MILWAUKEE BRACE TREATMENT OF SCOLIOSIS

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The Milwaukee Brace or CTLSO (cervico-thoraco-lumbo-sacral orthosis) is the first modem day brace used to treat spinal deformities. It was developed by Blount and Schmidt for the post-operative treatment of post-polio scoliosis, and was found to be effective in the non-operative treatment of idiopathic scoliosis. The current brace consists of a plastic pelvic section with an anterior and two posterior uprights connected superiorly by a neck ring with a throat mold anteriorly and occipital pads posteriorly, or newer designs with a plastic contoured low profile neck ring. Corrective pads are connected directly to the uprights, or suspended from them by nylon straps. It has been shown by Wong and Evans that the force exerted by the thoracic pad is related to the tension in the thoracic strap.

This section will describe the Milwaukee Brace treatment of scoliosis. The treatment of idiopathic scoliosis is described as it is the most common application of non-operative treatment of scoliosis. The Milwaukee Brace is also used non-operatively in scoliosis of other etiologies as well as post-operatively in juveniles. In addition it can be attached to a halo as a halo-Milwaukee Brace as described by Gotfried and co-workers.

Idiopathic scoliosis is the most common form of scoliosis. It develops in a perfectly healthy child during growth, and is divided into three types depending on the age of onset: infantile (birth to age 3), juvenile (age 3 to puberty) and adolescent (after puberty)

a. Infantile Idiopathic

No active treatment is necessary for the non-progressive variety of infantile idiopathic scoliosis, the curves resolving spontaneously without treatment. These curves are generally less than 35 degrees, and thus any curve over 35 degrees, or any progressive curve needs to be treated. The best treatment is the application of serial well fitting body casts applied under anesthesia, casting continuing until maximal curve correction has been obtained. At this stage a Milwaukee brace is fitted and worn on a full-time schedule (23+ hours a day). This is preferable to a TLSO, which, due to its circumferential fit, causes rib pressure with a resultant tubular thorax and reduced pulmonary function.

After a period of bracing allowing the spine to grow in the straightened position with maintenance of correction, the child is weaned from the brace. If no relapse occurs the brace is discontinued and the child observed to maturity. Mehta and Morel have reported that if the curve is totally corrected prior to the growth spurt, there will be no relapse during adolescence.

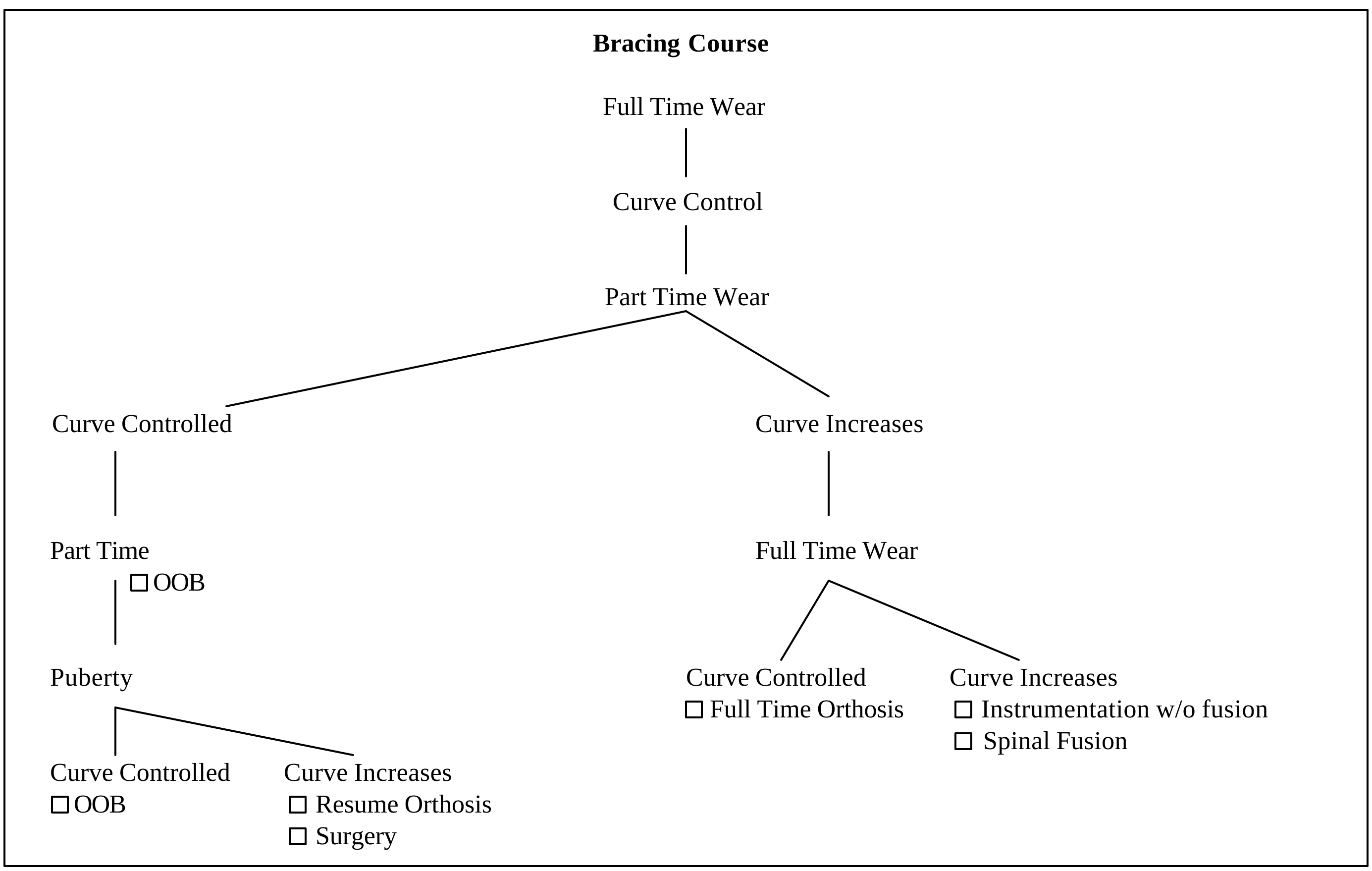
If curve control cannot be maintained with bracing, surgery is indicated. In the juvenile years this is usually instrumentation without fusion (“growing rod”), with external protection in a Milwaukee brace. Periodic lengthenings are performed which allows curve control and continued spinal growth, the construct being protected externally with the Milwaukee brace.

b. Juvenile Idiopathic

Curves first detected in the latter part of the juvenile years that are over 25 degrees or have shown documented progression should be treated non-operatively, the Milwaukee brace being the orthosis of choice. This is because it is easily adjustable for growth, and in addition, due to its open design, it does not compress the thorax with possible tubular thorax and respiratory restriction.

