A COMPREHENSIVE STUDY OF THE WHOLE ORTHOTIC TREATMENT PERIOD IN ADOLESCENT IDIOPATHIC SCOLIOSIS WITH THE CONSIDERATION OF FORCE APPLICATION, PATIENT'S CLINICAL FEATURES, AND TREATMENT COMPLIANCE

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A Comprehensive Study of the Whole Orthotic Treatment Period in Adolescent Idiopathic Scoliosis with the Consideration of Force Application, Patient's Clinical Features, and Treatment Compliance

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A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy

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CERTIFICATE OF ORIGINALITY

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ABSTRACT

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity that may progress rapidly during puberty, leading to pain, functional limitations, and psychosocial burden if left untreated. Thoracolumbosacral orthoses (TLSOs) represent the primary nonoperative intervention for moderate AIS in skeletally immature patients; however, treatment outcomes remain highly variable. Despite decades of clinical use, orthotic force application is still largely empirical. A critical gap lies in the lack of integrated evidence explaining how controlling force direction, its relationship to spinal deformity, patient-specific clinical features, and treatment compliance jointly influence orthotic effectiveness. This limitation constrains the development of evidence-based and personalized orthotic strategies. Accordingly, this doctoral thesis investigates the multifactorial determinants of orthotic treatment effectiveness in AIS through five interrelated sub-studies, with a particular focus on the biomechanics of controlling force direction (CFD) and its interaction with structural and patient-related factors.

The first sub-study developed a computer vision–based method to quantitatively estimate controlling force direction from CAD/CAM orthotic models and examined its association with treatment outcomes. When considered independently of structural orientation, CFD was not significantly associated with either immediate in-orthosis correction or long-term stabilization, indicating that force direction alone is insufficient to capture the complexity of corrective biomechanics.

The second sub-study introduced the concept of CFD–PMC alignment, defined as the angular difference between CFD and the plane of maximum curvature (PMC). Closer alignment, particularly within 15°–20°, was associated with significantly greater improvements in PMC-specific curvature, especially among patients with milder deformities. These findings support the premise that effective orthotic correction requires force application to be guided by individual structural orientation.

The third sub-study evaluated spinal flexibility, quantified by the reduction in Cobb angle from standing to supine radiographs, as a biomechanical moderator of treatment response. Flexibility demonstrated a modest association with in-orthosis correction and interacted with CFD–PMC alignment, suggesting that long-term outcomes depend on

how intrinsic flexibility translates into mechanical responsiveness under structure-guided force application.

The fourth sub-study examined body habitus using body mass index (BMI) and BMI-for-age Z-scores. Contrary to previously reported U-shaped associations, no significant relationships were identified between BMI and either in-orthosis correction or long-term outcomes. These results indicate that BMI contributes minimally to outcome variability, further emphasizing the central roles of force–structure alignment and compliance.

The fifth sub-study assessed orthotic compliance using both objective sensor-based wear-time data and subjective self-reports. Higher compliance was consistently associated with superior outcomes. Notably, among patients with comparable wear time, those with better CFD–PMC alignment achieved greater improvements, underscoring the combined importance of orthosis design and patient adherence.

Together, these findings establish an integrated biomechanical and clinical framework for understanding orthotic treatment in AIS. Rather than being driven by any single factor, treatment effectiveness emerges from the combined influence of force application, structural deformity, spinal flexibility, BMI, and compliance. This thesis advances the concept of structure-guided force alignment and highlights the potential for future CAD/CAM orthoses to optimize controlling force vectors relative to individualized spinal deformity, thereby enabling more personalized, reliable, and evidence-based scoliosis management.

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Liu S, Wong MS. Quantitative Estimation of Orthotic Controlling Force Direction and Its Association with Orthotic Treatment Outcomes in Adolescent Idiopathic Scoliosis. (Manuscript in preparation)

Liu S, Wong MS. Body Mass Index and Orthotic Treatment Effectiveness in Adolescent Idiopathic Scoliosis: The Mediating Role of Correction and Compliance. (Manuscript in preparation)

Liu S, Wong MS. Clinical Relevance of Supine Radiographic Flexibility for Individualizing Orthotic Treatment in Adolescent Idiopathic Scoliosis. (Manuscript in preparation)

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LIST OF ABBREVIATIONS

Adolescent idiopathic scoliosis	AIS
Thoracolumbosacral orthosis	TLSO
Three dimensional	3D
The International Society on Scoliosis Orthopaedic and Rehabilitation Treatment	SOSORT
Scoliosis Research Society	SRS
Controlling force direction	CFD
Computer-aided design/computer-aided manufacturing	CAD/CAM
Plane of maximum curvature	PMC
Finite element model	FEM
Receiver operating characteristic curve	ROC
Area under the curve	AUC
Body Mass Index	BMI
BMI for Age Z-score	BAZ
Odds Ratio	OR

CHAPTER I INTRODUCTION

1.1 Background: Adolescent Idiopathic Scoliosis and Orthotic Treatment

Scoliosis is a complex three-dimensional deformity of the spine, defined by a lateral curvature of at least 10° Cobb angle on a standing coronal radiograph [1, 2]. Adolescent idiopathic scoliosis (AIS) is the most common form of scoliosis, characterized by a lateral curvature with vertebral rotation and often abnormal sagittal alignment, typically affecting adolescents aged 10–16 [1, 2]. The overall prevalence of scoliosis (all types) is about 3.1% (95% CI: 1.5%–5.2%) [3], while reported AIS prevalence ranges from 0.47% to 5.2% across studies [4]. AIS is significantly more common in females than in males, with reported female-to-male ratios of roughly 1.5:1 in mild curves (10°–20°) and up to 7:1 in more severe curves (Cobb angle >40°) [4]. While AIS's exact etiology remains multifactorial and incompletely understood, if left untreated during the rapid pubertal growth spurt, AIS can progress quickly, leading to noticeable trunk deformity and, in severe cases, impaired cardiopulmonary function [5, 6].

For moderate AIS curves in skeletally immature patients (20°–45° Cobb angle), the standard non-surgical treatment is orthotic treatment (e.g., bracing) with a thoracolumbosacral orthosis (TLSO). The goal of bracing is to halt or slow curve progression until skeletal maturity, thereby avoiding surgery while maintaining spinal function and appearance [7-10]. Commonly used braces (e.g., the Boston brace, Chêneau brace) are custom-fitted rigid devices that apply external controlling forces to the torso in an effort to straighten the spine and prevent further curvature [11, 12]. High-quality longitudinal studies have shown that braces can significantly reduce the risk of curve progression and may even achieve partial curve correction during growth [7, 8, 13-16]. For instance, the landmark BrAIST trial demonstrated that wearing a TLSO significantly reduces the risk of curve progression to surgical thresholds. The study found that about 72% of braced patients in the trial avoided progression past 50°, compared to only 48% of patients who received observation [13]. Moreover, bracing effectiveness is strongly dose-dependent, which means patients who wear the brace for longer hours per day tend to achieve better outcomes [17-20]. Current bracing protocols, as recommended by orthopedic societies, typically call for full-time wear (18-23 hours per day) for high-risk curves to maximize effectiveness [7, 8].

Despite bracing's overall efficacy, treatment outcomes remain highly variable among individuals. Some adolescents experience complete curve stabilization or even improvement with diligent brace use, whereas others continue to worsen and ultimately require surgery, even under seemingly similar treatment protocols. This inconsistency reflects AIS's biomechanical complexity and inter-individual differences. Notably, even braces designed under similar protocols can yield markedly different results, depending on how forces are applied, how the spine responds, and how well patients adhere to the prescribed regimen.

From a biomechanical standpoint, braces rely on the three-point pressure system, a fundamental principle wherein a primary controlling force is applied laterally or posterolaterally at the apex of the curve, countered by two opposing forces located proximally and distally on the concave side of the trunk [21-23]. The rigid thoracolumbosacral orthosis (TLSO) primarily corrects the lateral curvature in the coronal plane, but has limited effectiveness in correcting transverse plane deformities (such as axial rotation and rib hump) and often flattens normal sagittal curvatures (e.g., reducing thoracic kyphosis and lumbar lordosis) [24-26]. Proper brace fitting, including pad placement, pad pressure, and tightening, and the direction and location of force application, has been associated with better prevention of curve progression [27-31]. While this concept is well established, the practical application of controlling forces—such as their optimal magnitude, exact anatomical placement, and directional orientation—remains imprecise and guided mainly by clinical intuition rather than empirical evidence [10, 32]. Moreover, these controlling forces are often oriented without systematic reference to the patient's individual curve geometry, limiting their effectiveness in achieving true 3D correction.

In addition to brace design and force application, numerous factors have been studied in relation to bracing outcomes: curve magnitude, type, skeletal maturity, in-brace correction, spinal flexibility, compliance, BMI, and psychosocial factors [19, 33-43]. Among them, high initial in-brace correction consistently emerges as a strong predictor of long-term bracing success [44-50]. Moreover, spinal flexibility—measured via supine or bending radiographs—also influences response, with more flexible curves generally responding better [44, 49, 51-55]. Meanwhile, patient compliance has long been recognized as critical [13, 17-20]; wearable sensor studies and clinical trials showed that patients who wear braces closer to the prescribed hours have markedly better outcomes than those who are less adherent [56-60]. However, inconsistencies remain in how these factors interact, and the thresholds for "sufficient" correction or wear time may vary across patients.

Recent clinical guidelines emphasize that bracing success cannot be attributed to any single factor but reflects the interplay of multiple influences. In practice, effectiveness depends on the interaction of orthosis design (how controlling forces are oriented and applied), patient-specific characteristics (e.g., spinal flexibility and body habitus), and behavioral adherence (particularly compliance with prescribed wear time). A central challenge in AIS orthotic management is therefore to clarify how these domains interact and to optimize strategies that integrate orthosis force application mechanics, patient-specific clinical features, and real-world orthosis-wearing compliance together.

1.2 Force Application, Patients' Clinical Features, and Compliance Framework

Building on the above context, adolescent idiopathic scoliosis (AIS) is a multifactorial condition, and its response to orthotic treatment depends on a complex interplay between brace mechanics, patients' characteristics, and treatment compliance elements. Prior studies have examined various predictive factors such as age, gender, skeletal maturity, curve type, in-brace correction, and compliance. However, most investigations have considered these variables in isolation, and not all are equally amenable to clinical or engineering intervention. For example, demographic traits such as age or sex are fixed, whereas brace design parameters or adherence behaviors are modifiable and therefore provide more direct opportunities for optimization. This thesis focuses on a subset of clinically relevant and potentially actionable factors. These include:

1) Controlling Force Direction (CFD): the direction of the forces applied by the brace, which can be adjusted by brace design.
2) Force Alignment with the Curve (CFD–PMC Alignment): the orientation of the brace's controlling force relative to the spine's three-dimensional curve plane (often termed the plane of maximum curvature, PMC), which could be optimized through advanced planning and customization.
3) Spinal Supine Flexibility: the intrinsic flexibility of the scoliotic spine (how

much the curve can straighten under external force or change of posture). While not directly modifiable, flexibility is critical for risk stratification and can inform realistic treatment goals.

4) Body Mass Index (BMI): the patient's body habitus, represented by BMI, a physiological factor that can influence brace fit, force transmission, and comfort. BMI itself cannot be acutely changed, but recognizing its impact allows for patient-specific adjustments and long-term health guidance.
5) Brace Compliance: the patient's adherence to wearing the brace. Compliance is a behavioral factor that is highly modifiable via patient education, monitoring, and support strategies.

To guide this thesis, we propose a mechanistic framework that organizes the determinants of brace success into three interrelated domains: brace mechanical, patient characteristics, and treatment compliance domains.

1) The brace mechanics domain concerns how controlling forces are applied to the body through orthotic design, including the direction and alignment with the deformity.
2) The patients' clinical features domain, such as spinal flexibility and body habitus, that influence how the spine responds to these forces.
3) The treatment compliance domain reflects how consistently the prescribed treatment is followed, with compliance playing a crucial role in translating the mechanical potential of the brace and patients' response to the brace into long-term therapeutic effect.

These domains are interdependent. A brace that is mechanically well-designed may still fail in a rigid spine or when worn inconsistently. Conversely, high compliance may partially compensate for suboptimal mechanics, particularly in flexible spines. Understanding these interactions is therefore essential for developing more effective and personalized bracing strategies. Guided by this framework, the five sub-studies of this thesis were designed to address each of these domains in a systematic way, with the first two studies focusing on the brace mechanics domain, followed by analyses of patient characteristics and treatment compliance. Together, these studies form an integrated investigation into why brace treatment succeeds or fails in AIS.

1.2.1 Brace mechanics: Force Application and CFD-PMC Alignment (Substudies 1 & 2)

The first study examines the controlling force direction (CFD) applied by the brace, a fundamental yet understudied parameter. While bracing principles are grounded in the three-point pressure system, few studies have quantified whether the *direction* of applied force itself matters. Drawing upon insights from finite element modeling (FEM) studies, we investigate whether certain CFD angles are more effective in achieving coronal and three-dimensional correction in clinical practice.

