

Brace Wear Compliance

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SRS BRACE MANUAL

COMPLIANCE IN BRACE WEARING

Introduction

Bracewear is the only proven means of conservative management in adolescent idiopathic scoliosis¹⁰.

The 3 essentials⁶ of good bracing are:-

- 1) a mobile, mild idiopathic curve that radiologically corrects well in the brace^{11,12,13}
- 2) a competent fully trained orthotist using a well designed brace
- 3) a compliant patient.

Undoubtedly compliance is the cinderella among the conditions to achieve successful bracing as it remains difficult to measure. It is usually taken for granted that the report of the patient and the parents as to how many hours per day the brace is worn is a reliable figure. Generally speaking those patients who confess to non-compliance tend to have worse results from bracing¹⁵. However as it is such a key area in which to have accurate information, it is surprising that techniques to measure bracewear accurately, such as brace timers, are not in routine use. It goes without saying that the time, expense and efforts of a skilled orthotist are totally wasted if the patient fails to wear the brace. Furthermore if the patient is not wearing the brace the reasons need to be investigated particularly as psychological upset can be a factor for low compliance and clearly in such a case a sympathetic approach is needed¹⁶.

Brace Timers

In 1986 Houghton¹⁹ presented the findings of a pressure activated timer concealed in the rib pad. The theory was that the clock started as soon as the brace was put on because of pad pressure. Similarly when it was taken off the clock recording ceased. The accumulated clock time was then read and divided by the number of days the brace was worn. Houghton's report to the SRS involved 30 patients monitored over 3 months. They all indicated poor compliance with the average daily bracewear being only about 3 hours. In London we tried using this timer but found it to be unreliable particularly if the child loosened the brace or bent forward reducing the

pad pressure. It was very easy for the pressure to drop below the critical point even with the brace on. Therefore the accumulated time on the clock was significantly lower than the time that the brace had been on. For this reason we abandoned the pressure timer. Since then another study²⁰ has also demonstrated that even with the patient under constant supervision in the hospital during the initial period of bracing the compliance is notoriously lower than prescribed. In the study quoted non-compliance was 38%. Therefore compliance in brace patients is still under suspicion.

The London Brace Timer

The current brace timer was developed in 1989 at the Medical Physics and Bio-Engineering Department at University College London and then evaluated over a trial period in the Scoliosis Brace Clinic at the Royal National Orthopaedic Hospital, London. The London Timer consisted of a standard digital watch mechanism connected to a temperature sensing switch set to turn on when the ambient temperature went above 30° C. Similarly if the temperature dropped below 30° C the system switched off. The clock and switch measures 2.5cms squared x 1.5 cms and is easily concealed within the polystyrene pad of the brace.

The Study

Thirty three AIS patients with progressive curves of between 20° and 39° were braced using the RNOH modified Boston TLSO. Within the brace pad of each of the 33 braces a concealed brace timer was installed. Preliminary studies had confirmed the accuracy of the switch. To obtain the brace time per day the total clock time was measured at the clinic and the number of days elapsing from the last attendance was divided into the total clock time. The patient and their parents were not informed about the timer and in only one instance was comment made about the device as revealed on the in-brace X-ray.

Patients attending the Scoliosis Brace Clinic followed a set protocol. After fitting of the brace an erect AP spinal radiograph was taken in the brace and the Cobb angle was noted. This angle was compared with the maximum Cobb angle out of the brace. The patient was recommended to wear the brace 20 hours per day. It was stressed that the 4 hours out of the brace was as important as the 20 hours in it and that the time out of the

brace should be used for recreation, sporting activities, etc. The patients were followed up 4-monthly. On the day of the appointment the patients were asked to take their brace off at the beginning of the day so at least 4 hours elapsed before the erect AP radiograph out of the brace was taken. After this the patient saw the clinician. This followed the protocol of the SRS brace trial ⁷. Once the patient had reached Risser sign 4, brace wear was reduced to nighttime for a period of one year. Compliance was then measured against a 10 hour every day norm.