The brace is worn full time for 18 to 24 months till the curve is controlled. If at this time there is good control with a curve maintained at 20 degrees or less, part time bracing can be started. A radiograph is taken after the child has been out of the brace for four hours. If the curve is still controlled, brace-wearing time is reduced to 20 hours per day. Three months later a radiograph is taken out of the brace 6 hours, and with continued curve control six hours are allowed out of the brace. As long as the curve is controlled, weaning is continued till the child is using the brace only at night. If the curve control is maintained an attempt is made to leave the child out of the brace. If no curve increase occurs, the brace use may be discontinued, even though the child has not reached the growth spurt. Observation continues, watching for curve increase, especially at the time of the adolescent growth spurt. If at this time the curve increases, bracing is resumed or a spinal fusion is performed.

If, with weaning, the curve increases, bracing remains at full time, this full time wear continuing till the growth spurt. If the curve increases at any time, surgery is indicated. Depending on the age of the child at the time of curve increase, the surgery is either instrumentation without fusion, or a definitive fusion, usually an anterior and posterior approach. In some cases control of the curve continues through the growth spurt till the end of growth, when weaning is instituted.



A child with juvenile idiopathic scoliosis thus can follow a number of bracing courses. The bracing can be only in the juvenile years with early weaning before the adolescent growth spurt, or continue through adolescence with weaning at the end of growth, or control of the scoliosis can be maintained through the juvenile years with curve increase at the onset of the adolescent growth spurt necessitating a fusion.

The reported success of nonoperative treatment is variable. In a recent large series the surgical rate was 50 percent, the most common time of fusion being at the onset of the adolescent growth spurt, good curve control being maintained prior to that. In general, in juvenile idiopathic scoliosis, one third of the children are observed, and two thirds require bracing. Of the latter group, bracing is successful in one half, and the other half the brace success is temporary, surgical stabilization eventually being required. Thus overall in juvenile idiopathic scoliosis one third do not progress, one third are successfully treated with bracing alone and one third undergo a spinal fusion.

c. Adolescent idiopathic scoliosis

The aim of non-operative treatment is to control the curve, prevent the curve from progressing and thus prevent the need for surgical stabilization. In addition, the cosmesis of the child should be improved whenever possible. The choices for non-operative therapy include orthotic treatment, exercises, electrical stimulation, manipulation, and biofeedback. Orthotic treatment has been proven to be the only treatment effective in altering the natural history, and thus is the non-operative treatment of choice.

The indications for orthotic treatment are a growing child who presents with a curve of 30 to 40 degrees or with curves less than 29 degrees that have shown documented progression. The curves of 25 to 29 in the very immature (Risser 0, Tanner 1 or 2) should also be treated immediately. The contraindications for bracing are conversely a child who has completed growth, or a growing child who has a curve over 45 degrees, or under 25 degrees without documented progression. True thoracic lordosis, because of the effect of orthoses on the thoracic spine, is also a contraindication to orthotic treatment. Obviously a child with a non-supportive home situation or a child who refuses to wear a brace is not a candidate for bracing.

The choices for orthotic treatment are the Milwaukee brace and the TLSO (thoraco-lumbo-sacral orthosis). The first successful orthosis for the treatment of adolescent idiopathic scoliosis was the Milwaukee brace. The pelvic section can be either custom made or a prefabricated module as in the Boston system. The TLSO is the generic name for a group of orthoses, which can be divided into two distinct types. Both have a pelvic portion similar to the pelvic section of the Milwaukee brace, with the underarm variety extending up to one or both axillae, and the lower type extending only to the lower thoracic area. There are many designs of these orthoses, which are generally named for the city or center of origin.

Historically the Milwaukee brace was used for thoracic and double curves, while the TLSO was prescribed for single lumbar and thoracolumbar curves. With widespread use of the TLSO these indications have changed. In general a TLSO is not used for a thoracic curve with an apex above T8, as due to the brace's configuration no corrective force can be applied to a curve apex above this level. Thus for all thoracic curves where the apex is above T8, a Milwaukee brace is the only effective orthosis available. For all other curves the choice is between the Milwaukee brace and TLSO, the decision being made by the treating physician based on the patient's age, cosmetic appearance, amount of decompensation and the structurality of the curve. The curve patterns that have to be treated in a Milwaukee brace are thus all patterns with a thoracic curve that has an apex at or above T8. These are the double thoracic pattern (high left and right thoracic curves) and other double patterns when the apex of the thoracic component is above T8 (double thoracic and lumbar, or double thoracic and thoracolumbar patterns).

Once a decision has been made which orthosis is to be used, pads specific to the curve pattern being treated are added to the brace: a trapezius pad for a high thoracic curve, a thoracic pad for a thoracic curve, a combination of an oval and a lumbar pad for a thoracolumbar curve, and a lumbar pad for a lumbar curve. In the Milwaukee the pads are suspended from the uprights or built into pelvic section, or they are built into the TLSO.

One must be aware of the sagittal profile of the spine, especially to any hypokyphosis present. In this situation, modifications to the brace's fabrication are made that prevent increasing the hypokyphosis, and maximize the thoracic pad's corrective force. The Milwaukee brace posterior uprights are contoured more posteriorly, and a large thoracic pad is used which is placed lateral to the posterior upright, and is attached anteriorly without an anterior outrigger. In addition an anterior gusset is sometimes used. These modifications move the corrective vector of the thoracic pad from posterior to posterolateral, thus minimizing the anterior force of the thoracic pad and any deleterious effect on the thoracic lordosis as shown by Wong and Evans. Similar modifications are made to the TLSO, but in general the Milwaukee Brace is more effective in cases with hypokyphosis.

The brace is prescribed for full-time wear with time out for bathing, swimming, physical education and sports. The child should be encouraged to be active in sports, and if they are active in e.g. skiing, skating or tennis, they should be encouraged to remain active in these sports in the brace if possible. Contact sports are not allowed in the brace, not because the child in the brace will be hurt, but to protect the other participants. In this case the child will play the sport (soccer, basketball, football, hockey) out of the brace. These activities generally total an average of two to four hours a day, so that the brace wearing is 20 to 22 hours per day. Use of the brace part time or only at night has been advocated by some treating physicians, and is widely used in some centers, but there is little long follow-up literature available that proves the effectiveness of this wearing regimen in adolescents, all series on effective orthotic treatment being with full-time wear. Some small series with short follow-up out of the brace suggest that part time bracing is effective. They do not compare their results to natural history or to full time bracing, and one series states that "the results are not as good as those obtained with full-time wear". A recent study of Boston brace use by Mitchell et al compared the results in the children according to the wearing regimen used by that child, being divided into non-compliant (<12 hours per day), part-time (12 -18 hours per day) and full-time (18 - 23 hours per day). The initial curves were similar in the three groups, with the final curves being largest in the non-compliant group (56°), and smallest in the full-time wearers (35°). In addition the surgical rate also depended on the brace compliance being 73% in the non-compliant patients, and falling to 9 % in the fully complaint group.