Building on this, the second study evaluates whether aligning the brace's force vector with the patient's individual curve orientation (i.e. the plane of maximum curvature) improves bracing efficacy; this study introduces a novel quantitative measure of force–curve alignment to test the hypothesis that better alignment yields better correction.

1.2.2 Patients' Clinical Features: Modulating Response Potential (Substudies 3 & 4)

The next two studies address patient-specific physiological factors. Study 3 investigates the role of spinal flexibility: it asks how pre-brace flexibility (measured by supine or bending radiographs) correlates with initial in-brace correction and long-term outcome, and whether a minimum flexibility threshold is required for effective bracing.

Beyond spinal stiffness, study 4 evaluates Body Mass Index (BMI) as a physiological surrogate for body composition. BMI may influence brace fit, force transmission, and soft-tissue buffering. By analyzing the role of BMI in shaping treatment response, this study adds nuance to the understanding of how patient physiology interfaces with brace mechanics.

1.2.3 Treatment Compliance: From Design to Real-world Delivery (Substudy 5)

Finally, the fifth study centers on the behavioral domain of compliance, the bridge between prescribed intervention and real-world implementation. Regardless of how well the brace is designed or how responsive the patient's spine is, insufficient wear time can nullify therapeutic potential. Study 5 assesses the impact of actual brace wear time on treatment success, using objective sensor data (and patient self-reports) to quantify compliance. It further examines whether high compliance can compensate for suboptimal mechanical correction, and conversely, whether poor compliance can undermine even a well-designed brace.

1.3 Integrating Force Application, Patients' Clinical Features, and Treatment Compliance Factors

The five components examined in this thesis, controlling force direction (CFD), CFD–PMC alignment, spinal flexibility, body mass index (BMI), and compliance, do not act in isolation. Instead, they reflect interdependent domains that collectively determine treatment response (Figure 1-1): brace mechanics (how controlling forces are applied by spinal orthosis and aligned with PMC), patients' clinical features (the patient's curve flexibility and BMI), and treatment compliance (what is the minimal orthosis-wearing hours for effective treatment).

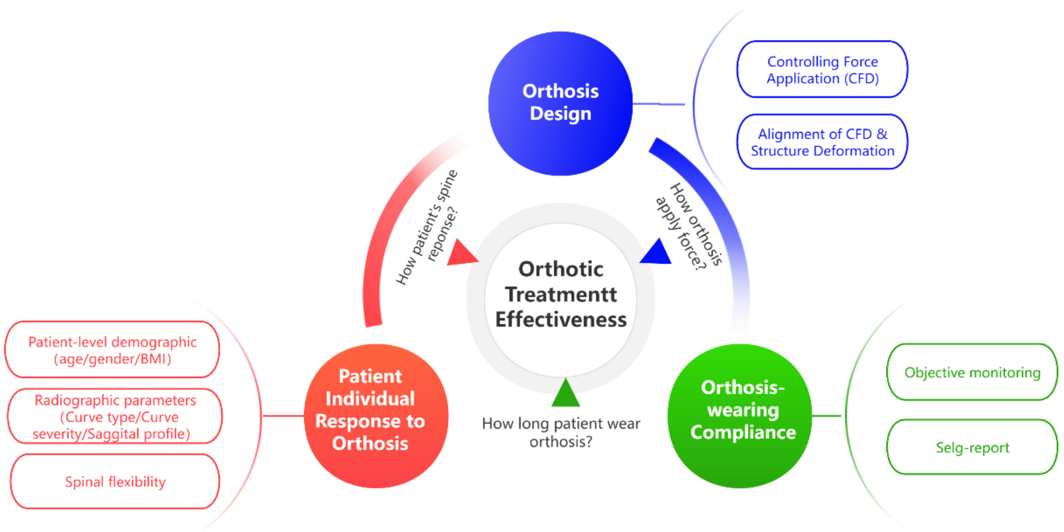

Figure 1-1. Integrated Conceptual Framework

A central premise of this thesis is that evaluating these domains together provides more meaningful insights than considering any single factor alone.For instance, the immediate structural effectiveness of a brace depends not only on how controlling forces are applied (CFD and its alignment with the PMC) but also on the spine's inherent flexibility. These two domains jointly determine whether sufficient in-brace correction is achieved, a short-term result strongly predictive of long-term success. Yet even the best in-brace correction cannot translate into durable benefit without adequate compliance. Conversely, high compliance may partially offset suboptimal force orientation, particularly in patients with highly flexible curves. Thus, long-term outcome emerges from the balance and interaction of these domains rather than from any one factor.

This integrative perspective highlights the need for models that account for both the quality of correction delivered and the effective dosage sustained through compliance. Importantly, these domains may interact in non-linear ways: spinal flexibility could modulate the importance of compliance (a flexible curve requiring fewer hours of wear, a rigid curve demanding near-perfect adherence), while CFD–PMC alignment may be especially critical for less flexible spines with limited capacity to compensate for misdirected forces. Such interactive mechanisms have received little attention in prior studies, which typically examined mechanical, physiological, or behavioral factors in isolation. By addressing these interdependencies, the present thesis seeks to advance a more personalized, systems-level understanding of bracing and to fill a critical gap in the literature.

1.4 Aims of the Thesis

The overarching aim of this thesis is to understand why brace treatment outcomes in adolescent idiopathic scoliosis by integrating mechanical, anatomical/structural, and behavioral determinants into a unified framework. Although thoracolumbosacral orthoses (TLSOs) are widely used, brace design and prescription remain largely empirical, with limited attention to how controlling forces interact with patient-specific spinal anatomy, intrinsic responsiveness, and adherence patterns. This thesis seeks to move the field toward a precision bracing paradigm by identifying measurable, modifiable predictors of treatment outcome.

The central hypothesis is that orthotic efficacy is governed not by any single parameter, but by the interplay between: (1) how controlling forces are applied (brace mechanics), (2) how the patient's spine responds structurally and mechanically (patient-specific factors), and (3) how consistently the brace is used (compliance). Accordingly, the thesis encompasses five interrelated sub-studies (Chapters. 3 to 7), each addressing one key domain yet contributing to a comprehensive understanding of treatment outcomes:

1) Force Application, which includes Controlling force Direction (CFD) and Structural Alignment with Plane of Maximum Curvature (CFD–PMC): To develop and validate an computational method for quantifying force direction in CAD/CAM brace models, and to determine whether braces whose force vectors are more closely aligned with the patient's plane of maximum curvature (PMC) achieve superior in-brace correction and long-term stabilization.
2) Spinal Flexibility: To evaluate whether supine flexibility predicts responsiveness to bracing, both immediately and at long-term follow-up, and to assess its interaction with force–structure alignment. The aim is to establish whether flexibility serves as a biomechanical moderator that amplifies or attenuates the brace effect.
3) Body Habitus (BMI): To conduct an exploratory analysis of whether baseline BMI and BMI-for-age z-scores influence correction quality, compliance, or outcomes, thereby clarifying inconsistent evidence in the literature and highlighting potential subgroups (e.g., underweight patients) that may require special attention.
4) Treatment Compliance: To quantify the relationship between objective wear time and treatment outcomes, to study the relationship between compliance and treatment outcomes, and to investigate the minimum orthosis-wearing time for patients to achieve effective treatment.

Through these aims, the thesis seeks to generate practical evidence for structure-guided, patient-tailored orthotic treatment strategies. By linking optimized controlling force direction, patient responsiveness, and their clinical feature, and treatment compliance together, this work aims to guide clinicians toward more precise, individualized orthosis design and treatment planning. For instance, if poor force–PMC alignment is found to be highly predictive of brace failure, orthotists could be trained to adjust force direction to improve alignment for those patients. If low pre-brace flexibility is confirmed as a significant risk factor, then adding stretching exercises might be advised for such patients. If a certain minimum daily wear threshold is shown to be virtually necessary to prevent progression, this underscores the importance of interventions to ensure patients meet that compliance target, such as routine monitoring and feedback or psychosocial support. The ultimate aim is to establish evidence-based guidance for personalized orthotic treatment in AIS, aligning force application by spinal orthosis and orthosis-wearing prescriptions with patient-specific clinical features to optimize the prevention of curve progression and the need for surgery.

1.5 Thesis Structure and Outline

This thesis is organised into eight chapters and comprises five interrelated sub-studies that collectively examine the multifactorial determinants of thoracolumbosacral orthosis (TLSO) effectiveness in adolescent idiopathic scoliosis (AIS). An overview of the study cohort, data sources, and the five sub-studies is provided in Figure 1-2.

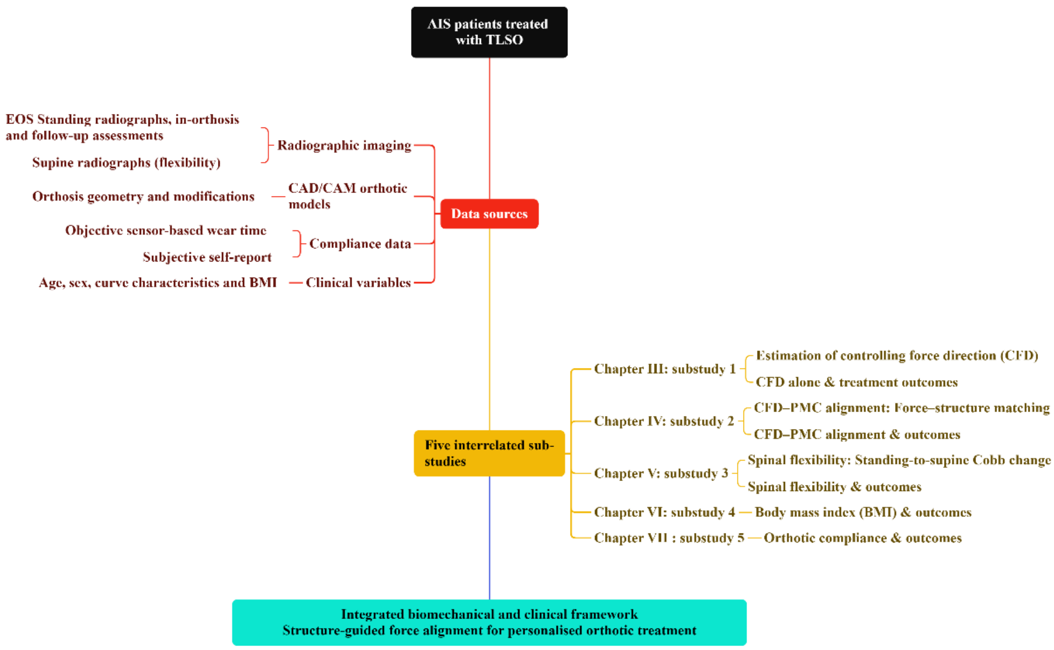

Figure 1-2. Overview of Five Substudies

Chapter II (Literature Review) summarises the biomechanics and clinical management of AIS, with emphasis on orthotic treatment. It synthesises current evidence regarding controlling force application, structure–mechanics considerations, patient-related factors (e.g., flexibility and body habitus), and treatment compliance, thereby defining the key research gaps addressed in this thesis.

Chapters III–VII present the five sub-studies. Chapter III describes the shared cohort, imaging protocols, computational workflow, and statistical analyses adopted across the sub-studies, including the proposed method for quantifying controlling force direction (CFD). Chapter IV evaluates CFD and introduces the concept of CFD–PMC alignment, investigating its association with orthotic outcomes. Chapter V examines spinal flexibility as a biomechanical contributor to in-orthosis correction and longer-term outcomes. Chapter VI explores body habitus using BMI and BMI-for-age Z-scores in an exploratory analysis. Chapter VII evaluates orthosis-wearing compliance, incorporating objective wear-time data to characterise dose–response effects and its interplay with orthosis design factors.

Chapter VIII (Synthesis, Discussion, and Conclusions) integrates findings across all sub-studies to form an overarching framework for understanding orthotic effectiveness in AIS. It discusses the combined roles of force application, structural orientation, patient biomechanics, and compliance, outlines clinical implications for a structure-guided and patient-tailored bracing strategy, and proposes directions for future work, including prospective validation studies.

Overall, by addressing key gaps in force application, patient-related modifiers, and real-world adherence, this thesis advances AIS bracing from predominantly empirical practice toward a more data-driven and personalised approach.

CHAPTER II LITERATURE REVIEW

2.1 Overview: Biomechanical Principles of AIS and Bracing

Adolescent idiopathic scoliosis is increasingly understood not as a simple lateral spinal deviation, but as a three-dimensional (3D) deformity involving complex interactions across the coronal, axial, and sagittal planes. Clinically, the hallmark of AIS remains the coronal curvature, typically measured as the Cobb angle on frontal radiographs. However, this lateral deviation is consistently accompanied by axial vertebral rotation and flattening or inversion of normal sagittal contours, particularly thoracic hypokyphosis and lumbar hypolordosis [61, 62].

This 3D nature of the deformity presents unique biomechanical challenges in non-surgical treatment. Effective correction requires not only reducing the magnitude of the lateral curve, but also addressing transverse plane asymmetries and restoring physiologic sagittal alignment [62-64]. To this end, bracing—particularly thoracolumbosacral orthoses (TLSOs)—has emerged as the most widely accepted non-invasive intervention for moderate AIS in skeletally immature patients [65, 66].