Each patient contributed to between 2 and 11 readings of the timer. Of the 33 patients, 25 have been out of the brace for one year. Two have progressed to surgery. All the braces were fitted by one orthotist who fully cooperated with the study and was responsible for playing the clock back at each attendance to register the total number of hours.

Results

The concealed brace timer showed a range of recordings of bracewear per day of 0.4 hours to 23 hours over a period that ranged from 4 months to 3 years. The following factors were analysed :-

1) Cobb Angle Correction in the Most Compliant Patient

The 8 most compliant patients who wore the brace over a period of 3 years were recorded as having worn the brace from between 14 and 19 hours per day. In this group the Cobb angle showed a mean correction of 12.7% with a mean reduction of the Cobb angle from 32° to 27°. The finding of these 8 most compliant patients are significantly different from the remaining group.

2) Correlation of Curve Correction with Brace Compliance

A significant change of curve was defined as increase or reduction of the Cobb angle by at least 6° at 2 consecutive visits over a 12 month period (this followed the pattern adopted by the SRS trial). Eight patients showed reduction of the scoliosis. Mean bracewear in this group was 15.9 hours per day. Twelve patients showed no overall change in the scoliosis Cobb angle. The mean bracewear in this group was 12 hours per day.

Thirteen patients showed a definite deterioration in the Cobb angle. The mean bracewear for these was 9.7 hours per day.

3) *Pattern of Brace Compliance*

- a) During the first 4 months bracewear was consistently less than the recommended time, approximately 10 hours per day. This represented the initial stage when the child was becoming accustomed to the brace and clearly tolerance was not up to the full recommended 20 hours.
- b) The second period, that is from 4 to 8 months after the brace was fitted, usually demonstrated the best compliance reading.
- c) The following factors were found as the pattern of compliance was assessed :-
 - i) Brace hours per day was significantly reduced during the summer months due to the hot weather,
 - ii) After 5-6 visits, that is after 2 years, the number of hours per day the brace was worn slowly declined,
 - iii) Brace compliance was related to menarchal status. Compliance was found to be much better in girls who had not yet reached the menarche.

4) *Clinical Judgment of Compliance*

In 24 patients the clinician recorded his own judgment as to whether the patient was compliant or not.

Considerations included:-

- a) the ease with which the brace was donned and taken off without help at the clinic,

- b) skin makings eg erythema and pigmentation in relation to the rib pad,
- c) wear and tear of the brace,
- d) general attitude of the patient and whether there was support of the attending parent.

The brace timer indicated that the clinician's judgment of compliance was wrong in 7 of the 24 of the cases, that is 29%.

Conclusions

The current findings show that compliance in bracewear is a significant factor in achieving a successful result. The most compliant brace wearers appeared to achieve the best results and the best curve corrections occur in those who wear the brace for the greatest time each day. However even the most compliant patients have recordings which range between 14 and 19 hours. Nobody achieved a consistent 20 hours. If the patient is recommended to wear the brace for between 12 and 16 hours a day rather than 20 hours this might be a more attainable goal and may result in more compliance. In fact 16 hours a day may be the optimum value as a balance between effectiveness of brace correction and tolerance of bracewear.

Studies with part-time bracing between 12 and 16 hours per day interestingly do not show inferior results compared with the 20 hour regime^{14,15}. Against this a meta-analysis of bracewear shows that, in regard to the Milwaukee brace, the most consistently successful results were those where the bracing had been recommended for 23 hours each day⁹. However there have been no brace timer studies to assess whether that actually was achievable. The question centres on whether a patient who is instructed to wear the brace for 20 or 23 hours a day is more likely to achieve what might be seen as the essential 16 or 18 hours whereas if he or she is only recommended 16 hours a day an accurate record may show that the brace is on for only 10 or 12 hours per day.