Follow up is every four to five months with radiographs taken in the brace at every visit. In addition the brace fit is checked, with appropriate adjustments made for growth. Some physicians obtain radiographs out of the brace, but this does not show the effect of the brace on the curve and on the child's alignment. Weaning from the brace occurs at the end of growth as evidenced by no height increase, a Risser of 4, and in girls 12 to 18 months post menarche. Obviously in boys this is going to be later chronologically as the growth spurt in boys starts later and is longer. The brace wearing can be gradually decreased, or wearing can be discontinued at the end of growth. In many cases to maintain curve control, gradual weaning is necessary, and there is no way to predict who will be successfully treated by brace discontinuation versus weaning. In addition, it is nearly impossible to re-establish a brace-wearing program in the adolescent once the brace has been discontinued. For these reasons it is better to treat all the children in the same manner with a gradual weaning program.

Once a decision has been made to start weaning, a standing PA radiograph is scheduled for four hours out of the brace, and this is compared to the most recent radiograph in the brace. If control of the curve is maintained, with minimal loss in the curve, the patient is allowed to be out of the brace four hours daily. This is repeated every four months, with an additional four hours out of the brace on every visit, till the child is just sleeping in the brace. This is continued for 6 months at which time a radiograph is obtained out of the brace one week, and then bracing is discontinued. This regimen has given the best results of bracing.

Results

There are many articles in the literature discussing the results of non operative treatment of adolescent idiopathic scoliosis treated with various orthoses: Milwaukee brace, Boston bracing system, Wilmington brace, Corset Lyonaisse, Charleston brace etc. There are some problems with the reported series. They include juveniles and adolescents, and have different curve magnitudes and different lengths of follow up. There are no matched untreated control groups, and the series do not compare the results of bracing to studies of natural history. In addition many studies evaluate the response of curves to the brace, rather the result of curve patterns, e.g. the thoracic curve in the single thoracic pattern is analyzed with the thoracic curves in the double thoracic and double thoracic and lumbar patterns.

The results of brace treatment are generally expressed two ways, as those that failed brace treatment and subsequently required surgical stabilization, and/or those who, at follow up, had progressed 5 or more degrees compared to their pre-brace curve. The surgical rates in the literature vary from 3-22 percent, but the series are not comparable as the range of the initial pre-brace curves vary tremendously, and the follow-up out of the brace also varies. It must be remembered that the indications for surgery are not stated, and these indications vary from city to city, country to country, and surgeon to surgeon. In addition in some cases surgery is indicated due to patient factors and not to brace failure.

Long-term studies of the Milwaukee brace give similar results, with an initial improvement in the brace, and then a gradual loss of correction, so that at the end of bracing the average curve is 10 to 15 percent better than the pre-brace curve. At followup five or more years out of the brace, the average curve is about the same as the prebrace curve. It must be remembered that the comparison is with the initial pre-brace curve, and <u>not</u> with what the curve would have been without treatment.

Only one study has compared the results to natural history and concentrated on curve patterns rather than curves. Lonstein and Winter reviewed 1020 adolescents treated with the Milwaukee brace, with the average time in the brace being 3.8 years, and 54 per cent of the patients had more than two years follow-up out of the brace. Two thirds of the pre-brace curves were between 20 and 39 degrees, and the single right thoracic pattern was the most common, constituting one third of the cases. The overall surgical rate was 22 per cent, the most common indications for surgery being an initial response in the brace and then curve increase, or no improvement in the curve with bracing. The surgical rate increased with increasing curve magnitude for initial curves over 30 degrees, and it was also greater in immature patients with a Risser sign of 0 or 1 compared to more mature patients with a Risser sign of 2 or more.

The results were also compared to natural history prediction, using the figures from the study of Lonstein and Carlson from the same center, and thus from a very similar patient base. Failure of bracing was defined as those cases needing surgery, plus those cases who at follow-up had curves that were 5 or more degrees larger than the prebrace curve. The four main curve patterns with initial curves of 20 to 39 degrees were analyzed. For curves of 20 to 29 degrees and a Risser of 0 or 1, the Milwaukee brace results showed a failure rate of 40 per cent compared to a natural history prediction of 68 per cent progression, a statistically significant difference (p=0.0001 chi-square). With the same curve magnitude and a Risser of 2 or more, the Milwaukee brace had 10 percent failures, compared to 23 percent with natural history, also a significant difference (p=0.022 chi-square). For the curves of 30 to 39 degrees, the corresponding figures were 43 per cent vs. 57 percent for a Risser of 0 or 1, and 22 vs. 43 percent for a Risser of 2 or more. Although the Milwaukee brace results are half of the natural history predictions, the number of cases in the natural history group is too small to get a statistical validation for this group. These results indicate that the Milwaukee brace alters the natural history of idiopathic scoliosis.

Salanova reviewed the long-term results of the Milwaukee brace in 761 cases of juvenile and adolescent idiopathic scoliosis. Two thirds were treated full-time and the rest 12 hours a day in the brace. In the 70 juvenile patients with curves between 20 and 29 degrees, a half were better or unchanged and half were worse, operated or converted to full-time. In the 244 adolescents with curves between 20 and 29 degrees, 57 percent were better with full-time wear, whereas 39 percent were better with part-time wear. To answer the question whether the brace effects are lasting, at an average of five years out of the brace, the juveniles increased from an average of 29 degrees at the end of bracing to an average of 31 degrees at follow-up, the transpubertal group from 24 to 28 degrees, and the adolescents from 25 to 26 degrees. This lasting effect of bracing was also shown by Montgomery and Willner who concluded that a follow-up 2 years after weaning is sufficient to predict the clinical result with great accuracy (97%)

Noonan and Weinstein in their recent article concluded that it is "currently impossible to state that bracing effectively alters the natural history of scoliosis in immature patients at high risk for progression". Of the 111 eligible patients over age 8, 23 were excluded leaving 88 patients evaluated with 117 variables. The problems with the study are that the number of patients is small, 15 had no initial x-rays for curve pattern or magnitude or Risser sign, it includes juveniles and adolescents, the average brace wearing time is short at 1+8 years, and there is no natural history group for comparison.

Questions arise as to the long term effects of bracing psychologically, on the curve and on the function of the patient. Noonan et al evaluated the long term psychosocial characteristics of patients treated for idiopathic scoliosis at an average follow-up of 7 years. They found in brace patients perceptions of discrimination and a lower satisfaction with overall appearance was recalled during the treatment phase with no difference between patients and controls at follow-up.