The fundamental biomechanical principle underlying brace design is the three-point pressure system, in which a primary controlling force is applied at the apex of the curve (usually on the convex side), countered by two opposing forces proximal and distal to the apex, typically on the concave side [65]. This triad of forces creates a bending moment aimed at realigning the spine toward neutral. While conceptually simple, this system operates within a complex anatomical and mechanical environment. The direction of force application, the location of pads, strap tension, the stiffness and morphology of the spine, and the mechanical coupling through soft tissues all affect the actual transmission of forces to bony structures [21, 22, 28, 32, 67-80].

In addition, brace effectiveness is inherently dynamic. The applied external forces must overcome not only gravitational loads and soft-tissue resistance, but also the intrinsic stiffness of the spine and its resistance to rotational and sagittal deformations [21, 64, 66, 72]. Moreover, controlling forces must be maintained over time and during growth, adding a temporal component to the mechanical model of brace therapy [74, 79].

In recent years, advanced imaging techniques (e.g. EOS, 3D reconstruction) and computational tools (e.g. finite element modeling) have deepened our understanding of how brace forces interact with the 3D structure of the spine [63, 66, 81-86]. These studies suggest that not just the presence of force, but the precise direction, vector alignment, and anatomical targeting are key determinants of biomechanical success [64, 65, 77, 87-92]. Yet translating these insights into everyday clinical practice remains challenging. Brace fabrication still largely relies on empirical design, often using surface-based references rather than internal structural parameters such as the plane of maximum curvature (PMC) or the rotational axis of deformity [61, 83, 93-98].

Thus, while the three-point pressure system is biomechanically intuitive, its clinical translation requires careful attention to force direction, structural anatomy, and patient-specific responses. Each of these elements is addressed by a variable examined in this thesis. The following sections review five critical and partially modifiable domains in scoliosis bracing: controlling force direction, CFD–PMC alignment, spinal flexibility, BMI-related body morphology, and compliance, each contributing to the broader goal of improving personalized, biomechanically grounded treatment strategies.

By examining these factors both individually and in combination, this thesis adopts a multifactorial approach to advance brace treatment toward greater precision. Instead of relying on an empirical “one-size-fits-all” model, the framework developed here seeks to establish a structure-guided, biological-informed, and behavior-aware paradigm for AIS bracing. The subsequent chapters elaborate on each domain in turn: first, the mechanical principles of force application; second, the structural alignment of these forces with patient anatomy; third, the physiological responsiveness reflected by flexibility and body BMI and finally, the behavioral dimension of adherence (compliance).

2.2 Controlling Force Direction in Brace Design

The first key component is the controlling force direction CFD applied by an orthotic brace. In bracing terminology, CFD refers to the vector or angle at which the brace’s pads push on the torso to correct the spinal curvature. Traditional brace designs apply forces roughly in a posterolateral direction on the convex side of the curve, following the three-point pressure principle [23, 32, 79, 91, 99]. The magnitude and direction of these forces will determine how the spine is deformed within the brace, ideally unloading and de-rotating the curved segments [29]. If the forces are misdirected, they may fail to correct the curve adequately or may induce undesirable effects on spinal alignment [32].

However, the orthosis design didn't explicitly quantify the 3D direction of forces applied [32]. In practice, an orthotist positions pads inside the brace to push on the body where deemed appropriate, but this placement may not fully account for the true spatial orientation of the patient's spinal deformity. Biomechanical studies underscore that both the level and direction of forces are crucial in deforming the spine [27, 28, 30]. Finite element simulations have shown, for example, that purely lateral (frontal-plane) forces versus posterolateral forces can have different effects on spinal curvature and rotation [64, 65, 69, 89, 90, 100]. Clinical research also demonstrated that precise pad positioning and force direction correlate with better in-brace corrections [28, 68, 78, 101], while other researchers have attempted innovative padS that adjusts pressure in real-time to maintain effective force levels [57]. These findings suggest that how the brace pushes on the body is as essential as its force.

One recent clinical study attempted to categorize and compare different CFD orientations in patients with AIS who wore CAD/CAM braces [32]. They divided the posterior quadrant of the torso (where a typical thoracic brace pad acts) into four "zones" of pad orientation: from near-posterior (zone 1), through mid-posterolateral (~45° off sagittal, zone 3), to purely lateral (~90°, zone 4). Patients whose brace pads exerted forces in the mid-range posterolateral directions (approximately 45–68° from the sagittal plane, corresponding to zone 3) showed the most favorable balance of outcomes: they had significant curve correction in the coronal plane without suffering a large loss of thoracic kyphosis. By contrast, those with more posteriorly directed forces (e.g., zone 2, around 22–45°) still achieved curve correction but tended to experience a marked decrease in thoracic kyphosis (flattening of the normal sagittal profile). This suggests that overly posterior forces may inadvertently "push the spine straight back," reducing desirable kyphosis, whereas a more optimally angled force can correct the lateral curve while preserving sagittal alignment. Although further research is needed to generalize these results, this study provides quantitative evidence that CFD relative to the patient's anatomy influences the 3D outcome of bracing [32]. In essence, brace efficacy may be maximized when controlling forces are applied in the correct direction. Determining that direction likely depends on the individual curve morphology, which leads to the next consideration: the orientation of the scoliotic curve itself in three dimensions.

2.3 Aligning CFD with the Plane of Maximum Curvature

AIS is fundamentally a three-dimensional deformity, meaning the scoliotic curve does not lie purely in the coronal plane. Instead, each curve has its own oblique orientation through the body, often described by the concept of the Plane of Maximum Curvature (PMC)[93, 95, 102, 103]. The PMC is defined as the vertical plane in which the scoliotic curve's deviation is greatest; in other words, if one projects the spine onto various planes, the plane that yields the largest Cobb angle is the PMC [102, 103]. This plane is typically rotated somewhat between the true coronal and sagittal planes, reflecting the combination of lateral bend and vertebral rotation in AIS. The PMC angle (or orientation) describes how far this plane is twisted relative to the anatomical sagittal plane [104]. Recent advances in 3D radiographic analysis have highlighted that measuring curvature in the PMC (a "3D Cobb angle") provides a more accurate gauge of true deformity severity than the traditional coronal Cobb on a frontal X-ray [95, 102, 104-106].

By extension, the PMC concept has important implications for bracing: logically, applying controlling forces in the same plane as the curve's maximum deformity should yield more effective correction. If the brace's force vector is not aligned with the curve's plane, part of the applied force may be wasted on out-of-plane deformation (for example, unnecessarily flattening or twisting the spine) rather than directly correcting the primary curvature. Misalignment between the force direction and the curve orientation could thus reduce the efficiency of bracing.

Considering the alignment between CFD and the PMC is a novel, structure-guided approach that links brace design with patient-specific curve anatomy. Ideally, if a patient's scoliotic curve lies in an oblique plane (say 30° off the coronal plane toward the sagittal plane), the brace's pad should exert force along that same 30° trajectory, directly into the curve's apex. In practice, however, braces are usually designed and applied with reference to the patient's frontal anatomy, and achieving true 3D force alignment is challenging without advanced imaging and customization. Research in this area is just emerging. A computational study by Wu *et al.* developed a method to estimate a patient's PMC and suggested that aligning controlling forces closer to the PMC orientation might improve in-brace correction [104-106]. The clinical "zonal force" study mentioned above also hints at this concept: the most effective pad orientation (zone 3) likely corresponded to forces more aligned with the typical plane of thoracic scoliotic curves. In contrast, forces applied in zone 2 (more directly posterior) were essentially pushing more in the sagittal plane than the curve's actual deformity plane, leading to off-plane effects like excessive kyphosis reduction. In those cases, the brace was not optimally aligned to the spine's curvature plane; by comparison, zone 3 forces (more lateral) were closer to the deformity plane, correcting the coronal component without as much sagittal distortion.

Aligning CFD with the PMC can be viewed as matching the brace's "attack angle" to the spine's "defect angle." From a clinical perspective, this implies a more personalized orthotic design strategy: instead of a one-size-fits-all approach of pushing purely laterally, one would determine each patient's curve orientation (using 3D imaging such as EOS or MRI) and then place the pads so that their force vectors lie in that same plane. In theory, such alignment would increase the efficiency of force use—more of the brace's pressure would go directly into correcting the curvature rather than deflecting it into another plane—and it could also minimize unwanted iatrogenic effects (like brace-induced flattening of normal kyphosis). While this concept is intuitively compelling, it remains to be rigorously tested. This thesis will investigate whether *quantitatively* smaller angles between the brace's CFD and the patient's PMC correlate with better in-brace and long-term outcomes. In summary, integrating the PMC into brace design represents an evolution from purely surface-based bracing techniques to a more structure-guided strategy that addresses the 3D nature of AIS.

2.4 Spinal Flexibility and Brace Responsiveness

Beyond brace design considerations, the intrinsic flexibility of the scoliotic spine is a crucial patient-specific factor that influences orthotic treatment results [51, 52, 107]. Spinal flexibility in AIS refers to how much the curve can correct or "bend back" toward normal alignment when external forces or gravity act upon it. Clinically, flexibility is often assessed via bending radiographs (e.g., side-bending or supine X-rays) that show the maximum reducibility of the curve [108-115]. There were also studies that used ultrasound to assess spinal curvature in different positions and evaluate spinal flexibility with no extra radiation [116-119]. A highly flexible curve might partially straighten out on a supine radiograph, whereas a rigid curve remains nearly the same as when standing. Intuitively, one would expect a flexible spine to be easier to correct with a brace – much like a green twig bends under pressure more than a dry stick. Indeed, flexibility has been used by surgeons to plan scoliosis surgery (to predict correction achievable) [108, 111, 115, 120-123], and analogously, it is thought to influence brace treatment [34, 42, 44, 53-55, 75, 107, 124-126]. Multiple studies have found that patients with more flexible curves tend to achieve greater initial correction in braces and have a lower risk of curve progression over time [34, 42, 44, 51, 53-55, 107, 119, 124]. For example, Cheung *et al.* reported that for every 1% increase in supine flexibility (percentage Cobb angle reduction on a supine film), the odds of curve progression under bracing dropped by about 4% [124]. In a large cohort, a threshold of approximately 28% flexibility on supine radiographs was identified as a cutoff: patients below 28% flexibility had a significantly higher likelihood of brace failure (progression ≥5°) compared to those above 28% [54]. This suggests that extremely stiff curves (which hardly correct at all when unloaded) often do not respond sufficiently to braces. Consistently, a recent systematic review concluded there is high-quality evidence that greater pre-brace flexibility predicts less risk of progression, and it highlighted flexibility <28% as a risk factor for poor outcome [107].

However, the literature on flexibility is not entirely uniform. Luo et al.'s review indicated that, although spinal flexibility was strongly correlated with the in-brace Cobb angle or correction rate, moderate evidence supported the notion that spinal flexibility could serve as a predictor of bracing outcomes. Additionally, a few studies have reported no strong correlation between flexibility and final brace outcome [127, 128], possibly due to differences in measurement methods or confounding factors. For instance, Cheung et l's study only included patients with more than 16 hrs/day of orthosis wearing compliance [54]. That indicated that some rigid curves can still be halted with a brace if they are small and the patient is highly compliant. In contrast, some flexible large curves might progress if the brace is ineffective or underused. In general, though, most evidence supports the idea that flexibility is a moderator of brace efficacy rather than a direct cause of success: flexibility enables better correction but does not guarantee it. In practice, flexibility usually exerts its influence through the magnitude of initial in-brace correction: a flexible spine will show a significant Cobb angle reduction on the first in-brace X-ray (which is one of the strongest predictors of long-term success) [42, 44, 50, 125, 129-131]. Conversely, if a patient's in-brace correction is minimal (often due to rigidity), it signals that even with optimal brace design, the curve may be biologically resistant to change. This has important implications for setting expectations and considering adjunct treatments. For very stiff curves, clinicians might consider more aggressive brace designs, additional physiotherapy to increase mobility, or even early surgical referral in extreme cases.

It also raises the question of whether anything can be done to improve a spine's flexibility or better leverage the flexibility that exists. If even a slight improvement in flexibility can be achieved, it might in turn augment the spine's responsiveness to bracing, particularly for otherwise rigid curves. Some brace protocols incorporate exercise regimens, e.g., physiotherapeutic scoliosis-specific exercises (PSSE) or stretching exercises, or passive mechanical stretching, aimed at maintaining spinal mobility and muscle flexibility, to ultimately enhance brace results [119, 132-134]. Emerging technologies like dynamic braces. which can intermittently adjust the force application [74] or nighttime bending braces [135] attempt to take advantage of any residual flexibility as well. Some studies investigated the effects of a novel mechanical 3-dimensional scoliosis correction protocol developed to enhance the side-bending spinal flexibility [101, 136]. This consideration supports including flexibility not only as a stratification tool (to predict bracing success) but also as a potential, albeit indirect, target for adjunct therapy aimed at improving overall outcomes.

