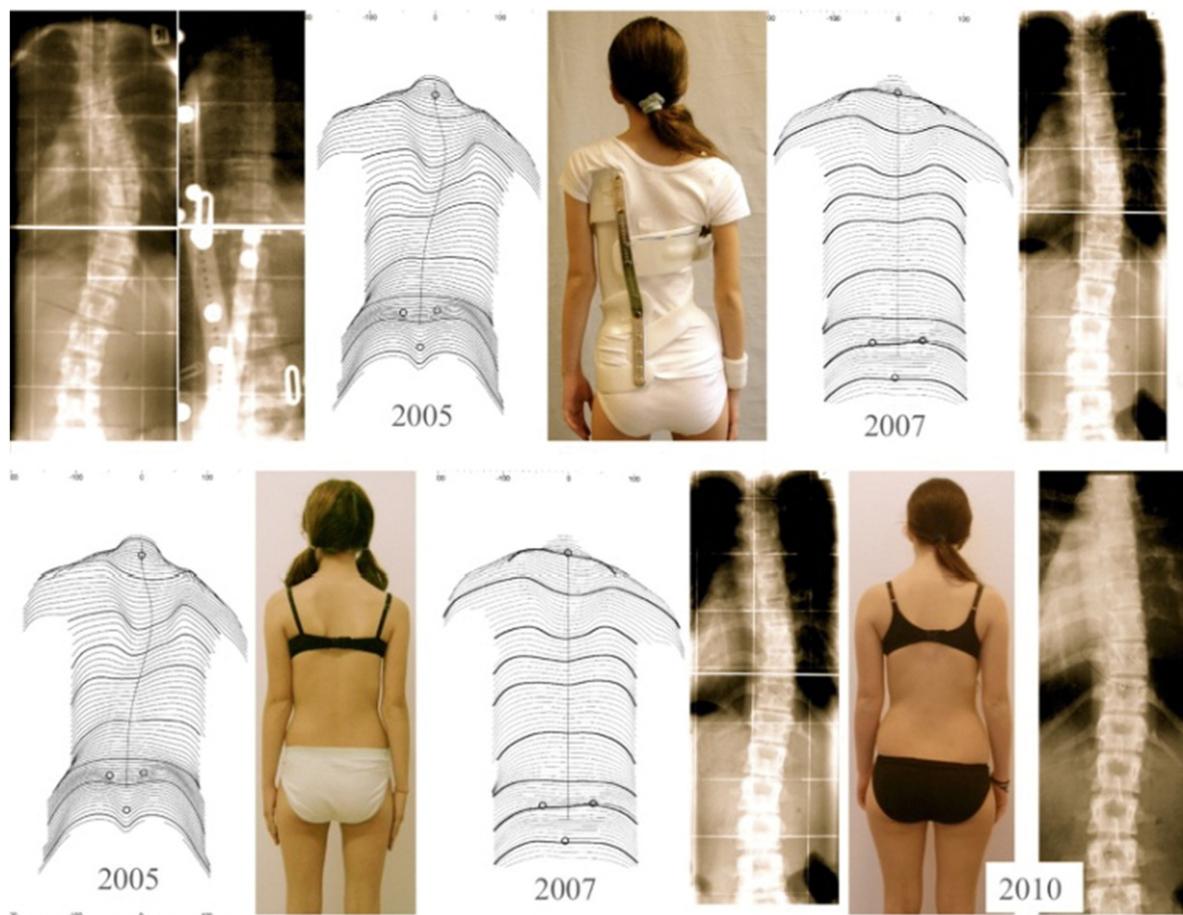


Fig. 1 – Example of a patient with an initial overcorrection in a Chêneau light brace. *Upper line:* Overcorrection of a thoracic curve from 38° to -14° in a T2 “Chêneau light” model in an 11-year old premenstrual girl with Tanner II displayed in the left three pictures. After 2 years of treatment the curve without the brace on was corrected to 19° . *Lower line:* Patient with the complete documentation – images to the left (2005) at the start with 38° , images in the middle (2007) show a compensated appearance with 18° and, finally, images to the right (2010) after weaning off (at 16 years of age) with a balanced clinical appearance and the curve of 12° . There was no change in July 2011.