The long term results of bracing were covered in a recent review by Danielsson and Nachemson presented the average 22 year follow-up of patients with adolescent idiopathic scoliosis. One hundred and thirty six were surgically treated, 111 brace treated, and these were compared with 100 sex and age matched controls. The Milwaukee Brace was used in 95% of the brace treated patients. The average initial curve in this group was 33°, averaging 30° at the end of treatment with a loss to an average 38° at follow-up. Thirty-three patients had an increase of 11° to 20°, with 5 increasing 21° to 25°, and only one brace treated patient had a subsequent fusion. Degenerative lumbar disc disease was higher in both the treated groups compared to the controls. This can be as a result of the lumbar spine immobilization required by treatment or can be due to an underlying disc biochemical abnormality that may be present in idiopathic scoliosis. Functionally there was no difference in overall back pain, back pain with pregnancy, childbearing rate or the rate of Caesarean sections. There was a difference in the patients braced with a higher mean age at 1st pregnancy, and a significant increase in subjective back stiffness with a correlated increase in limitation of sexual function.

Summary

With knowledge of the natural history of adolescent idiopathic scoliosis the important factors in the patient evaluation are highlighted. The decision making process uses these factors and aids in the decision to treat or not, and with treatment, what type of treatment is to be instituted. As studies have shown that non-operative treatment of adolescent idiopathic scoliosis with an orthosis is effective, a logical and appropriate treatment plan can be outlined for each patient. This will give control of appropriate curves with reduction in the need for surgery.

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BRACING MANUAL
SCOLIOSIS RESEARCH SOCIETY
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THE MILWAUKEE BRACE

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I. HISTORY, DEVELOPMENT AND BIOMECHANICS OF THE MILWAUKEE BRACE

The Milwaukee Brace (MB) is a cervico-thoracic-lumbar-sacral-orthosis (CTLSO) originally developed by Dr. Walter Blount in Wisconsin in the 1940's for the postoperative management of polio patients following spinal fusion surgery. The brace was first introduced publicly at the American Academy of Orthopaedics meeting in 1946 by Dr. Walter Blount and Dr. A.C. Schmitt.[2,6] Initially, the MB was utilized to manage scoliosis, first by Dr. Blount in the late 1940's and then Dr. John Moe and others in the early 1950's. In 1958, Dr. Blount first described the use of the MB in the sagittal plane deformity of kyphosis and it has been commonly used for non-operative management of both spinal deformities since that time.

Principle of Design:

Like most orthoses developed to stabilize Adolescent Idiopathic Scoliosis (AIS), the MB was based on the concept that the lumbar lordosis must be flattened to achieve correction of scoliosis. Consequently, the foundation of the Milwaukee Brace is the pelvic module that has close contact with the iliac crest and lumbar spine. Erected from this pelvic base are 3 metal uprights, one anterior and two posterior, connecting to a neck ring above the shoulders. The attachments to the neck ring have changed through the past several decades. A chin rest contacting the mandible was originally part of the brace, but evidence of developing malocclusion in patients caused abandonment of the chin rest with substitution of the throat mold still commonly in use today.[4] The brace also has an occipital pad or rest posteriorly to cradle the posterior aspect of the skull. Some physicians currently use a low profile modified version of the brace with neither rest attached to the ring.[3] To provide corrective forces to rib prominences and the convexity of scoliosis, pads can be attached to or suspended from the metal uprights, or incorporated within the pelvic nodule.

Biomechanics

The original design of the MB was to permit corrective forces to be applied to the spine in 2 ways to help stabilize and correct the deformity. The pelvic module in conjunction with the neck ring with or without a chin rest and the occipital pad did provide a longitudinal traction force to the spine. This force has been documented and measured in patients with scoliosis.[2] The placement of pads laterally provides corrective forces to the apex of the convexity of scoliosis in the transverse plane. Alternatively, when placed posteriorly over the apex of the kyphosis, pads generate a corrective anteriorly directed force over the posterior prominence. Both the longitudinal and especially the transverse forces applied by the brace are effective in correcting both coronal and sagittal plane deformities in patients with flexible spinal deformities.[11] (See Figure 1)

Originally it was theorized that correction of spinal deformity in a brace was achieved by two means: passively by the effect of brace pressure from pads or traction from the brace design, and actively from muscle contractions and movement of the body away from the pad. Research has suggested that the actual amount of correction of spinal deformity seen on radiographs in a brace is generated by the passive correction inherent in the brace with very little to any correction provided by active muscle action.[2]

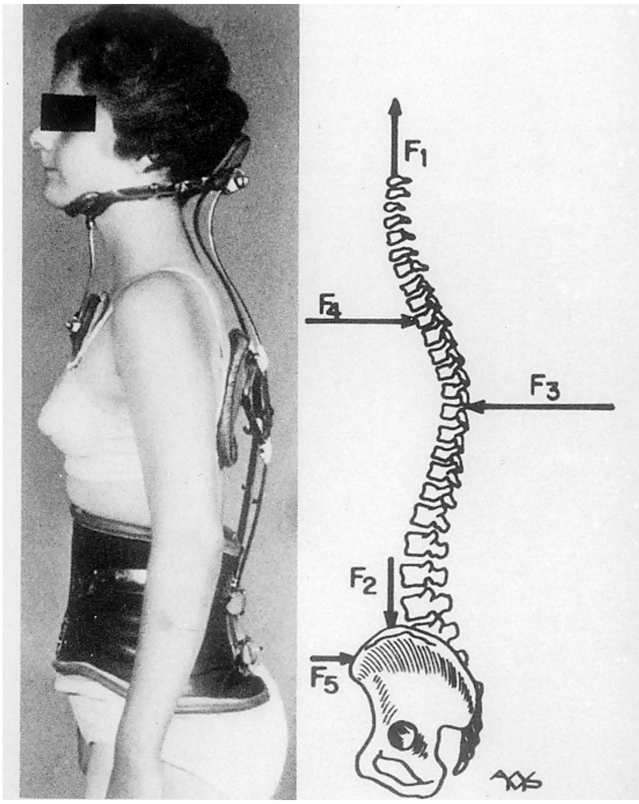

Figure 1: Depicted here is the original Milwaukee Brace design, demonstrating the chin rest that comes in contact with the mandible. This construct has since been modified so as to avoid mandibular pressure. The forces applied to the spine by the Milwaukee brace are well illustrated in this diagram. (Reprinted with permission from Clinical Biomechanics of the Spine, 2nd Edition, by A.A. White and M.M. Panjabi, Lippincott, 1990.)