In summary, spinal flexibility represents a physiological parameter that moderates structural correction. A comprehensive approach to AIS bracing should account for flexibility: assessing it beforehand and factoring it into treatment decisions and prognoses. Patients with low-flexibility curves may require closer monitoring, more aggressive interventions, or realistic counseling that bracing alone has limitations. In contrast, those with highly flexible spines are often good candidates for successful brace treatment. One objective of this thesis is to clarify how pre-brace flexibility and the achieved initial in-brace correction relate to long-term outcomes, and whether integrating flexibility measurements can improve predictive models of brace success.

2.5 Body Mass Index (BMI) and Patients′ Response to Brace

While not a modifiable factor in the short term, body mass index (BMI) represents a physiological characteristic that may influence how controlling forces are transmitted through the body and how tolerable the brace is to wear. As a proxy for body composition, BMI can affect both the mechanical interaction between the brace and the torso and the patient's compliance with bracing, especially in terms of comfort.

Biomechanically, a higher BMI (overweight or obese habitus) may reduce force transmission efficiency by adding a layer of soft-tissue "buffer" between the brace pads and the spine. The brace's controlling forces can be dissipated in this adipose tissue, leading to diminished in-brace curve correction [137, 138]. At the same time, higher pressure may be exerted on peripheral soft tissues, contributing to discomfort or skin issues. In contrast, patients with a very low BMI (thin body habitus) have little natural padding, so brace forces are more concentrated on bony prominences (such as ribs or iliac crests), which can cause pain or skin irritation [139-141]. Both extremes of body habitus, notably underweight and obese patients, thus pose challenges: they may experience reduced mechanical effectiveness of the brace and greater discomfort, which in turn can undermine compliance and overall treatment success.

In current literature, there are still some controversial findings on the effects of BMI on the effectiveness of brace treatment. Some studies have reported a U-shaped relationship between BMI and brace outcomes: both high-BMI and low-BMI adolescents tend to have a higher risk of curve progression [142], whereas those in a middle, healthy BMI range achieve better correction and are more likely to be compliant. Sun et al. demonstrated that low BMI was associated with treatment failure [141], and Koral found that the low BMI group had a higher risk of surgery than those with a normal BMI group [143] . However, Lang et al's study reported there is no significant correlation between BMI and in-brace correction [47]. Zaina et al. found that no relationship between overweight and treatment failure [144].

Therefore, In this thesis, BMI is evaluated as an exploratory factor to better understand its role in modulating both the structural and behavioral aspects of bracing. On the structural side, we examine whether BMI correlates with the amount of in-brace correction achieved (as an indirect measure of force transmission efficiency) and whether outcomes differ by body habitus. On the behavioral side, we consider how BMI might influence brace wear time and comfort (for example, whether higher or lower BMI is associated with lower compliance). Although BMI is not a primary focus on par with the other factors, its inclusion adds a broader perspective on patient-specific physical traits that influence brace responsiveness.

Over the long term, BMI is a physiologically actionable variable. BMI may have the potential in brace treatment planning, helping clinicians anticipate which patients might need closer follow-up, special modifications to their braces (e.g., extra padding or different pressure distribution), or additional support to maintain adherence. While it cannot be changed quickly, there is potential for intervention over the course of treatment. Nutritional counseling and exercise programs might help underweight patients gain healthy mass or overweight patients lose excess weight, potentially improving brace fit and comfort. Such changes require time and commitment, but acknowledging this factor reinforces the importance of a holistic treatment approach that extends beyond the brace design alone. In summary, recognizing BMI's influence on bracing can guide individualized adjustments (in brace construction or patient counseling) and, in the bigger picture, encourage complementary health interventions that support the orthotic treatment.

2.6 Compliance: The Behavioral Challenge in AIS Bracing

No matter how well a brace is engineered or how potentially correctable the spine is, the treatment cannot be effective without adequate patient compliance. In the context of scoliosis, compliance refers to how fully the adolescent patient adheres to the prescribed brace-wearing regimen (typically measured in hours of daily wear). Bracing an adolescent is as much a behavioral and psychosocial challenge as it is a biomechanical one [56]. Teens often face discomfort, inconvenience, and self-consciousness while wearing a brace, all of which can lead to poor adherence. Yet the importance of compliance cannot be overstated: numerous studies have identified brace wear duration as one of the most decisive factors in treatment success [20, 42, 145, 146]. The landmark BRAIST randomized trial and subsequent analyses demonstrated a clear dose-response relationship between wear time and outcome – patients who wore their brace closer to full-time had significantly lower rates of curve progression to surgical thresholds [13]. As noted earlier, wearing a brace >13 hours daily was associated with around 90% success in preventing progression, whereas wearing it <7 hours yielded success closer to 40% [147, 148]. In short, even the best-designed brace will fail if it is not worn as intended.

Ensuring high compliance is challenging. Objectively measured wear time (via thermal or pressure sensors in the brace) has revealed that actual wear often falls short of prescribed wear, with many patients being non-compliant unbeknownst to their clinicians [149-151]. Factors affecting compliance range from physical discomfort and pain to social stigma and emotional distress. Braces can cause skin irritation, restrict mobility, and disturb sleep, making it hard for adolescents to tolerate them for long durations. Psychologically, wearing a visible brace can affect a teenager's body image and invite unwanted attention, impacting quality of life [152, 153]. Studies find that the early period of bracing is critical. If a patient adapts and incorporates the brace into daily life, long-term compliance is better, but those who struggle early tend to abandon wear whenever possible [154]. Interventions to improve compliance have been widely explored, including patient and family education, support groups, cognitive-behavioral techniques, and technological improvements in brace comfort and appearance [19, 56, 57, 60]. For example, lighter and slimmer brace designs or the option of nighttime-only braces in select cases are aimed at improving wearability [155].

Compliance does not act in isolation; it often interacts with the other factors discussed. If a brace is poorly fitting or applies excessive pressure (for instance, due to a stiff curve requiring strong forces), the patient may experience more pain and be less inclined to wear it; thus, mechanical factors can indirectly reduce compliance [155, 156]. Conversely, a well-designed brace that achieves good correction with minimal discomfort may promote better compliance. BMI is an example of a patient factor that links biomechanics and compliance: obese adolescents often report greater heat and discomfort in a brace (due to soft tissue bulk and sweat), and indeed, higher BMI has been associated with lower average wear times [137, 138, 143]. Those patients also tend to show less initial curve correction, as excess adipose tissue can "cushion" or dissipate the brace forces [137, 138]. On the other end, very thin (low BMI) patients sometimes have pain from pressure over prominent ribs or hip bones and may also under-wear the brace [139, 141]. Intriguingly, both high-BMI and low-BMI extremes have been linked to higher rates of brace failure (curve progression), whereas teens of average body weight see the best outcomes [142]. The reasons are multifactorial: biomechanically, force transmission is suboptimal at the extremes of habitus, and behaviorally, compliance tends to be lower in those groups, resulting in a compounding adverse effect. These observations underscore how compliance is intertwined with structural effectiveness. Sufficient wear time is needed to capitalize on whatever controlling forces a brace can impart; if either the force or the wear time is lacking, the outcome is jeopardized.

In clinical practice, improving compliance is therefore a top priority. Regular follow-up visits, personalized counseling, and the use of compliance monitors (with feedback and positive reinforcement) are common tactics to keep patients on track [19, 56-58, 60, 150, 157]. For this thesis, it is crucial to consider behavioral adherence alongside biomechanical design when evaluating brace outcomes. Accordingly, this research incorporates objective compliance data from smart brace sensors to quantify actual wear patterns. In the analyses, we examine how differences in wear time contribute to differences in outcome and explore to what extent boosting compliance could improve results, relative to other factors. Ultimately, addressing the behavioral dimension is key to translating a brace's mechanical potential into real-world therapeutic effect.

2.7 Summary of Gaps and Rationale for This Thesis

Despite decades of research on bracing for AIS, clinical outcomes remain highly variable and difficult to predict. The literature has identified numerous potential influencing factors—such as controlling force application, structural flexibility, and treatment adherence—but these have often been studied in isolation. A recurring limitation is the lack of integrative frameworks that consider how mechanical, structural, and behavioral dimensions interact in real-world treatment scenarios.

More importantly, several clinically modifiable variables remain poorly understood or under-researched. For example, although biomechanical simulations suggest that controlling force direction (CFD) plays a key role in three-dimensional spinal correction, no large-scale clinical studies have directly quantified real-world CFD and evaluated its relationship with treatment outcomes. Similarly, while the concept of the Plane of Maximum Curvature (PMC) provides a more anatomically faithful representation of scoliosis deformity, it has not yet been incorporated into clinical brace design in a systematic, quantifiable way. Whether aligning the direction of applied brace forces with the patient's PMC improves correction remains unknown.

Spinal flexibility has long been considered a prognostic factor, particularly in determining in-brace correction. However, conflicting findings exist regarding its predictive value for long-term outcomes, and no study has explored whether flexibility moderates the effectiveness of force–structure alignment. In addition, the role of body morphology, particularly BMI, has been noted in passing. Yet, little is known about how BMI affects the mechanical coupling between brace and spine, or how it interacts with compliance and comfort. Lastly, while the relationship between compliance and outcomes is well documented, the minimum effective wear time (MEWT) for different patient subgroups remains undetermined. The literature gaps and thesis contributions were summarized in Table 2-1.

This thesis addresses these gaps by adopting a structured, clinically relevant framework that integrates structural, clinical, and behavioral determinants of scoliosis bracing. By examining factors that can be optimized through brace design (e.g., CFD and alignment) or guided by clinical management (e.g., flexibility, BMI, compliance), it aims to clarify which combinations most strongly predict treatment success and under what circumstances they interact. This integrative approach provides a foundation for more individualized and evidence-based bracing strategies.

Table 2-1. Literature Gaps and Thesis Contributions

Factor	Existing Evidence	Key Gap	This Thesis Addresses
Controlling Force Direction	FEM studies show directional impact on 3D correction	No real-world quantification of CFD in clinical braces	Quantifies CFD from brace models and examines its association with outcomes

CFD–PMC Alignment	PMC concept well-defined; alignment proposed in theory	No clinical validation of CFD–PMC alignment on correction	Develops and tests a metric for CFD–PMC alignment in a clinical cohort
Spinal Flexibility	Strong predictor of in-brace correction; mixed for long-term	Unclear if flexibility moderates the effect of CFD or alignment	Explores flexibility as both a predictor and a moderator of brace response
BMI	Known to influence brace fit and comfort	Rarely studied systematically; unclear biomechanical and behavioral effects	Analyzes BMI's role in brace force transmission and compliance interactions
Compliance	Dose–response relationship exists	Minimum adequate wear time not defined for subgroups	Estimates MEWT thresholds

CHAPTER III CONTROLLING FORCE DIRECTION N BRACE TREATMENT FOR ADOLESCENT IDIOPATHIC SCOLIOSIS: ITS ASSOCIATION WITH SHORT- AND LONG-TERM OUTCOMES

3.1 Abstract

Background:

Controlling force Direction (CFD) is a critical yet often unmeasured parameter in orthotic management of adolescent idiopathic scoliosis. While biomechanical modeling supports the importance of transverse-plane force vectors, it remains unclear whether specific CFD angles are associated with favorable clinical outcomes. This study aimed to quantify CFD in a large AIS cohort and examine its relationship with structural correction and long-term treatment response.

Methods:

A total of 265 AIS patients (mean age 12.5 ± 1.4 years; 85% female) treated with CAD/CAM-designed thoracolumbosacral orthoses were retrospectively analyzed. CFD was estimated from 4–8 axial brace slices near the curve apex using a Python/OpenCV pipeline that extracted net surface deformation vectors. The coronal component of the CFD angle was quantified relative to the sagittal plane. Outcome variables included Cobb angle changes at three timepoints: in-brace (T2–T0), off-brace (T3–T0), and post-treatment follow-up (T4–T0). Patients were also classified into four treatment outcomes (Improved, Stable, Progressed, Surgery). Associations were analyzed using correlation, group comparison, and logistic regression models, with subgroup analyses by curve type.

Results:

The CFD angle ranged from 8.1° to 76.7° (mean 48.9° ± 11.1°), with 83.3% clustering between 30° and 60°, suggesting a prevailing design heuristic centered around 45°. However, no significant linear correlations were observed between CFD and: in-brace correction (ΔCobb: r = –0.05, p = 0.38), off-brace correction (r = 0.03, p = 0.58), and long-term follow-up correction (r = 0.01, p = 0.82). Grouping CFD into <30°, 30–60°, and >60° categories also showed no significant differences in any outcome measure (*all* p > 0.2). Curve-type stratification (thoracic, lumbar, thoracolumbar) did not modify

these associations.

Conclusion:

Although the majority of braces exhibited CFD angles within an empirically favored range (~45°), this parameter alone did not predict either immediate or sustained treatment response. These findings call into question the biomechanical sufficiency of fixed-angle design rules and highlight the need to contextualize CFD within individual curve morphology. CFD angle alone may not be enough to influence orthotic effectiveness.