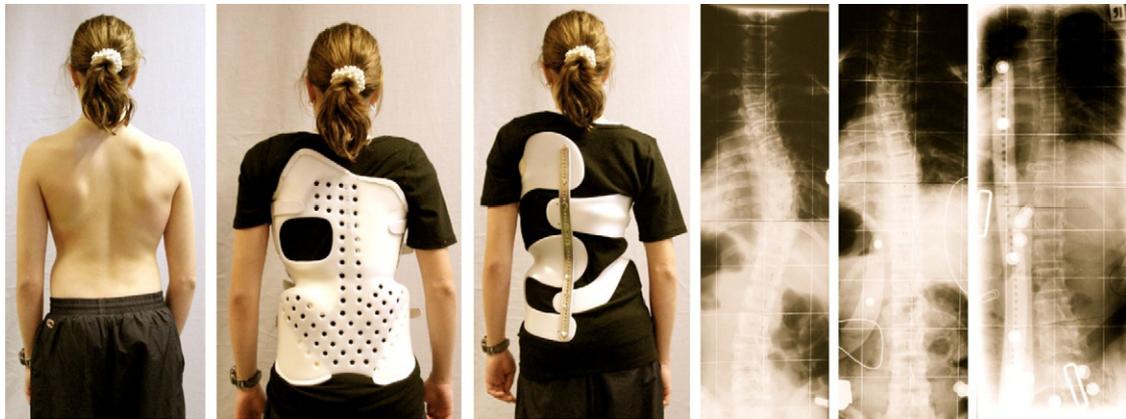


Fig. 2 – A 13-year old girl with AIS (39° thoracic). In the previous brace she had 22° high thoracic, 12° low thoracic and 5° lumbar, while in the Chêneau light brace she has 22° high thoracic, 8° low thoracic and 11° lumbar. The lumbar correction has not been improved since this X-ray in order to achieve a better balance of curves after treatment and a better cosmetic result. The reduction of material in the Chêneau light brace compared to the previous brace is clearly visible. Brace change was necessary due to severe pains experienced in the previous brace.³⁶



Fig. 3 – Patient with overcorrection from 41° to -12° after 6 weeks and clinical improvement at that stage already (right compared to left).

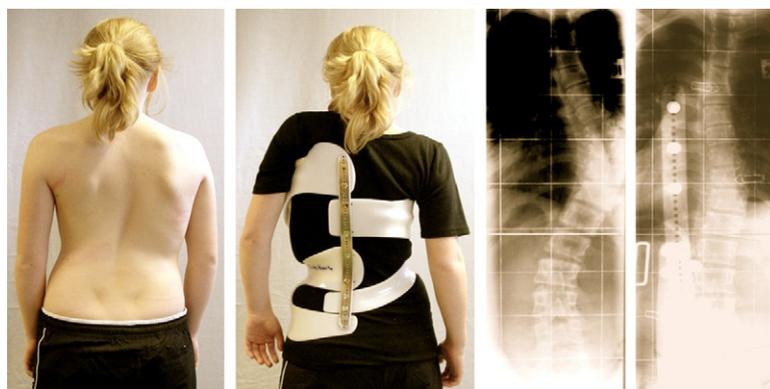


Fig. 4 – A 13-year old girl with 50° Cobb angle corrected to 16° in the brace. This is only possible when the brace is adjusted well and the voids (in this case a void ventral on the rib hump side and a void lateral to the concavity) are clearly visible. In order to achieve maximum possible 3D-correction the concavity must be opened in order to allow for corrective rib movement.

corrective movement (Figs. 3 and 4) and – when adjusted properly – eliminates compression effects leading to pressure sores. As a matter of fact, with contemporary Chêneau braces pressure sores have become a very rare complication.