Those studies which have thrown doubt on the ability for the TLSO or Milwaukee Brace to control progression may need to be re-assessed as to whether poor compliance was a major factor in brace failure^{2,3}. Again it is surprising that many of the longterm reviews do not consider compliance^{4,5,8}.

Further Developments

To put a timer in every brace would add to the expense of the orthosis and is probably not necessary. The most valuable period is the first 8 months of bracewear when the compliance will be evident. This finding together with the correctibility of the curve in the brace can help the clinician to decide whether bracewear is worth persisting with it all. Such a decision would need to be discussed openly with patient and parents as persistence with such a treatment would only be a deception.

If the brace timer suggests that for climatic or psychological reasons the brace is only being worn for part of the time probably at night then it would be a realistic option to use the Charleston bending brace as perhaps the most effective night orthosis^{17,18}.

References

- 1 Goldberg C J et al, "A Statistical Comparison Between Natural History of AIS and Brace Treatment in Skeletally Immature Adolescent Girls". Spine, 1993, 18(7) : 902-8
- 2 Noonan K J et al, "Use of the Milwaukee Brace for Progressive Idiopathic Scoliosis". JBJS, April 1996, 78A : 557-671
- 3 Bancel P et al, "The Boston Bracing System for Idiopathic Scoliosis. Follow up Results in 295 Patients". Spine, 1986 11: 792-801
- 4 Carr W A et al, "Treatment of Idiopathic Scoliosis in the Milwaukee Brace. Long Term Results" . JBJS, 1980, 62A : 599-12.
- 5 Edgar M A, "Editorial : To Brace or Not to Brace" . JBJS, March 1985, 67B : 173-4
- 6 Nachemson A L et al, "Effectiveness of Treatment with a Brace in Girls Who Have Adolescent Idiopathic Scoliosis" . JBJS, 1995, 77A (6) : 815-22
- 7 Fernandez-Feliberti R et al, "Effectiveness of TLSO Bracing in the Conservative Treatment of AIS". JPO, 1995 15(2) : 176-81
- 8 Rowe D E et al, "A Meta-Analysis of the Efficacy of Non-Operative Treatments for Idiopathic Scoliosis". JBJS, 1997, 79A : 664-74
- 9 Winter R B, "The Pendulum has Swung Too Far. Bracing for Adolescent Scoliosis in the 1990's" . Orthop Clinics of North America, 1994, 25(2) : 195-204
- 10 Lonstein J E & Winter R B, "The Milwaukee Brace for the Treatment of AIS. A Review of One thousand Twenty Patients". JBJS, August 1994, 76A (8): 1207-21
- 11 Olafsson Y et al, "Boston Brace in the Treatment of IS". JPO, 1995, 15(4) : 524-7
- 12 Upadhyay S S et al, "New Prognostic Factors to Predict the Final Outcome of Brace Treatment in AIS". Spine, 1995, 20(5) : 537-45
- 13 Allington N J & Bowen J R, "AIS : Treatment with the Wilmington Brace. A Comparison of Full-Time and Part-Time Use". JBJS, July 1996, 78A (7) : 1056-62
- 14 Green N E, "Part-Time Bracing of Adolescent Idiopathic Scoliosis". JBJS, 1986, 68A : 738-42
- 15 MacLean W E et al , "Stress and Coping with Scoliosis : Psychological Effects on Adolescents and their Families" . JPO, 1989, 9(2) : 257-61

- 16 Price C T et al, "Nighttime Bracing for Adolescent Idiopathic Scoliosis with The Charleston Bending Brace – A Preliminary Report" . Spine, 1990, 15(12) : 1294-9
- 17 Federico D J & Renshaw T S, "Results of Treatment of Idiopathic Scoliosis with the Charleston Bending Orthosis." Spine, 1990, 15(9) : 886-7.
- 18 Houghton G R, "Monitoring True Brace Compliance", Abstracts of the Scoliosis Research Society Combined Meeting with the British Scoliosis Society, Bermuda, September 1986.
- 19 Edelman, personal communication, 1992.