3.2 Introduction

Adolescent idiopathic scoliosis is a three-dimensional spinal deformity involving lateral curvature, axial vertebral rotation, and often altered sagittal alignment. Bracing is the mainstay non-surgical treatment for moderate AIS in growing patients, as evidenced by the Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST), which showed bracing significantly reduces curve progression compared to observation [13]. However, brace treatment outcomes vary widely between individuals. Aside from patient factors like initial curve magnitude, skeletal maturity, and compliance, an often overlooked factor is the biomechanical interaction between the brace and spine, particularly the direction in which controlling forces are applied [32, 68-70, 74, 76, 79, 100, 158].

In current practice, controlling forces are delivered through pads in the thoracolumbosacral orthosis, and their orientation is usually determined empirically by orthotists [67, 68, 78, 79, 159]. Commonly, a posterolateral-to-anteromedial force vector to the coronal plane is applied, almost regardless of curve type [32, 73, 160]. This convention stems from traditional three-point pressure principles, whereby a lateral deformity is countered by a lateral pad push with posterior stabilization [21, 161]. While force magnitude and pad pressure are often considered (e.g., via strap tension adjustments) [80, 162], the direction of force application has remained largely unquantified and not rigorously studied in clinical settings [10, 32, 67]. If the applied force direction deviates from the patient's specific curve geometry, it may correct the deformity less efficiently or impart unintended mechanical effects. To date, no consensus exists on optimal force direction for different curve patterns, highlighting a critical gap between empirical brace design and biomechanical optimization [32, 78, 163].

Recent studies have hinted that force direction could influence bracing efficacy. Previous studies correlated strap tension [68, 74, 78, 80, 159, 164] and pad placement [10, 30, 72, 78, 165] with spinal correction, underscoring that proper pad positioning and force orientation are important for achieving correction. Finite-element simulations further support that both the magnitude [90] and direction of forces [90, 100] affect spinal deformity reduction. For example, Cobetto *et al.* found that certain oblique force vectors improved correction, while purely horizontal forces were less effective [64]. Clinically, Wu et al. introduced a novel method to estimate the brace's controlling force direction and categorized 78 AIS patients by this angle [32]. Their retrospective analysis revealed that braces applying forces in the posterolateral quadrant (approximately 22.5°–67.5° from the sagittal plane) produced significant in-brace curve corrections. Notably, forces in a mid-range (around 45–67°) achieved coronal Cobb angle reduction without causing undue sagittal plane flattening of the spine. This suggests that the *direction* of pad force might impact not only frontal plane correction but also secondary outcomes like thoracic kyphosis maintenance. Still, beyond such exploratory findings, it remains unclear whether variations in CFD within the typical range materially affect short- or long-term treatment success.

It is well established that achieving a strong initial in-brace correction is prognostic of favorable long-term results [46, 49, 129, 166]. Patients with higher initial Cobb angle reduction (often expressed as correction percentage) have a higher likelihood of avoiding curve progression. Therefore, understanding which modifiable brace factors improve the initial correction is clinically important [48, 50, 64, 80, 100, 167]. CFD is a plausible factor: a more appropriately directed force could conceivably produce greater immediate Cobb angle reduction, which in turn could translate to better final outcomes [45, 46, 65, 100]. On the other hand, if most braces inherently apply a similar 3D force vector (~45° posterolaterally), outcome differences might be dominated by other factors (brace tightness, patient flexibility, etc.) rather than the subtle deviations in pad angle [43, 45, 47-49, 163].

This substudy aimed to investigate the relationship between the brace's controlling force direction and clinical treatment outcomes in AIS. The research question is whether the CFD, quantified as an angle in the transverse plane, is associated with the degree of curve correction achieved at various time points (immediate in-brace, end of bracing, and long-term follow-up). We also explored whether this relationship differs by curve pattern (thoracic vs. lumbar curves, etc.), given that different curve types might respond optimally to different force directions. By analyzing a large retrospective cohort with standardized brace designs, the current study aims to determine if any particular force direction confers a measurable advantage in terms of Cobb angle reduction or prevention of progression.

3.3 Methods

3.3.1 Overview of Study Design, Cohort, and Data Availability of the Whole Thesis

This thesis comprises five interrelated sub-studies (Chapters III–VII) based on a shared retrospective, single-center cohort of adolescents with idiopathic scoliosis (AIS) undergoing orthotic treatment. Although each sub-study addresses a distinct research question, all analyses were conducted within a unified clinical framework, with consistent diagnostic criteria, brace prescription principles, and follow-up protocols.

A total of 675 potential AIS cases receiving thoracolumbosacral orthoses were initially identified between 2016 and 2018. Following standardized clinical screening based on SRS/SOSORT criteria and confirmation of AIS diagnosis, patients who completed a full course of brace treatment or reached predefined clinical endpoints (skeletal maturity or surgical threshold) were retained. Subsequent eligibility checks were applied based on data availability, including radiographic records, demographic information, CAD/CAM brace models, and orthosis-wearing compliance data.

Due to differences in data completeness across domains, the effective sample size varied among sub-studies. Radiographic and clinical outcome data were available for the majority of patients, whereas CAD/CAM brace models required for controlling force direction (CFD) estimation and objective compliance data were available in smaller subsets. Each sub-study therefore analyzed the largest eligible cohort appropriate for its specific research question, while maintaining consistent inclusion criteria and clinical management across analyses.

An overview of patient identification, screening procedures, and data availability across the five sub-studies is provided in Figure 3-1.

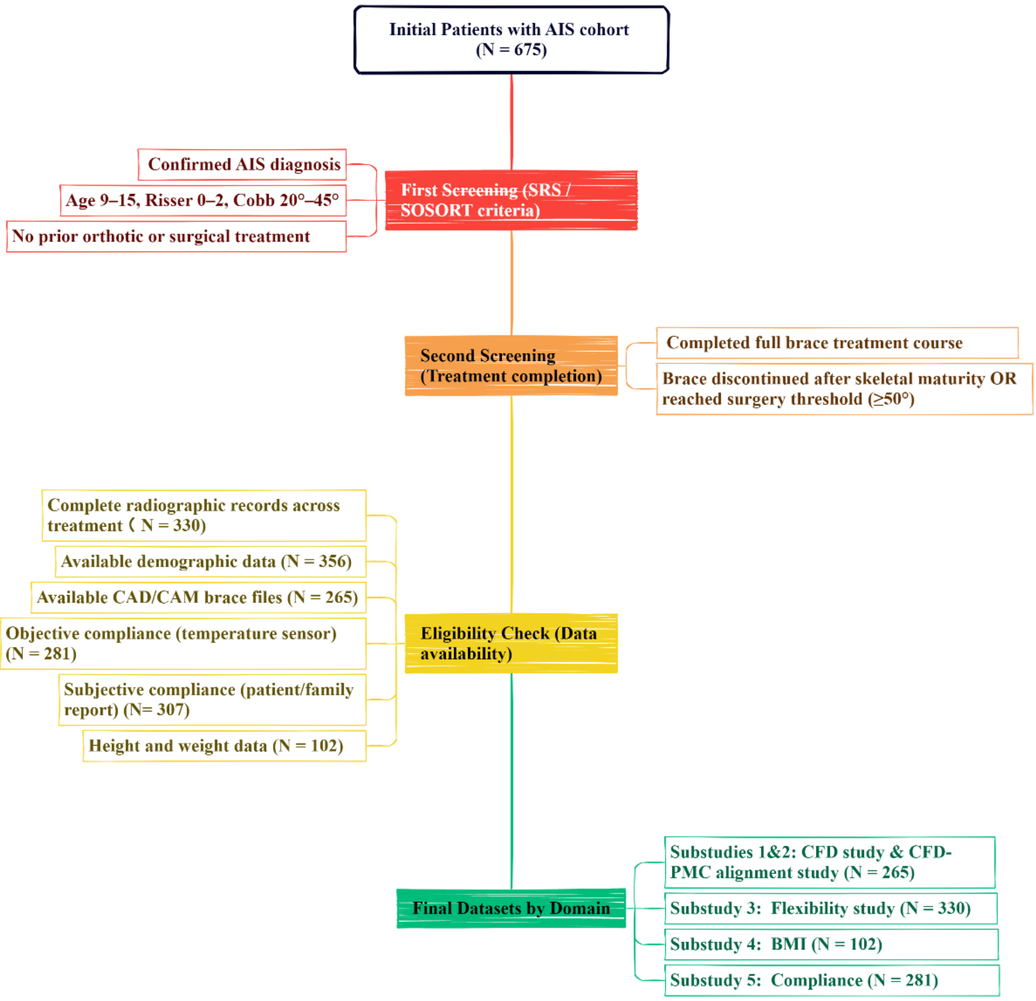

Figure 3-1. Overview of Study Design, Cohort, and Data Availability

3.3.2 Study type, Participant screening, and Recruitment

This sub-study was conducted as part of a retrospective observational investigation of AIS patients treated with custom CAD/CAM-manufactured thoracolumbosacral orthoses between 2016 and 2018 at a single center, as described in 3.3.1. The orthopedic doctor managed the subjects involved in the study, and their spinal orthoses were designed and tailor-made by an experienced orthotist. The stable healthcare team, including orthopedic surgeons and orthotists, had extensive experience in standardized orthotic management for patients with AIS.

Patients were identified, screened for eligibility, and recruited according to predefined inclusion and exclusion criteria. To be eligible for this study, subjects were required to fulfil the following criteria:

Inclusion criteria

1) Subjects should meet the diagnostic criteria of AIS after detailed clinical and radiological evaluation by an experienced orthopedic doctor, and;
2) Age range of 10-14 years, and;
3) Coronal Cobb angle of 20°-45°, and;
4) Skeletal immaturity with a Risser sign grade 0-2, and;
5) Should have before and after orthotic treatment EOS images, and;
6) Should have had before orthotic treatment supine X-ray images.

Exclusion criteria

1) Subject who hasn’t finished the orthotic treatment, and;
2) Demographic information of the subject is not available.
3) X-ray images of the subject are not available, and;
4) CAD/CAM information of the subject is not available, and;
5) Subjects who were diagnosed with spinal malformations other than AIS should be excluded from the proposed study.

3.3.3 Ethical consideration

Ethical approvals from the institutional review board (IRB) in both the Hong Kong Polytechnic University and the local hospital were obtained. To maintain the confidentiality of subjects' identities and protect their interests, no information that could enable the identification of any subject will be recorded during data collection. Once the researcher has recorded the data, it is not clear which data belongs to a patient. Additionally, subjects’ records will be kept in a coded protected file and stored in a coded USB disc; encryption when sending subjects' information over the internet; and a hard copy of the subjects’ files will be kept in locked doors and drawers. Moreover, the collected raw data can only be opened by one researcher with a password and can only be used for data analysis for the research purpose.

3.3.4 Instrument and Equipment

EOS X-ray imaging system

EOS® X-ray imaging system (Formerly Biospace Med, Paris, France), invented by Georges Charpak, provides biplanar full-body stereo-radiographic images in either standing or seated positions with a low dose of radiation [168]. It is very useful for diagnosing spinal deformities such as scoliosis, which is considered a 3D deformity.

CAD/CAM System

Canfit™ Computer-aided design & computer-aided manufacture (CAD/CAM) system (Vorum, British Columbia, Canada), which includes 3D torso scan function, torso modification tools, and 3D printing function, allows orthotists to design and manufacture custom orthoses for patients with AIS [169]. In the CAD/CAM software, the estimation of the orientation of the applied controlling forces will be done.

3.3.5 Data collection

After participant recruitment, their clinical data at every visit will be collected, including demographic information, X-ray images, CAD/CAM images, and orthosis wearing compliance. The demographic information of subjects consists of gender, and date of birth (DOB), weight (kg), height (m), BMI (kg/m2), Menarche status (female only), family history of scoliosis, and the data in every clinical appointment time, including before orthotic treatment clinical appointment, immediately in-orthosis, all the follow-up clinical in-orthosis appointments, and after orthotic treatment follow-up appointments until two years after skeletal maturity of the subjects, will be collected.

3.3.6 Brace Design Under the CAD/CAM workflow

All braces were designed and fabricated using a computer-aided design/manufacturing (CAD/CAM) workflow, starting from a 3D torso scan of the patient. Orthotists applied virtual modifications to create corrective pressure zones (pad areas) and relief zones on the model, then milled a custom rigid TLSO from these specifications.

Each brace's digital model was exported for analysis. As shown in Figure 3-2. The

Designed Orthosis in Canfit^{TM} Software, it displays the three dimensions (sagittal plane, coronal plane and transverse plane) of the torso of the subject and the designed orthosis in the Canfit^{TM} software. In the sagittal plane, the black horizontal line is located in the transverse plane of the body and the orthosis. In the coronal plane, the red part means the pressure zone and the blue part means the expansion zone. In transverse plane, the red curve shows the transverse plane of subject's torso while the blue curve demonstrates the transverse plane of the designed orthosis.