II. INDICATIONS FOR MB TREATMENT

Scoliosis:

The prevailing standard recommendations for initiating brace treatment for patients with idiopathic scoliosis include any skeletally immature patient (<Risser 2 and < 1 year post-menarchal) with a scoliosis of 25 degrees or greater, or with documented progression of at lease 5 degrees.[4] In addition, Roach has noted that any curve in a skeletally immature patient between 30-40 degrees is a strong indication for prompt bracing and that the curve to be braced be cosmetically acceptable.[8] Thoracic curves with an apex of T7 or above are felt by some authors to represent an indication for CTLSO bracing with the MB rather than TLSO's.[4]

Bracing is continued until signs of maturity are present as evidenced by Risser 4 on radiograph, minimal or no change in height on successive visits, post-menarchal 18-24 months, and closure of the vertebral ring apophyses.[4,8] Brace weaning is commenced at maturity as noted above and varies depending upon the physician. A common method is to decrease the number of hours of brace wear until nocturnal use only is the final brace regimen. Weaning is guided by the size of the curve on radiographs taken at least 48 or more hours out of the brace.

Kyphosis:
Generally acceptable indications for utilization of the MB in patient with Scheuermann's Kyphosis included skeletal immaturity and open vertebral ring apophyses and a kyphotic deformity of 45-50 degrees or greater with vertebral wedging. Bracing is recommended 20-23 hours per day until evidence of maturity, including apophyseal closure on x-rays, when weaning may start.[4,8]

Definitive indications for bracing are lacking in Scheuermann's Kyphosis because of the lack of clear long term studies on the natural history of juvenile kyphosis and uncertainty about whether brace treatment decreases the incidence of pain in adults with kyphotic deformities.[4]

III. CLINICAL RESULTS OF MILWAUKEE BRACE TREATMENT

Scoliosis:
The MB remains the orthosis with the longest clinical history of utilization in Adolescent Idiopathic Scoliosis and the brace with the highest reported success rate in halting progression of scoliosis during adolescence. Lonstein and Winter reported on a group of over 1000 patients with idiopathic scoliosis with long term follow-up and found that the brace affected the natural history of scoliosis in over 60% of patients.[5] A meta-analysis of non-operative treatment for scoliosis identified the MB on the most successful brace in affecting outcome and preventing progression of adolescent idiopathic scoliosis.[9] Initial reports suggested that MB treatment could produce improvement of scoliosis following completion of treatment but longer follow-up demonstrated most curves drifted back to their original pre-brace size.[6,5]

Kyphosis:
Similar positive results have been reported for the management of kyphotic patients with the MB. Initially, correction of deformity after completion of brace treatment for Scheuermann's kyphosis was reported, but longer follow-up documented loss of correction back to the pre-brace size at 5 years post-brace in most studies with modest permanent correction reported in others.[1,10] The MB remains the sole and primary means of orthotic management in sagittal plane kyphotic deformities of the spine in adolescents.

IV. COMPONENTS OF THE MILWAUKEE BRACE

In basic terms, the MB functions by applying a three point force system to the spine. These forces are directed in either the sagittal or coronal planes depending on the control or correction required. The orthosis consists of three basic components: the pelvic section; the superstructure; and the pads. These elements, when carefully applied, can achieve curve control in the transverse plane for scoliosis, or curve correction in the sagittal plane for Scheuermann's Kyphosis.

Pelvic section: Traditionally, the pelvic portion of the MB was custom molded from a cast of the patient. Leather and steel were skillfully hand crafted to this plaster model and the patient shape duplicated. Today, thermoplastics are used almost exclusively in the fabrication of these orthoses. A foam interface is stretched over the plaster model, then hot plastic is draped over it with a vacuum applied, such that the copolymer polypropylene takes the shape of the model. Some orthotists exclusively hand cast the patient to create the plaster model, although now pre-fabricated modules of varying sizes are commercially available. Clinical preference determines whether a cast is used to make a plaster model for fabrication, or if the patient is measured and a pre-fabricated pelvic module is ordered. In the presence of pelvic obliquity or atypical spinal deformity, custom molding of the pelvic module is usually indicated. Regardless whether it is achieved by a custom mold or a measured brace, effective pelvic stabilization is the biomechanical goal for the pelvic section or module, in order to provide the foundation from which the pads gain mechanical advantage.[11]

Superstructure: The most visually apparent part of the MB, the superstructure is comprised of the neck ring and the three metal bars that attach the pelvic section inferiorly to the neck ring superiorly. The single anterior bar is often made of aluminum to enhance radiolucency. To provide strength and rigidity, the two posterior bars are usually steel.

In terms of orthotic design and theory, the superstructure component of the MB has changed the most from the original brace. Initially, the superstructure's neck ring with chin piece provided actual distraction at the mandible. However, the recognition of malocclusion in treated patients resulted in modification of the neck ring. The current superstructure design with a throat mold and occipital piece still does provide some axial distraction force to the spine, and functions to achieve two other basic goals: first, to provide a means of pad suspension and permit force application to the body; and second, to provide a superior end point of control.[11]

Two primary design options exist for the superstructure which vary only in neck ring shape and superior height. In the high profile design, the neck ring with throat mold is placed just inferior to, but not in contact with, the mandible. The neck ring is at the level of the sternal notch and thus much more inconspicuous in the low profile brace. From a biomechanical standpoint, either ring functions as the end control point in an orthotic system that attempts to make the spine both more structurally rigid and better aligned.

Pads: Since corrective forces are applied directly to the spine through them, the pads can be considered the most important part of the MB. Unless the pads are thoughtfully and accurately placed on the body, the patient derives no benefit from wearing a MB with a perfectly fabricated pelvic module and elegantly contoured superstructure. The thoracic pads are usually constructed of a rigid layer like aluminum or plastic which is foam backed and covered with a vinyl or leather material. The pads must be stiff enough to impart forces onto bone, but pressure sensitive enough to prevent skin breakdown. Lumbar pads are usually made or foam and are positioned intrinsically within the pelvic section. Axilla slings and rings are used to provide the counter force against the thoracic pads and permit maximal force to be applied to the spine while helping to maintain compensation. Adjustment of axilla strap tension allows alteration of thoracic pad force to patient tolerance while ensuring that the ring is centered properly relative to the cervical spine.

The pads are referred to as “Floating” when they are suspended from the superstructure by straps. The straps can be fabricated in a variety of ways , but straps that allow for maximum pad adjustment are ideal. It is crucial that one can vary the pad position as well as the magnitude and angle of applied force. Having the ability to make to make gradual increases in pad force during the weaning period as well as making subtle changes in pad height or the angle of pull, helps to improve the correction in the brace, enhances patient compliance, and can optimize the overall outcome.

V. INITIAL FITTING OF MB

Assessing Initial Fit: Scoliosis

Since pelvic stabilization and reduction of lordosis are the primary goals of the pelvic module, this component of the brace should adequately contour to the patient’s body such that excessive gaping anteriorly or posteriorly should not be observed. The generic pelvic shape in some braces fabricated from measurements may not fit the patient well, with insufficient pelvic control as a result. With the patient wearing the orthosis, if fingers fit easily inside the module anteriorly to palpate the ASIS, then it is unlikely that pelvic control will exist once pad forces are applied. Once this situation is identified, a custom molded pelvic section is indicated rather than a measured orthosis.