Pattern specific bracing is desirable to allow for correction of the individual curve patterns appropriately, as theoretically there might be an unlimited number of curve patterns. Therefore, a classification is necessary in order to come as near as possible to addressing the biomechanical properties of the individual curve pattern of the patient treated.³⁶

1.1. Brace description

The ScolioLogiC off the shelf bracing system enables the CPO to construct a light brace for scoliosis correction from a variety of pattern specific shells to be connected to an anterior and a posterior upright. This brace is called Chêneau light brace. The advantage of this new bracing system is that the brace is available immediately, easily adjustable and that it can also be easily modified. This allows one to avoid construction periods of sometimes more than 6 weeks, when the curve may drastically increase during periods of fast growth. The disadvantage of this bracing system is that there is a wide variability of possibilities for arrangement of the different shells during adjustment. Therefore, the technician has to acquire a thorough understanding of basic biomechanics, functional diagnosis and curve pattern identification before being able to properly apply Chêneau light braces.

Shells are available for the treatment of right thoracic and left lumbar curves in three sizes allowing brace adjustments for most of the adolescent patients. For patients with thoracolumbar curve patterns, for left thoracic, right lumbar curve patterns and for smaller sizes a Chêneau light brace can be constructed using the plaster cast technique.³⁶

Braces to address functional 3-curve patterns and braces to address functional 4-curve patterns are available.³⁶ In single lumbar curves, in the 4-curve brace the upper shell carrying the axillary pressure area is cut, as is the dorsal upright.

The brace is usually assembled as a standard “try on” brace first, using the drill holes marked on the individual shells. Then the brace is adjusted according to the individual curve pattern with the help of the pattern specific blueprints.

Studies investigating the outcome of conservative scoliosis treatment differ widely with respect to the inclusion criteria used. Prospective cohort studies are available using the Scoliosis Research Society (SRS) inclusion criteria for studies on bracing.^{4,41} These seem to provide a great advantage in comparing different strategies of bracing against each other. As all data pertaining to patients treated with a Chêneau light brace had been gathered between June 2005 and November 2007, it was possible to identify that sample of patients fulfilling the SRS inclusion criteria²² from the entire sample.

2. Aim

The aim of this study is to investigate treatment outcomes in patients treated with Chêneau light brace, who meet the SRS inclusion criteria for studies on bracing.

3. Materials and methods

In total, 34 patients (of 152) fulfilled the SRS inclusion criteria having an average age of 12.06 years (10–13 years), an average Cobb angle of 31° (25–40°), an average Risser stage of 0.35, an average in-brace Cobb angle of 13° (i.e., 59% of in-brace correction). There were 17 thoracic, 10 double major, 6 lumbar and 2 thoracolumbar curve patterns. After a change of workplace concerning the first author, patients could not be followed up on as was originally planned. Therefore, simple structured telephone interviews were performed by the second author.

The patients or their parents were asked (1) as to whether they knew about any progression of the spinal curvature, (2) as to whether they had meanwhile undergone surgery, (3) as to whether they were satisfied with their final result, and (4) as to whether they would like to provide any other comment.

4. Results and discussion

In total, 28 patients (average age of 16.5 years) have been contacted, 9 of them still undergoing treatment. No patient has been operated on (the rate of surgery is 0%) and only 1 is not satisfied with the cosmetic outcome of treatment. However, this patient is not the one with the largest curvature finally.

As far as we were able to look at the few final X-ray results to be found (12 images), 5 patients have been progressive and 5 have improved (more than 5°). The biggest curvature within this study was 40° at the start. This patient was progressive to 50° at the end of growth. However, this patient was satisfied with the clinical result achieved after the end of the treatment and would not consider surgical treatment. Another patient, starting with 38° at the age of 11 years in 2005 ended up with 14° in 2010 and now is stable after 1.5 years following brace weaning (July 2011). This patient has been recently consulted in our outpatient practice. As it has been already observed, it is not the brace which guarantees the outcome, but compliance, though this is not a new aspect.^{13,21}

As 6 patients from the sample have not been reached (9%), in a worst case scenario, this may be estimated as having undergone surgery.