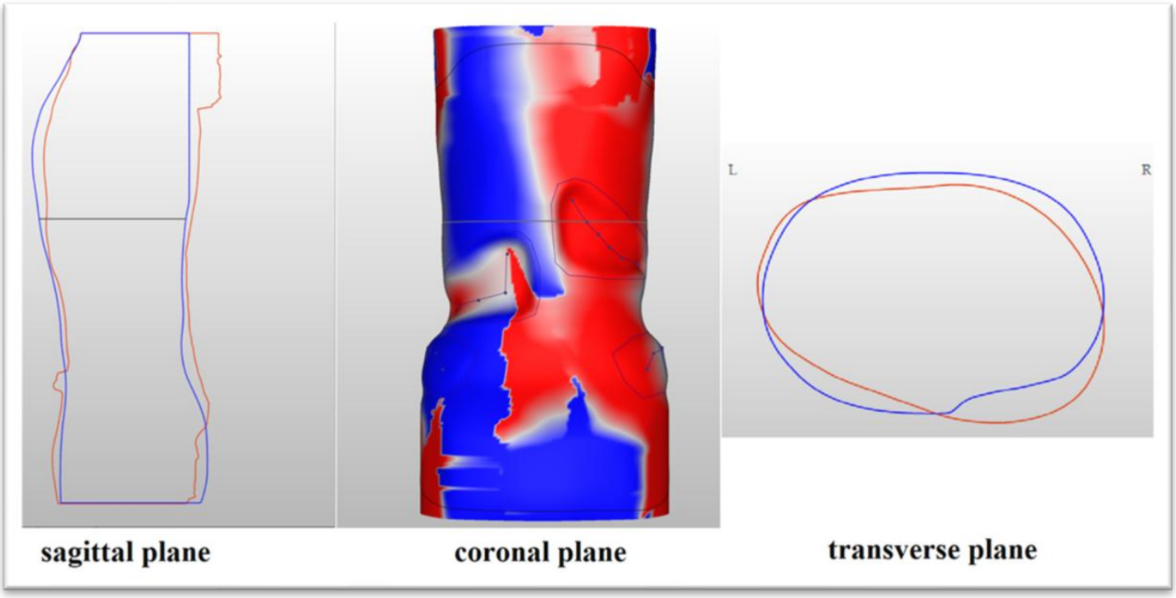

Figure 3-2. The Designed Orthosis in Canfit^{TM} Software

3.3.7 CFD Estimation

In this thesis, controlling force direction (CFD) refers to a quantitatively estimated representation of the dominant corrective force vector generated by the orthosis, derived from CAD/CAM orthotic models using a computer vision–based approach. As direct in-brace force measurements were not available in this retrospective cohort, CFD was not measured directly but estimated based on geometric deformation patterns of the orthotic shell. Accordingly, CFD is interpreted as an approximation of force application direction rather than a direct physical measurement, and is used to examine relative differences in force orientation across patients and orthosis designs. The details were listed as follows.

The controlling force direction was estimated using a multi-slice vector summation method developed in-house. First, the region of the primary pressure pad around the curve apex was identified on the 3D brace model. Transverse cross-sections (6–10 axial slices spanning the pad height) were extracted through this region. On each slice, the brace–torso contact area corresponding to the pressure pad was segmented (pad regions were distinguished by color in the model, e.g., red for high-pressure zones).

For each segmented contour, local surface normal vectors were computed, representing the direction of force application at each point. These normals were projected onto the transverse (horizontal) plane to obtain a slice-level resultant force vector, under the assumption that the brace pad exerts pressure approximately perpendicular to the body surface. The slice-level vectors were then averaged to generate a single net controlling force vector in the transverse plane for the brace. A detailed explanation of this method is provided in ***Error! Reference source not found.***.

The CFD angle was defined as the angle between this net force vector and the patient's sagittal (y) axis, where 0° represents a pure posterior-to-anterior push (aligned with the sagittal plane) and 90° represents a pure lateral push (aligned with the coronal plane). Thus, smaller angles indicate forces directed more anterior–posteriorly, while larger angles indicate forces directed more laterally. For consistency across curve sides, all CFD angles were expressed as absolute values relative to the sagittal plane, such that a posterolateral force pointing forward and toward the midline would typically have a CFD between 0° and 90°.

Two derived variables were also calculated for subsequent analysis:

1. Directional Deviation from 45°: the signed difference between the CFD and the conventional 45° reference, indicating whether the force was directed more anteriorly (positive) or posteriorly (negative) relative to 45°.
2. Absolute Deviation from 45°: the unsigned difference between the CFD and 45°, representing the magnitude of deviation regardless of direction.

Table 3-1. Definitions of Controlling Force Direction and Derived Variables

Variable name	Definition	Units	Calculation	Interpretation / Clinical meaning
CFD	Angle between	degrees	Estimated from multi-	Describes how

(Controlling force Direction)	the net controlling force vector (in the transverse plane) and the patient's sagittal (y) axis.	(°)	slice vector summation of brace pad surface normals projected onto the transverse plane. 0° = pure posterior-to-anterior push (sagittal), 90° = pure lateral push (coronal).	medially/laterally directed the controlling force is. Smaller = more anterior–posterior; larger = more lateral.
Directional Deviation from 45°	Signed difference between CFD and the conventional 45° reference.	degrees (°)	CFD – 45°. Positive = more anteriorly directed than 45°; negative = more posteriorly directed.	Indicates whether the force is biased anteriorly or posteriorly relative to the conventional design.
Absolute Deviation from 45°	Absolute difference between CFD and the 45° reference.	degrees (°)		CFD – 45°

3.3.8 Radiographic Measurements

Standard biplanar radiographs (posteroanterior and lateral) were taken at baseline (pre-brace), immediately after brace fitting (in-brace, T2), at the end of treatment (brace removal at skeletal maturity, T3), and at final follow-up after brace discontinuation (T4).

3.3.9 Outcome measurements

Cobb Angle Change (ΔCobb)

Cobb angle is a golden standard measurement to evaluate the coronal curvature of the spine, recommended by SOSORT and SRS [8]. The data type of the coronal Cobb angle is continuous data. The coronal Cobb angle before orthotic treatment, in-orthosis follow-up, and after treatment will be measured and collected. The Cobb method of angle measurement is shown in Figure 3-3. Cobb Angle Measurement should follow the below procedures: 1) Identify the upper and lower end vertebrae; 2) Draw lines extending along the vertebral borders; 3) Measure the Cobb angle directly or geometrically.

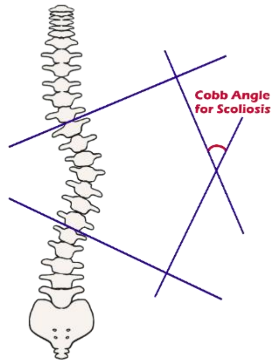

Figure 3-3. Cobb Angle Measurement

At each time point, the Cobb angle of the significant curve was measured on standing PA radiographs. All Cobb measurements were performed by trained personnel using standardized EOS imaging protocols and verified by two independent raters. For consistency, all changes were calculated in the curve as identified at baseline.

In-brace Cobb angles were measured on radiographs taken with the patient wearing the brace (after an acclimation period). We define the in-brace correction as the change in Cobb angle from pre-brace to in-brace (a positive correction indicates Cobb angle reduction). Similarly, end-of-brace change was calculated as the Cobb angle difference from baseline to the end-of-treatment radiograph, and long-term change from baseline to final follow-up (off brace), the difference in curve Cobb angle between baseline (T0) and subsequent timepoints.

- T0–T2: Baseline (pre-brace) to in-brace X-ray (short-term effect)
- T0–T3: Baseline to end-of-bracing (medium-term effect)
- T0–T4: Baseline to final follow-up after brace removal (long-term maintenance)

PMC-Cobb angle change (ΔPMC-Cobb)

Defined as the projection of the spinal curve onto the PMC plane, capturing the maximal 3D curvature, assessed at baseline (T0) and subsequent timepoints. PMC-Cobb angle is the angle of maximum curvature of the spine and the data type of PMC-Cobb is continuous data, which can reflect the 3D deformity of the spine in patients with AIS. The PMC-Cobb angle, measured from EOS images taken before, during, and after orthotic treatment, will be collected.

The computational method (CM) developed by our team would be used to calculate the PMC-Cobb angle in this proposed research and was validated with high both intra (>0.91) and inter (>0.84) ICC values [104]. In this method, PMC angle and orientation will be calculated by locating the two marginal points at the superior endplate of upper-end vertebra and the inferior endplate of lower-end vertebra in the coronal and sagittal X-ray images of the spine separately (eight corner points in total) [104]. As showed in Figure 3-4. PMC Parameters Calculation, eight corner points (C1, C2, C3, C4, C5, C6, C7 and C8) were identified orderly in the PMC software, in which the 2D coordinates of the eight points could be obtained, and then the PMC orientation and PMC-Cobb angle will be calculated automatically based on the algorithm in the PMC Calculator software which developed by our team.

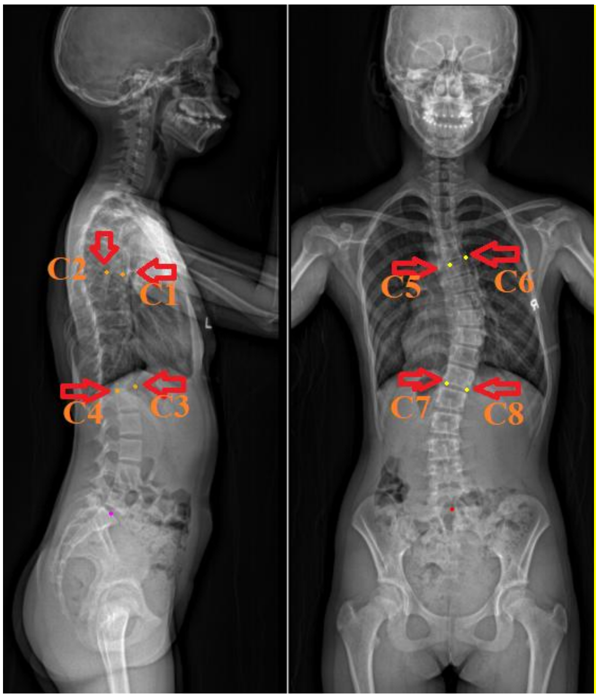

Figure 3-4. PMC Parameters Calculation

Categorical treatment result classification (Tx Results):

The study assessed the orthotic management outcomes, which were defined as improvement, deterioration, and stabilization when the post-treatment (t3) major curve Cobb angle decreased ≥ 5°, increased ≥ 5°, and changed within ± 5° compared to pre-treatment (t0) Cobb angle according to the SOSORT guidelines. The tertiary outcome is the rate of required surgery at the treatment endpoint (t3), which is defined by underwent or was scheduled for surgery, or the curve Cobb angle progressed to more than the surgery indication of 50° at skeletal maturity.

3.3.10 Statistical Analysis

All statistical analyses were performed using SPSS version 26 (IBM Corp., Armonk, NY, USA). First, the distribution of controlling force direction (CFD) angles in the entire cohort was summarized (mean, standard deviation, and range), with additional breakdown by curve type (thoracic, thoracolumbar, lumbar). Differences in mean CFD between curve types were assessed using one-way analysis of variance (ANOVA). Next, we investigated the relationship between CFD and treatment outcomes. Pearson correlation coefficients were calculated between (1) the CFD angle and (2) the deviation of CFD from 45° (as a continuous variable) and the changes in coronal Cobb angle at each outcome timepoint: in-brace correction, end-of-brace change, and long-term change after brace removal. Subgroup correlation analyses were also performed within each curve type to assess whether these associations varied between thoracic, thoracolumbar, and lumbar curves.

To further explore potential threshold effects, patients were categorized into three CFD orientation groups based on the overall distribution: CFD < 30° (posteriorly directed forces), 30°–60° (mid-range, near the conventional 45°), and Group C: > 60° (laterally directed forces). These cut-offs divide the posterolateral quadrant into approximately equal thirds. Mean in-brace Cobb correction and final Cobb change were compared across the three groups using one-way ANOVA, while differences in progression rates were evaluated using chi-square tests. All categorical and continuous comparisons were repeated within each curve-type subgroup to examine potential interactions with curve geometry. A two-tailed p-value of <0.05 was considered statistically significant for all analyses.

3.4 Results

3.4.1 Participant Characteristics

As shown in Table 3-2, a total of 265 patients with moderate AIS were included in this retrospective analysis. The cohort comprised 225 females (84.9%) and 40 males (15.1%), with a mean age of 12.5 ± 1.1 years at baseline. Skeletal maturity was assessed using the Risser sign, with most patients at Risser 0 (51.3%), followed by Risser 1

(23.8%) and Risser 2 (24.9%). The average duration of brace treatment was 2.5 ± 0.7 years, and the mean follow-up duration after brace completion was 0.8 ± 0.7 years. Their age, gender, Risser sign distribution, and treatment duration were not significantly different among different curve types.

At baseline, the baseline curve Cobb angle was 30.6° ± 5.7°, and the corresponding PMC Cobb angle, which represents the maximal curvature within the three-dimensional PMC plane, was slightly higher, with a mean of 34.1° ± 7.3°. No significant differences in the baseline Curve Cobb angles among thoracic (30.4 ± 6.0), thoracolumbar (30.8 ± 5.8), and lumbar (30.7 ± 4.6) curves. But the PMC Cobb angles were significantly lower in the thoracic than in both the thoracolumbar ($p = 0.001$) and lumbar ($p < 0.001$) curves, and there were no significant differences between the thoracolumbar and lumbar curves ($p = 0.854$).