The width of the posterior opening should be of magnitude equal to or slightly larger than that of the largest lumbar vertebral body. In practical terms, this is usually two or three inches wide and insures that the lumbar derotation pad will not be exerting force centrally over the body but more laterally where it can induce counter-rotation.

The superstructure should contour to the body walls both anteriorly and posteriorly, with only 2 to 4 cm clearance from the patient required. The high profile design uses a ring which is positioned anteriorly 2-3 cm inferior to the mandible and posteriorly 2-3 cm inferior to the anion of the occiput. Laterally and posteriorly, there should be 2-3 cm of clearance of the soft tissue within this ring. Anteriorly, the throat piece should be close to but not actually contact the patient.

The low profile design incorporates a padded yoke-shaped piece which is attached anteriorly to the level of the sternal notch, is contoured over the shoulders and attaches to the posterior uprights.

The thoracic pad is positioned posterolaterally so as to provide both a derotating force as well as a laterally directed force which can act in the coronal plane for correction of the thoracic scoliosis. The superior edge of the pad must be no higher than the rib inferior to the apical rib. Careful assessment of this pad placement is critically important. If the pad placement is too superior, it will apply forces onto the apical rib which articulates both at and above the apex of the curve, limiting the correction of the scoliosis.[7]

The lumbar pad should be positioned at the level of the apex of the lumbar curve or the null point. The axillary pad or sling should be positioned as superior as the patient will tolerate without experiencing pain or paresthesias.

Standard upright radiographs of the spine are obtained in the brace at the time of brace delivery and are essential for assessment of pad placement and curve correction. Adjustment of pad position may be appropriately made at this time.

Assessing Initial Fit: Kyphosis

The management of sagittal plane spinal deformity with the MB starts, as in scoliosis , with pelvic stabilization. The criteria for fit of the pelvic module is therefore the same when the MB is used in the treatment of kyphosis as in scoliosis.

Two orthotic designs can be utilized to direct forces on the kyphos, which differ in the nature of the posterior pressure point. Within the three point force system used to achieve correction, either bilateral paraspinal pads or a heightened superior trim line of the pelvic module may be employed. (See Figure 2) Either of these designs can provide the anteriorly directed counterforce with which the kyphos is reduced.

The neck ring design may offer some choice which may impact ultimately on compliance with the brace. The high profile design incorporates a ring which is positioned anteriorly just beneath the mandible and posteriorly below the anion of the occiput. Laterally and posteriorly, there should be 2-3 cm of clearance of the soft tissue within this ring. Anteriorly, the throat piece of the ring should contact the patient only at "rest," however they should be able to move away from the this pressure by simple postural adjustment. In this way, the brace acts actively throughout the day via the patient's continuous self-correction. (See Figure 2)

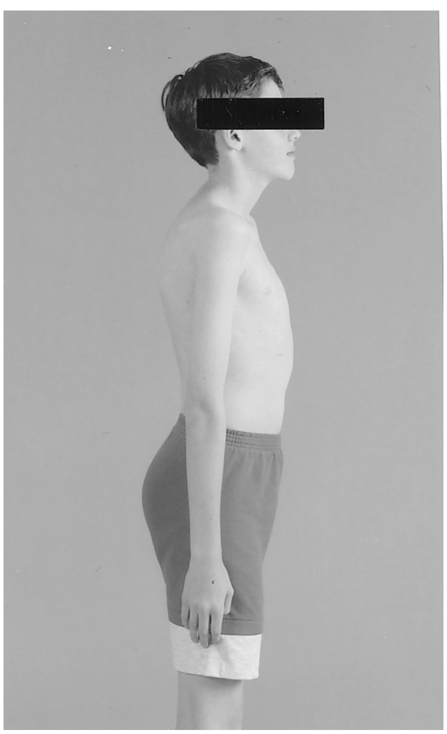

Figure 2A: This is a 14 year old boy with an adolescent roundback deformity/early Scheuermann's kyphosis at the time of Milwaukee Brace delivery.