One of the latest developments in scoliosis braces is the ScolioLogiC off the shelf system enabling the CPO to construct a light brace for scoliosis correction from a variety of pattern specific shells to be connected to an anterior and a posterior upright designed for full day treatment. This off the shelf system is named ScolioLogiC, while the brace after proper adjustment is called Chêneau light brace.

Having improved the in-brace correction of the braces also in the sagittal plane, we were able to improve the correction effect in the frontal plane as well.^{27,35} Compared to the correction effects we achieved in 2003 with other braces,²³ the results now have improved significantly.

In the normal range of brace indications, a correction effect of at least 20% seems necessary to prevent progression,³ while a correction effect of an average 30% promises some final corrections.¹ A correction effect of 40% and more in a growing adolescent may lead to a final correction of an average 7° Cobb angle.¹³

Wong et al.³⁹ reported correction effects of an average of 40% in patients with an average Cobb angle of 30.6° (21.0–43.0°). However, in this collective study no patients with a double curve pattern were included, which generally corrects worse than single curves in our preliminary study.²⁵

Therefore, the Chêneau light brace can be regarded as an effective tool (possibly to be worn full time with good correction effects) for the treatment of adolescents with scoliosis in the majority of cases.

Increased in-brace corrections²⁹ and decreased in-brace stress³⁰ promise an effective treatment when the brace is adjusted well by a certified CPO undergoing our quality management procedures.

The rate of surgery was far less than reported in recent studies using the same inclusion criteria, even when all drop outs were rated as failures.^{4,41}

The rate of surgery has been used in the estimation of treatment outcomes since 2001.⁹ A recent study has even promoted this outcome parameter as a valuable determinant of treatment success.⁶ However, as there are no measurable clinical or radiological parameters associated with the term “rate of surgery,” this term does not seem to be appropriate to serve as a valid measurement of the outcome. Nevertheless, Dolan as the senior author has averaged the rate of surgery to compare a wide range of rates as published with recent data.⁶ However, this procedure does not seem to make sense. A proportion of patients having undergone surgery will never be able to serve as an outcome parameter as it is the patient’s decision to undergo surgery and there is no precise data to determine the necessity of surgery.^{10,11,31,32} As scoliosis surgery does not change signs and symptoms of scoliosis^{10,11,31,32} and as the lifetime risk for complications from this kind of surgery has to be estimated far higher than the surgeons usually tell their patients,^{2,33} it should always be the patient’s decision and at least in those patients with AIS cannot be a medical indication.

Therefore, as well as for the generalizing conclusions the Dolan et al. paper⁶ has been deemed flawed. However, this aspect has been criticized as well, as the conclusions cannot be regarded as valid.³⁴ Scientifically, when the subject investigated is not defined, no conclusions can be drawn! But even more than that, the author⁶ has drawn the conclusion that “the brace does not work.” This kind of generalization cannot be regarded as an appropriate approach to the problem and this is why today there is still no proof against braces, but there are many studies supporting braces.^{5,8,12,13,15,16,21,23,26,32,40,41}

In this paper, however, we had to use the outcome parameter “rate of surgery” because the final data could not be completed due to organizational problems. As the first author had no access to the data he initially had gathered, there was no other choice for estimating the outcome of treatment with this specific brace.

For future studies, of course, it will be the aim to use parameters of more density, mainly the Cobb angle.