Table 3-2. Participants Characteristics

	Total (N = 265)	Thoracic Curves (N = 126)	Thoracolumbar Curves (N = 98)	Lumbar Curves (N = 41)	Inter-group comparison (p value)
Age (years) (Mean ± SD)	12.5 ± 1.1	12.5 ± 1.1	12.5 ± 1.1	12.3 ± 1.1	0.388
Female (N, %)	225, 84.9%	105, 83.3%	83, 84.7%	37, 90.2%	0.560
Male (N, %)	40, 15.1%	21, 16.7%	15, 15.3%	4, 9.8%	
Risser 0 (N, %)	136, 51.3%	73, 57.9%	45, 57.9%	18, 43.9%	0.314
Risser 1 (N, %)	63, 23.8%	27, 21.4%	24, 24.5%	12, 29.3%	
Risser 2 (N, %)	66, 24.9%	26, 29.3%	29, 29.6%	11, 26.8%	
Treatment duration (years) (Mean ± SD)	2.5 ± 0.7	2.4 ± 0.7	2.5 ± 0.7	2.6 ± 0.7	0.238
Follow-up duration (years) (Mean ± SD)	0.8 ± 0.7	0.8 ± 0.7	0.8 ± 0.7	0.7 ± 0.6	0.804

	Total (N = 265)	Thoracic Curves (N = 126)	Thoracolumbar Curves (N = 98)	Lumbar Curves (N = 41)	Inter-group comparison (p value)
Baseline Coronal Cobb angle (Mean ± SD)	30.6 ± 5.7	30.4 ± 6.0	30.8 ± 5.8	30.7 ± 4.6	0.866
Baseline PMC Cobb angle (Mean ± SD)	34.1 ± 7.3	32.3 ± 6.2	34.9 ± 7.7	37.4 ± 7.7	0.000
CFD (Mean ± SD)	41.1 ± 11.3	44.3 ± 11.5	38.8 ± 9.9	36.6 ± 10.7	0.000
Absolute CFD deviation from 45°(Mean ± SD)	9.3 ± 7.4	8.9 ± 7.3	9.2 ± 7.3	10.8 ± 8.2	0.238
Directional CFD deviation from 45°	-3.9 ± 11.3	-0.7 ± 11.5	-6.2 ± 9.9	-8.4 ± 10.7	0.000

3.4.2 Distribution and Structural Consistency of Controlling force Direction (CFD)

The mean CFD for the entire cohort was 41.1° ± 11.3°, ranging from 12.1° to 68.2°. When stratified by curve location, thoracic curves exhibited the largest mean CFD (44.3° ± 11.5°), followed by thoracolumbar (38.8° ± 10.0°) and lumbar curves (36.6° ± 10.7°) as shown in Figure 3-5. One-way ANOVA revealed a significant difference in CFD between curve types ($F = 11.24$, $p < 0.001$). Post-hoc Bonferroni comparisons showed that thoracic curves had significantly higher CFD than thoracolumbar (mean difference = 5.5°, $p = 0.001$) and lumbar curves (mean difference = 7.7°, $p < 0.001$), while no significant difference was observed between thoracolumbar and lumbar curves ($p = 0.854$).

The concentration of CFD angles within a relatively narrow range suggests a non-random, experience-informed bias in force direction, despite inter-individual anatomical variability. This raises a key question: does such empirical standardization of force orientation align with the structural direction of deformity (PMC orientation)? To address this, we further investigated the correlation between PMC orientation and CFD angle, which will be reported in Chapter 4.

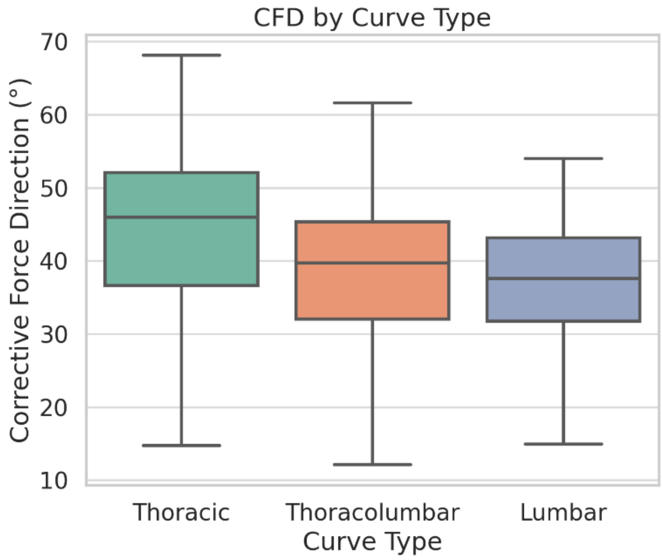

Figure 3-5. CFD By Curve Type

The Absolute Deviation from 45° averaged 9.3° ± 7.4° across the cohort, without significant differences between thoracic (9.0° ± 7.3°), thoracolumbar (9.2° ± 7.3°), and lumbar curves (10.8° ± 8.2°) ($F = 1.00$, $p = 0.370$) as shown in Figure 3-6. These results indicate that, on average, the applied controlling force direction deviated from the 45° reference by approximately 9° in all curve types, with no curve-type-specific trend in deviation magnitude.

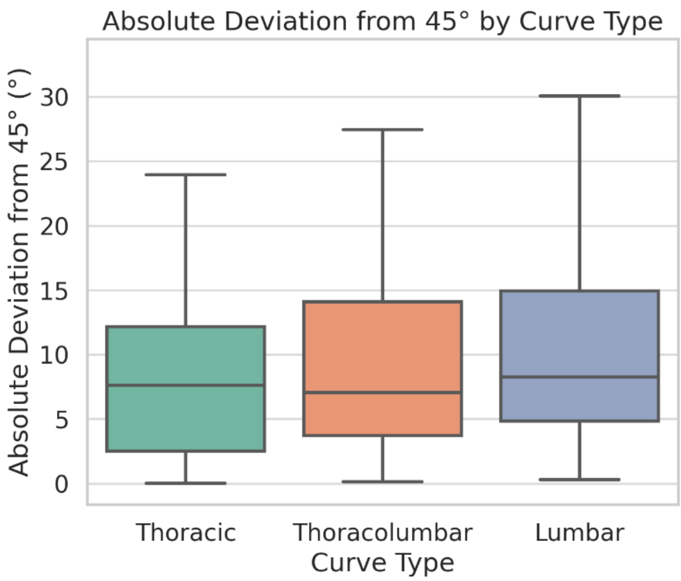

Figure 3-6. Absolute Deviation From 45° By Curve Type

The Directional Deviation from 45° had a cohort mean of –3.9° ± 11.3°, indicating a slight posterior bias relative to the 45° reference. Thoracic curves showed near-zero deviation (–0.7° ± 11.5°), whereas thoracolumbar (–6.2° ± 10.0°) and lumbar (–8.4° ± 10.7°) curves demonstrated progressively larger posterior deviations as shown in Figure 3-7. ANOVA confirmed significant between-group differences ($F = 11.24$, $p < 0.001$), with Bonferroni tests showing thoracic curves differed significantly from both thoracolumbar (mean difference = 5.5°, $p = 0.001$) and lumbar curves (mean difference = 7.7°, $p < 0.001$), while thoracolumbar and lumbar curves were not significantly different ($p = 0.854$).

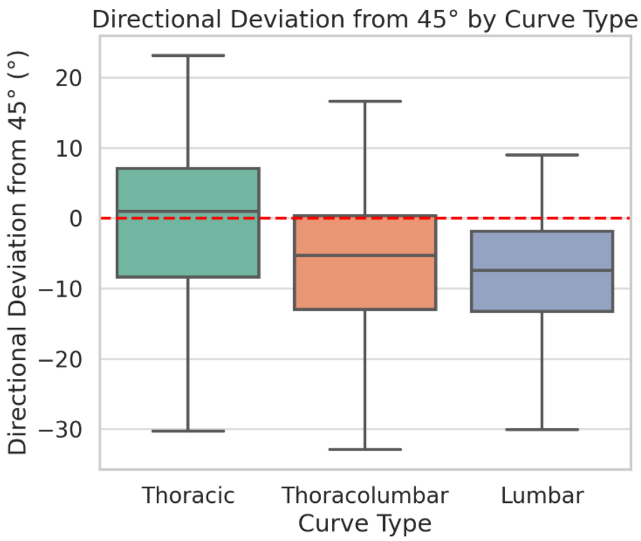

Figure 3-7. Directional Deviation From 45° By Curve Type

Taken together, these findings suggest that although the magnitude of deviation from the 45° reference was similar across curve types, the direction of deviation (anterior vs. posterior) varied systematically with curve location. Thoracic curves tended to have force directions closer to or slightly anterior to the 45° reference, whereas thoracolumbar and lumbar curves were more often posteriorly oriented. This structural consistency pattern indicates a potential influence of curve location on force direction bias, despite similar absolute deviations from the conventional 45° guideline.

3.4.3 Correlation Between CFD Angle and Continuous Treatment Outcomes

3.4.3.1 For the whole cohort

Building on the distribution patterns, we first examined whether the controlling force direction was associated with changes in coronal Cobb angle and PMC-based 3D parameters. As shown in Table 3-3, CFD was not related to changes in 2D Cobb angle or PMC-based parameters. Across the whole cohort, CFD showed no significant correlation with Cobb angle change at immediate in-brace (T0–T2: r = 0.025, p = 0.691), mid-term post-brace (T0–T3: r = 0.001, p = 0.982), or long-term follow-up (T0–T4: r = –0.016, p = 0.802). Similar null results were observed for PMC Cobb (r = –0.061 to –0.046, all p > 0.27), PMC sagittal (r = –0.058 to 0.026, all p > 0.34), and PMC orientation (r = 0.001 to 0.071, all p > 0.24) changes.

Table 3-3. The correlation analysis between CFD and treatment outcome

CFD & Parameters		Mean	SD	Pearson Correlation	Sig.
Coronal Cobb angle changes (°)	ΔT0T2	13.0	6.3	0.025	0.691
	ΔT0T3	-0.8	9.7	0.001	0.982
	ΔT0T4	-2.3	9.9	-0.016	0.802
PMC Cobb angle changes (°)	ΔT0T2	-13.1	7.5	-0.061	0.325
	ΔT0T3	0.8	10.1	-0.068	0.273
	ΔT0T4	2.0	10.2	-0.046	0.455
PMC Sagittal angle changes (°)	ΔT0T2	-4.0	8.8	0.026	0.675
	ΔT0T3	-1.1	9.2	-0.025	0.69
	ΔT0T4	-0.5	9.1	-0.058	0.346
PMC Orientation changes (°)	ΔT0T2	-5.9	17.3	0.001	0.987
	ΔT0T3	1.1	13.9	0.023	0.71
	ΔT0T4	1.1	13.7	0.071	0.247

3.4.3.2 Subgroup analysis by curve type

When stratified by curve type, neither thoracic nor thoracolumbar curves demonstrated significant correlations. In lumbar curves, a single mid-term result reached statistical significance—a negative correlation between CFD_Major and PMC Cobb change at T0–T3 (r = –0.33, p = 0.035)—suggesting that larger sagittal CFD angles may relate to smaller mid-term 3D correction. However, the lack of consistent findings at other timepoints and the small lumbar sample size indicate this is likely an isolated rather than generalisable effect (Table 3-4).