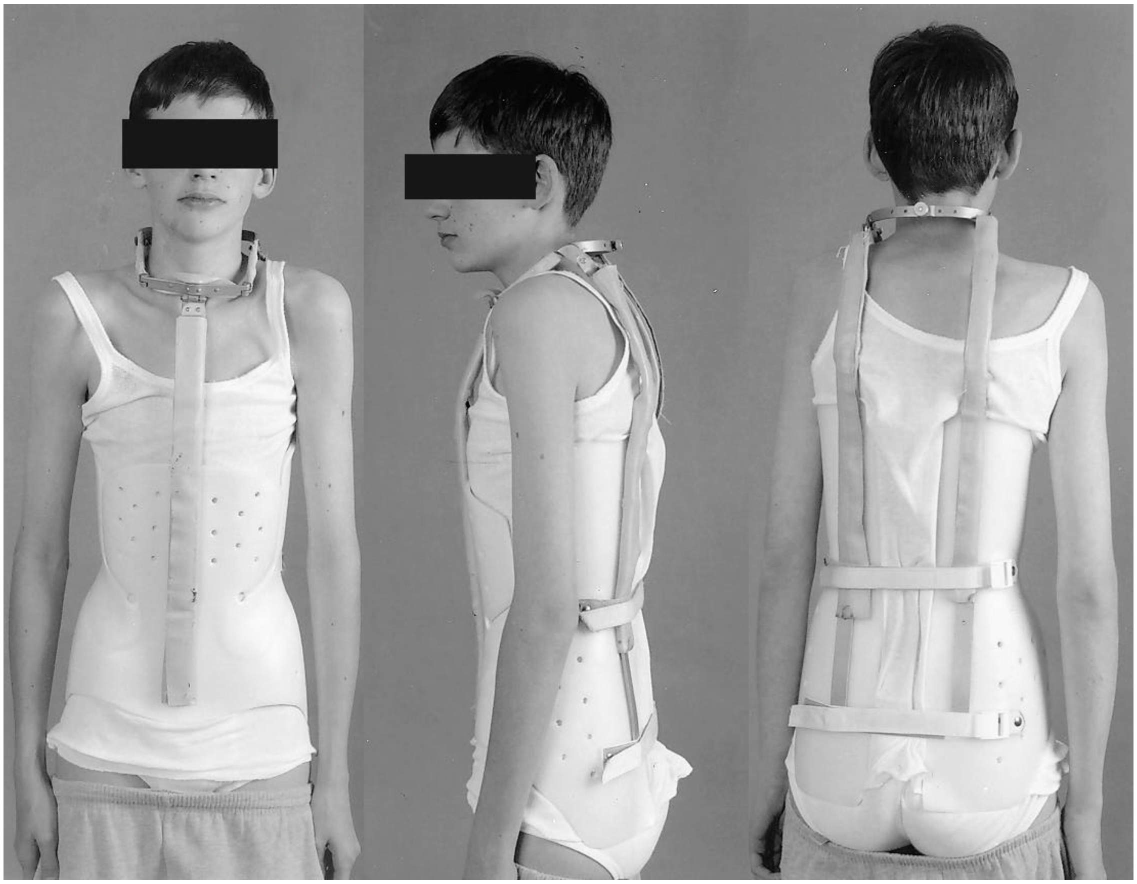

Figure 2B: Front, side and back views of the patient in a standard high-profile Milwaukee Brace design at the time of brace delivery. Note the position of the neck ring and throat mold relative to the patient. The superstructure needs to be raised at least 2cm to gain better superior end point control and to meet the appropriate fit criteria. To accomplish re-positioning of the neck ring to the right, either an axillary strap may be added on the right, or a new pelvic module incorporating a left trochanteric extension could be fabricated. In this brace, the extended superior trim line of the pelvic module acts to produce an anterior directed force over the kyphos.

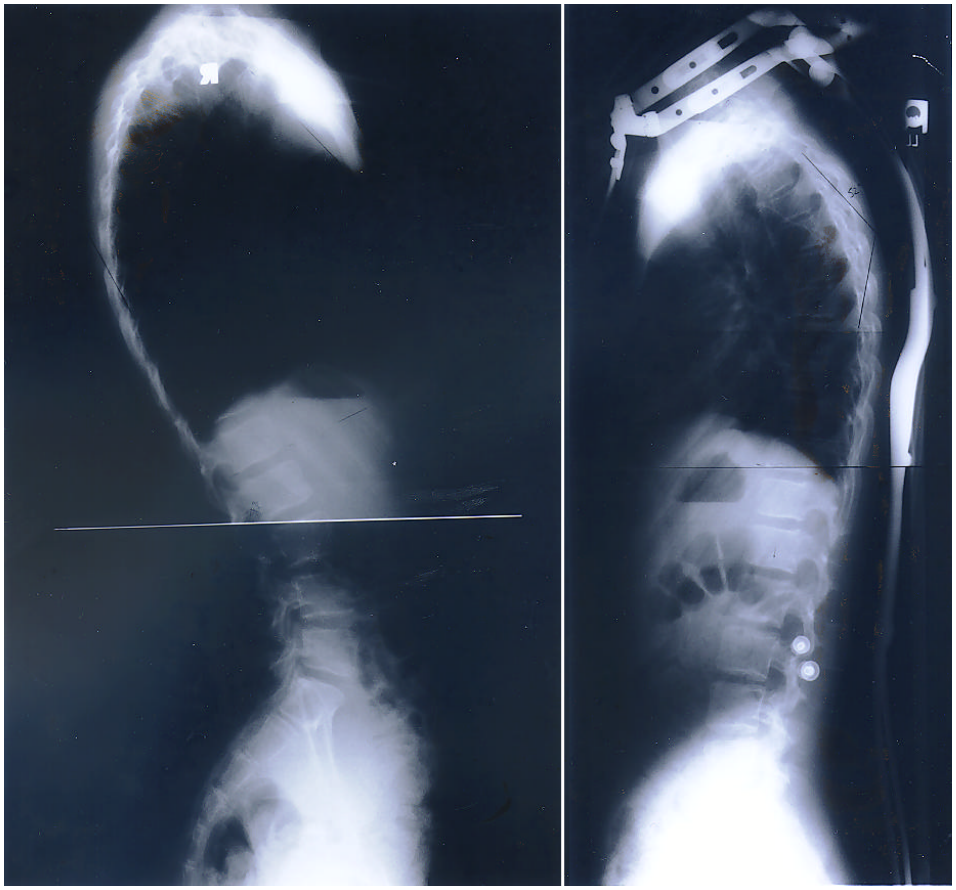

Figure 2C: On the left is a pre-brace radiograph demonstrating the patient's 74 degree thoracic kyphosis. The radiograph on the right shows correction to 52 degrees in the Milwaukee brace.

The low profile design utilizes more direct pressure than its high profile counterpart. This design employs a padded yoke-shaped piece which is attached anteriorly to the level of the sternal notch, and thus imparts the superior posteriorly-directed force of the 3 point force system. The patient should be able to unweight the pad posturally, but not have enough space to pull away from the pad completely. Posterior clearance thus requires attention. Because the patient needs to self-correct posture in order to reduce the sternal pressure of the pad, the posterior element of the ring must be adjusted so as to not impede this movement. Since the pad is relatively broad, more direct force can be applied to act on the spine. Thus, this pad permits the MB to function in both an active (postural self-correction) and passive (direct pad pressure) mode to achieve sagittal plane correction. One limiting factor of the low profile design is that with its lower superior end point control versus the high profile design, deformities with an apex of T9 or above are not well controlled in this type of brace, and thus a relative contra-indication to its use. (See Figure 3)

The superstructure should be closely contoured to match the anatomy of the patient. The metal uprights should clear the soft tissue completely, with 2-3 cm of clearance (or a finger's breadth) usually adequate. Excessive clearance is not necessary and from the patient's standpoint makes the orthosis less cosmetically appealing. The kyphos or paraspinal pads should be centered adjacent to the apex of the deformity and placed over the paraspinal musculature. If the superior trim line of the module is employed as the “kyphos pad,” then the trim line should be at the level of the apex of the kyphosis. (See Figures 2B and 3) Again, as in scoliosis, standing radiographs of the patient in the MB are vitally important in assessing pad placement and deformity correction in the brace.

Figure 3: Front, side and back views of the low-profile Milwaukee Brace. Again, in this brace, the superior trim line of the orthosis itself acts to generate an anteriorly directed corrective force over the kyphosis. Note the minimal clearance and careful contouring of the uprights to the patient’s body. Ideally, the anterior upright in this brace should be adjusted to achieve more contact of the pad in the sternal notch area if the patient is in the resting position. However, with active extension of the spine, the patient should have enough posterior clearance to pull away from and unweight the sternal notch pad, which he appears to be doing here.

V. MANAGEMENT OF PATIENTS IN THE MILWAUKEE BRACE

Brace Adjustment During Treatment: Pelvic Module

At follow-up examinations, the width of the posterior opening is often found to increase with time, secondary to weight gain and pelvic width changes occurring with normal maturation in growing adolescents. As the width of the opening increases, the pelvic section becomes less effective at controlling the pelvis and usually less comfortable to wear full time. In some cases where a lumbar pad is not required (e.g., kyphosis), the width of the posterior opening becomes less critical because pad alignment and position are not considerations. In these patients, maintaining patient comfort and compliance may take precedence over a slightly enlarging posterior opening. In patients requiring accurate lumbar pad placement for management of spinal deformity, excessive posterior width may require re-fabricating a custom-molded pelvic module.