The results achieved in this study are better than in those studies employing other bracing concepts and the same inclusion criteria. However, we must admit that the outcome parameter “rate of surgery” used cannot be regarded as being highly reliable. Soft braces, as already reported, have a far higher “rate of surgery” than the Chêneau brace^{4,41} and this is consistent with previous studies performed on this topic.^{26,40}

As there is no evidence for scoliosis surgery and as there exists the highest evidence for brace treatment (level II), claims are not justified to operate upon scoliosis patients rather than treating them conservatively.^{10,11,31,32}

There are also some disadvantages associated with the Chêneau light brace adjustment which have to be discussed. These are the following:

1. A high level of expertise is needed to obtain good in-brace corrections. Most customers who used the system were not able to reach similar results as achieved in our bracing

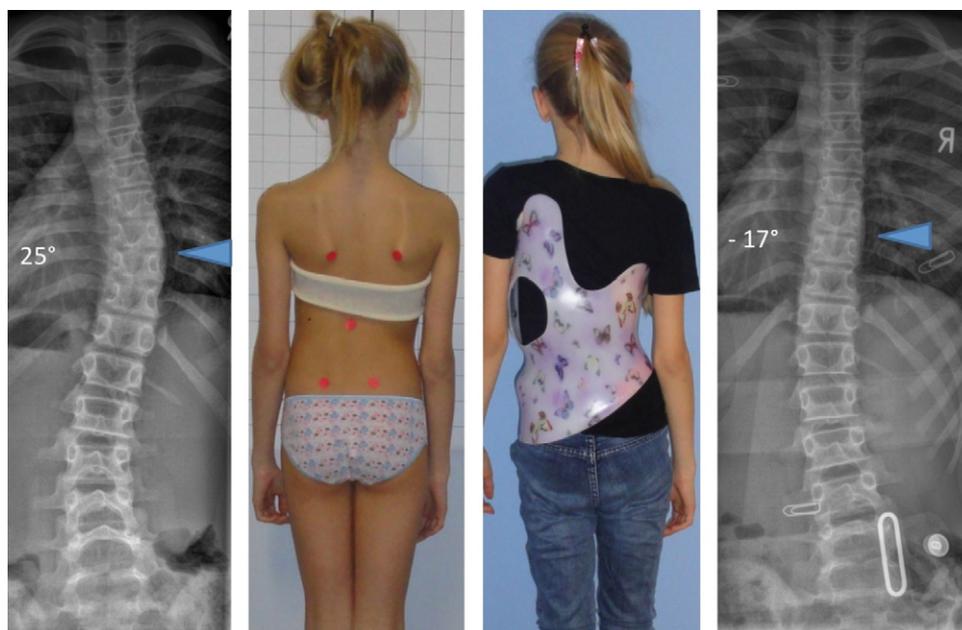


Fig. 5 – Immature patient in the Gensingen brace with an overcorrection. The brace clearly mirrors the deformity.