Pad Adjustment During Treatment: Scoliosis

The patient should be seen several weeks after delivery of the orthosis, usually at the end of the weaning in period, so that pad pressure can be re-assessed. Usually the patient will be able to tolerate more pad force, and thoracic pad pressure can be adjusted by placement of the pad on the upright. Both parents and patients need to be educated and encouraged to permit increased pad force if this is well tolerated so as to optimize curve correction in the orthosis and ultimately the outcome of treatment.

Superstructure Adjustment During Treatment: Kyphosis

Since the majority of patients treated for coronal or sagittal plane deformities with a MB are adolescents, careful attention to and frequent adjustment of brace fit is required simply to accommodate changes in the patients related to growth. Since biologic creep is an important factor in the management of kyphosis in the MB, frequent adjustment of the brace by the orthotist is especially necessary in these patients. In kyphosis patients, the potential for ongoing correction of the deformity is real and can be facilitated by frequent brace adjustments made in response to the gradual elongation or stretch of the soft connective tissue of the spine. Initially, the patient's brace may require re-adjustment by the orthotist every 2 to 3 weeks to meet the fit criteria outlined above. Eventually, the interval between orthotic visits may be increased to every 2 to 3 months when assessments reveal more modest changes of position within the superstructure.

As the kyphosis becomes less fixed, the superstructure is adjusted by bringing it into more extension. When reduction of the kyphosis is significant, the patient's relative trunk stature is increased. Consequently, the superstructure needs to be raised to accommodate increasing height so that it does not apply pressure to the upper trapezius or clavicle. When kyphos pads are being used, their pressure should also be increased as tolerated. The relative flexed or kyphotic shape of the posterior superstructure is reduced with bending irons, thereby increasing pad pressure posteriorly and thus enhancing the posterior moment arm and often correction of the deformity.

Trouble-Shooting Fitting Problems: Scoliosis

In the presence of a large, usually left-sided lumbar curve, for example greater than 30 degrees, a left lumbar pad will be necessary. In more rigid curves, a left lumbar trochanteric extension is often required to decrease the tendency for the brace to rotate off a left lumbar curve. The more rigid the lumbar curve, the more essential it is to incorporate a trochanteric extension in the pelvic module in order to maximize the derotation force exerted on the lumbar curve by a lumbar pad.

Prior to applying any thoracic pad force, the patient should have appropriate soft tissue clearance within the neck ring. The thoracic curve needs to be loaded to the maximum capacity the patient can tolerate, thus obtaining the greatest possible curve correction in the brace. The thoracic pad is always countered by some type of contralateral sling, ring or pad. The limiting factor in the application of thoracic pad pressure is the patient's skin tolerance. Loading of the thoracic pad will tend to push the patient's body away. In the case of a right thoracic curve, with increasing thoracic pad pressure, there will be a tendency for progressively more contact of the neck ring with the left side of the neck. Balancing the neck ring with an opposing axillary sling will minimize or eliminate this neck ring contact. Thus, in a patient presenting with neck ring pressure opposite a thoracic pad, either the axillary pad or sling force must be increased to re-balance the neck ring or the thoracic pad force must be decreased. It is important that the patient and their families understand this concept so that as the patient weans into the MB and their curves accommodate increasing thoracic pad pressure and/or achieve greater correction in the MB, that appropriate adjustments to the brace can be made.

Growth of patients during the period of MB treatment may be significant. The height of the superstructure may need to be adjusted every two to three months during the rapid growth phase. With superstructure changes, the pad height requires careful attention. It is vital that the thoracic and lumbar pads are either raised or lowered as needed to maximize biomechanical potential for curve correction. Adjustments to the pad straps will ensure that the pad lies flat on the body wall and maximum tolerable pad pressure is achieved.

Pelvic growth in the adolescent girls often requires heat flaring of the pelvic module to accommodate increasing pelvic width or more prominence of the Anterior Superior Iliac Spines (ASIS). With significant growth in the hips and pelvis, the pelvic section of the orthosis will not be maintained in the proper position and will tend to migrate superiorly. This proximal migration may not cause discomfort around the pelvic area, but may place the neck ring in an uncomfortably cephalad position. Examination of the patient in the orthosis will reveal that the ASIS are no longer contained within the pelvic section and that the superstructure and the neck ring are positioned too superiorly. For patients presenting with these findings, a new pelvic module must often be fabricated.

Trouble-Shooting Fitting Problems: Kyphosis

Changes in the relative height of the superstructure from standing to sitting can present a challenge in the MB treatment of some patients with kyphosis. Especially in the overweight patient, it is critical to gain as much control of the pelvis as possible. Less than ideal fit or suspension around the waist may result in significant cephalad migration of the brace when the patient sits. The posterior inferior trim line should not be too long, or this may also contribute to superior displacement of the brace when the patient sits. Occasionally, if the orthosis is otherwise appropriate, the neck ring may need to be lowered to better accommodate the seated position.

Contour of the superstructure may adversely affect anterior neck ring or sternal pad pressure. If there is excessive anterior contact or pressure at the neck ring or sternal pad, then either posterior pad pressure must be reduced or the superstructure must be adjusted into slightly more kyphosis. Since the patient must be able to unweight the sternal pad or pull completely off the throat component of the neck ring, too much extension of the superstructure must be avoided.

In patients with kyphoscoliosis for whom the MB is being used primarily for treatment of the sagittal plane deformity, a trochanteric extension or pad or an axillary strap or both may be required to maintain neck ring balance in the coronal plane. (See Figure 2B)

Complications of Milwaukee Brace Treatment:

In the early reports on MB treatment of scoliosis, problems tolerating the brace both secondary to skin contact pressure and mandibular pressure were reported. As mentioned, the development of malocclusion and dental abnormalities caused abandonment of the chin rest in favor of a throat mold, thereby avoiding mandibular pressure.

Moe and Kettleson reported a 16.5% incidence of pressure sores primarily over the iliac area. More recent studies do not describe similar levels of skin problems. [6]

One of the biggest "complications" of MB treatment regimens is the inability to enlist the support of patients and families in complying with prescribed utilization of the brace 20-23 hours per day. Teenagers typically have a heightened awareness of physical appearance and body image and the relatively high profile of the MB neck ring makes the brace cosmetically unacceptable to many patients. Non-compliance with MB treatment remains an ongoing challenge to the physician and can be enhanced by a supportive family, a lower profile design (if appropriate), a comfortable well-fitting orthosis, and a compassionate and caring physician.

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