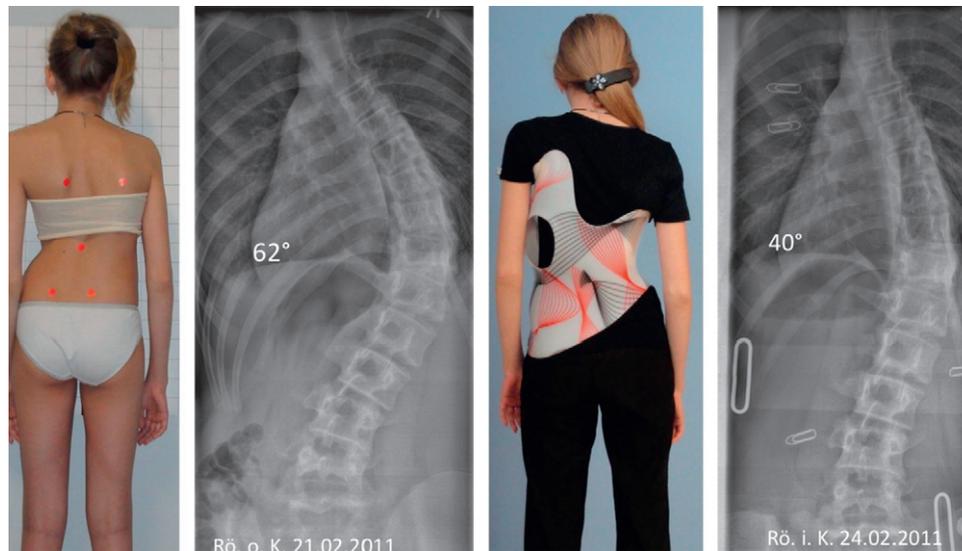


Fig. 6 – Patient with a curvature exceeding 60°. This patient from Russia did not agree to undergo surgery. A satisfactory in-brace correction has been achieved and the brace clearly mirrors the deformity. Curve deviation has been reduced drastically and, therefore, this brace promises an improved clinical outcome.³⁸

unit. Therefore, the system is no longer sold outside, except for one bracing center in Ukraine.

2. The parts available do not fit every possible curve pattern. For instance, certain thoracolumbar curve patterns as well as left thoracic and right lumbar curves need a pattern specific CAD or plaster based construction as long as specific shells are not available to address also those curves.

Therefore, it is necessary to additionally apply other concepts of bracing, mainly CAD/CAM based braces. In our department we have the opportunity to use the Gensingen brace CAD/CAM library³⁷ for patients who refuse the Chêneau light brace or for patients with curvature patterns for which no adjustable parts are available.

The Gensingen brace as the latest Chêneau derivate is based on the same principles of curve correction and, therefore, a comparable outcome will be achievable also with this new brace derivate (Figs. 5 and 6).

The very low “rate of surgery” as achieved within this sample may also be due to the fact that the Chêneau derivatives of the latest standard can improve clinical outcomes^{17,18,19,28,38} as well as radiological ones.^{26,29} Compensating curvatures and improving clinical outcomes may be more important for the patient than radiological outcomes.

Due to incomplete data we have concerning this preliminary report we would not go as far as to compete with the outcome of the Zaborowska-Sapeta et al. study.^{41,42} In our worst case analysis we would expect 9% of the patients undergoing surgery compared to 13% in the Zaborowska-Sapeta et al. study.^{41,42} Nevertheless, as comparable inclusion criteria are used in this study, in another study on the Chêneau treatment^{41,42} and in a sample of patients treated with a soft brace,⁴ we may allow ourselves to compare the rate of surgery in the Chêneau samples (9%, 13%) to the rate of surgery in the soft brace sample (23%). As in the latter sample the rate of surgery is about twice that found in the Chêneau samples, we see no indication for soft braces as

these findings compare quite well to previous independent studies demonstrating the lack of effectiveness of soft braces compared to hard braces.^{26,40}

5. Conclusions

1. The use of the Chêneau light brace leads to correction effects above average when compared to other braces described in literature. The reduction of material seems to increase a patient's comfort and reduces the stress patients may suffer from whilst in the brace.
2. The rate of surgery can be reduced with the help of Chêneau braces of the latest standard and satisfactory in-brace correction can be obtained compared to other bracing systems for which comparable studies are available.
3. The “rate of surgery” has to be regarded as a “low density” parameter and does not necessarily reflect evidence for a treatment regime.
4. Brace treatment with the Chêneau brace seems effective and, therefore, is clearly indicated.
5. Clinical outcomes may be more important for patients than radiological outcomes.
6. The indication for soft braces is questionable.

Conflict of interest

The first author is applying for a patent relating to the content of this paper and is advisor of Koob-Scolitech, Abtweiler, Germany.

Mario Werkmann declares to have no competitive interest.

Authors' contributions

HRW: Analysis and interpretation of data, preparation of the manuscript, acquisition of pictures and additional materials, corresponding author.

MW: Patient acquisition, telephone interviews, pictures.

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Written informed consents were obtained from all persons visible on the pictures submitted.

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