Table 3-4. Correlation analysis between CFD and treatment outcome under different curve types

			M	SD	Pearson Correlation	Sig.
Thoracic	Coronal Cobb angle changes (°)	ΔT0T2	12.7	6.2	0.052	0.564
		ΔT0T3	-2.3	9.9	0.049	0.584
		ΔT0T4	-3.9	9.9	0.023	0.802
	PMC Cobb angle changes (°)	ΔT0T2	-12.5	6.8	-0.13	0.147
		ΔT0T3	1.8	10.1	-0.1	0.264
		ΔT0T4	3.2	10.2	-0.097	0.281
	PMC Sagittal angle changes (°)	ΔT0T2	-2.0	7.3	-0.097	0.282
		ΔT0T3	-1.1	7.4	0.039	0.664
		ΔT0T4	-1.0	7.5	-0.048	0.591
	PMC Orientation changes (°)	ΔT0T2	-8.4	17.4	0.121	0.178
		ΔT0T3	2.4	11.8	-0.092	0.308
		ΔT0T4	3.1	11.0	0.002	0.979
Thoracolumbar	Coronal Cobb angle changes (°)	ΔT0T2	13.9	6.9	0.112	0.272
		ΔT0T3	0.1	10.1	0.014	0.888
		ΔT0T4	-1.6	10.7	0.015	0.884
	PMC Cobb angle changes (°)	ΔT0T2	-14.0	7.9	-0.079	0.442
		ΔT0T3	0.3	10.7	-0.03	0.768
		ΔT0T4	1.6	10.7	-0.03	0.769
	PMC Sagittal angle changes (°)	ΔT0T2	-5.9	9.3	-0.008	0.941
		ΔT0T3	-1.1	10.8	-0.018	0.858
		ΔT0T4	-0.6	10.0	-0.042	0.683
	PMC Orientation changes (°)	ΔT0T2	-4.0	17.7	-0.079	0.441
		ΔT0T3	0.0	15.9	0.076	0.459
		ΔT0T4	0.2	15.6	0.094	0.355
Lumbar	Coronal Cobb angle changes (°)	ΔT0T2	11.9	5.1	-0.28	0.076
		ΔT0T3	1.5	6.7	0.153	0.341
		ΔT0T4	1.1	6.6	0.172	0.283
	PMC Cobb angle changes (°)	ΔT0T2	-12.9	8.3	0.04	0.806
		ΔT0T3	-1.5	8.4	-0.331	0.035
		ΔT0T4	-0.5	8.5	-0.191	0.231
	PMC Sagittal angle changes (°)	ΔT0T2	-6.0	10.0	0.033	0.838
		ΔT0T3	-1.1	10.3	-0.204	0.2
		ΔT0T4	0.8	11.2	-0.049	0.759
	PMC Orientation	ΔT0T2	-2.7	14.8	0.067	0.679
		ΔT0T3	-0.7	14.5	0.037	0.817

		M	SD	Pearson Correlation	Sig.
changes (°)	ΔT0T4	-3.0	15.2	-0.047	0.771

3.4.4 *Correlation between Deviation from the Theoretical 45° Target and Continuous Outcomes*

3.4.4.1 *For the whole cohort*

Given that 45° is a common empirical target for sagittal-plane force orientation, we next evaluated whether controlling force direction (CFD) approaching 45° is associated with better treatment outcomes. In the whole cohort, the mean absolute deviation was 9.33° (SD 7.4°), with a slight posterior bias indicated by a signed mean of –3.94° (SD 11.3°). Neither absolute nor signed deviation from 45° showed significant correlations with changes in Cobb angle, PMC Cobb, PMC sagittal, or PMC orientation at any follow-up timepoint (all $p > 0.20$) (Table 3-5).

Table 3-5. Pearson correlation coefficients between Absolute CFD deviation from 45° and Directional CFD deviation from 45° with changes in radiographic parameters for the whole cohort

		Absolute CFD deviation from 45°		Directional CFD deviation from 45°	
		Pearson Correlation	Sig.	Pearson Correlation	Sig.
Coronal Cobb angle changes (°)	ΔT0T2	-0.07	0.255	0.025	0.691
	ΔT0T3	-0.018	0.766	0.001	0.982
	ΔT0T4	0	1	-0.016	0.802
PMC Cobb angle changes (°)	ΔT0T2	0.019	0.762	0.001	0.987
	ΔT0T3	-0.02	0.743	0.023	0.71
	ΔT0T4	-0.011	0.86	0.071	0.247
PMC Sagittal angle changes (°)	ΔT0T2	0.063	0.308	-0.061	0.325
	ΔT0T3	0.079	0.202	-0.068	0.273
	ΔT0T4	0.035	0.569	-0.046	0.455
PMC Orientation changes (°)	ΔT0T2	0.025	0.686	0.026	0.675
	ΔT0T3	0.068	0.272	-0.025	0.69
	ΔT0T4	0.039	0.522	-0.058	0.346

3.4.4.2 *Subgroup analysis by curve type*

Subgroup analyses based on curve type also failed to demonstrate any consistent pattern (Table 3-6). A marginal trend was observed in the lumbar group, where a higher CFD deviation was associated with poorer Cobb angle improvement at T0–T4 (r = –0.291, *p* = .065), though it did not reach statistical significance.

Table 3-6. Pearson correlation coefficients between Absolute CFD deviation from 45° and Directional CFD deviation from 45° with changes in radiographic parameters, stratified by curve type

Curve location			**Absolute CFD deviation from 45°**		**Directional CFD deviation from 45°)**	
			Pearson Correlation	Sig.	Pearson Correlation	Sig.
Thoracic	Coronal Cobb angle changes (°)	ΔT0T2	-0.066	0.46	0.052	0.564
		ΔT0T3	-0.014	0.875	0.049	0.584
		ΔT0T4	0.016	0.86	0.023	0.802
	PMC Cobb angle changes (°)	ΔT0T2	-0.023	0.797	0.121	0.178
		ΔT0T3	0.014	0.873	-0.092	0.308
		ΔT0T4	-0.014	0.878	0.002	0.979
	PMC Sagittal angle changes (°)	ΔT0T2	0.022	0.811	-0.13	0.147
		ΔT0T3	0.065	0.468	-0.1	0.264
		ΔT0T4	0.045	0.614	-0.097	0.281
	PMC Orientation changes (°)	ΔT0T2	0.032	0.719	-0.097	0.282
		ΔT0T3	0.028	0.759	0.039	0.664
		ΔT0T4	0.067	0.454	-0.048	0.591
Thoracolumbar	Coronal Cobb angle changes (°)	ΔT0T2	-0.106	0.299	0.112	0.272
		ΔT0T3	0.029	0.779	0.014	0.888
		ΔT0T4	0.028	0.784	0.015	0.884
	PMC Cobb angle changes (°)	ΔT0T2	0.061	0.553	-0.079	0.441
		ΔT0T3	-0.102	0.317	0.076	0.459
		ΔT0T4	-0.081	0.429	0.094	0.355
	PMC Sagittal angle changes (°)	ΔT0T2	0.072	0.482	-0.079	0.442
		ΔT0T3	0.029	0.774	-0.03	0.768
		ΔT0T4	0	0.997	-0.03	0.769
	PMC Orientation changes (°)	ΔT0T2	0.068	0.507	-0.008	0.941
		ΔT0T3	0.104	0.307	-0.018	0.858
		ΔT0T4	0.068	0.504	-0.042	0.683
Lumbar	Coronal Cobb angle changes (°)	ΔT0T2	0.048	0.764	-0.28	0.076
		ΔT0T3	-0.286	0.07	0.153	0.341
		ΔT0T4	-0.291	0.065	0.172	0.283
	PMC Cobb angle changes (°)	ΔT0T2	-0.01	0.949	0.067	0.679
		ΔT0T3	0.126	0.434	0.037	0.817
		ΔT0T4	0.213	0.182	-0.047	0.771
	PMC Sagittal angle changes (°)	ΔT0T2	0.143	0.372	0.04	0.806
		ΔT0T3	0.333	0.033	-0.331	0.035
		ΔT0T4	0.175	0.273	-0.191	0.231
	PMC Orientation changes (°)	ΔT0T2	-0.012	0.941	0.033	0.838
		ΔT0T3	0.073	0.652	-0.204	0.2
		ΔT0T4	-0.092	0.568	-0.049	0.759

3.4.5 CFD and Deviation from 45° Across Categorical Treatment Outcomes

3.4.5.1 For the whole cohort

To further explore whether CFD characteristics differ among categorical treatment outcomes, patients were stratified into four groups: Improvement (I), Stabilization (S), Non-surgical deterioration (ND), and Surgery recommendation (SD). Across the whole cohort, mean CFD values were 41.9° ± 11.3° in the I group, 40.5° ± 11.1° in the S group, 40.2° ± 10.8° in the ND group, and 39.8° ± 12.5° in the SD group (Table 3-7). One-way ANOVA revealed no significant differences in CFD among the four outcome categories ($p > 0.05$).

Table 3-7. CFD across categorical treatment outcomes for the whole cohort

Clinical outcomes	**N**	**Mean**	**Std. Deviation**	**95% Confidence Interval for Mean**		**Minimum**	**Maximum**	**Sig. (ANOVA)**
				Lower Bound	Upper Bound			
Improvement	72	40.8	10.5	38.4	43.3	15.2	68.2	0.981
Stabilization	119	41.3	11.7	39.1	43.4	12.1	64.3	
Non-surgery deterioration	55	40.7	11.9	37.5	43.9	12.2	66.6	
Surgery deterioration	19	41.7	9.8	37.0	46.4	20.3	57.1	

As shown in Table 3-8, the mean *Absolute CFD deviation from 45°* ranged from 8.5° to 10.2° across groups (I: 8.6° ± 7.0°; S: 9.1° ± 7.2°; ND: 9.8° ± 7.7°; SD: 10.2° ± 7.9°), with no significant differences detected ($p > 0.05$). Similarly, *Directional CFD deviation from 45°* did not differ significantly between groups (I: –3.1° ± 11.2°; S: –4.0° ± 10.9°; ND: –4.7° ± 11.4°; SD: –4.9° ± 12.1°; $p > 0.05$).

Table 3-8. Absolute and directional CFD deviation from 45° across categorical treatment outcomes for the whole cohort

		N	**Mean**	**SD**	**95% CI**		**Minimum**	**Maximum**	**Sig. (ANOVA)**
Absolute CFD deviation from 45°	Surgery deterioration	19	8.2	6.1	5.2	11.1	0.6	24.7	0.856
	Non-surgery deterioration	55	9.8	7.9	7.7	12.0	0.1	32.8	
	Stabilization	119	9.4	7.9	8.0	10.8	0.0	32.9	
	Improvement	72	9.2	6.6	7.6	10.7	0.2	29.8	
Directional	Surgery	19	-3.3	9.8	-8.0	1.4	-24.7	12.1	0.981

CFD deviation from 45°	deterioration							
	Non-surgery deterioration	55	-4.3	11.9	-7.5	-1.1	-32.8	21.6
	Stabilization	119	-3.7	11.7	-5.9	-1.6	-32.9	19.3
	Improvement	72	-4.2	10.5	-6.6	-1.7	-29.8	23.2

3.4.5.2 Subgroup analysis by curve type

When stratified by curve type, thoracic and thoracolumbar curves showed no significant between-group differences for any of the three metrics, including CFD (Table 3-9), Absolute deviation and Directional deviation (

Table 3-10). In lumbar curves, there was a non-significant trend for smaller *Absolute CFD deviation from 45°* in the Improvement group (mean 7.3° ± 6.1°) compared with the Stable (11.2° ± 8.0°) and ND (10.8° ± 8.4°) groups ($p = 0.081$), suggesting a possible relationship between closer-to-45° force orientation and improved outcomes. However, this pattern did not reach statistical significance, and the small lumbar sample size limits interpretability.

These findings indicate that, in the overall cohort, neither absolute CFD, nor deviation from a 45° reference, nor the directionality of that deviation, is systematically associated with categorical treatment outcomes. The isolated trends observed in the lumbar subgroup may warrant further investigation in larger samples but are insufficient to establish a robust effect.

Table 3-9. CFD across categorical treatment outcomes by curve type

Curve location	Clinical outcomes	N	Mean	SD	95% CI for Mean		Mini	Max	Sig.
					Lower Bound	Upper Bound			
Thoracic	Improvement	23	44.5	12.4	39.1	49.8	15.2	68.2	0.820
	Stabilization	62	44.5	11.1	41.6	47.3	14.8	64.3	
	Non-surgery deterioration	30	42.9	13.0	38.0	47.8	12.2	66.6	
	Surgery deterioration	11	46.7	8.3	41.1	52.3	29.9	57.1	
Thoracolumbar	Improvement	35	39.7	9.6	36.4	43.0	24.3	61.7	0.461
	Stabilization	36	37.7	11.0	34.0	41.5	12.1	52.5	
	Non-surgery deterioration	19	40.6	9.5	36.0	45.2	25.3	54.7	
	Surgery deterioration	8	34.8	7.3	28.7	40.9	20.3	41.8	
Lumbar	Improvement	14	37.6	7.9	33.1	42.1	18.5	48.3	0.292
	Stabilization	21	37.8	12.6	32.0	43.5	14.9	64.1	
	Non-surgery deterioration	6	30.2	8.1	21.7	38.7	17.7	38.9	

Table 3-10. Absolute and directional CFD deviation from 45° across categorical treatment outcomes by curve type

			N	Mean	SD	95% CI		Minimum	Maximum	Sig.
Thoracic	Absolute CFD deviation from 45°	Surgery deterioration	11	6.7	4.8	3.4	9.9	0.6	15.1	0.523
		Non-surgery deterioration	30	10.0	8.5	6.8	13.1	0.1	32.8	
		Stabilization	62	8.5	7.1	6.7	10.3	0.0	30.3	
		Improvement	23	9.9	7.2	6.8	13.0	0.5	29.8	
	Directional CFD deviation from 45°	Surgery deterioration	11	1.7	8.3	-3.9	7.3	-15.1	12.1	0.82
		Non-surgery deterioration	30	-2.1	13.0	-7.0	2.8	-32.8	21.6	
		Stabilization	62	-0.5	11.1	-3.4	2.3	-30.3	19.3	
		Improvement	23	-0.5	12.4	-5.9	4.8	-29.8	23.2	
Thoracolumbar	Absolute CFD deviation from 45°	Surgery deterioration	8	10.2	7.3	4.1	16.3	3.2	24.7	0.853
		Non-surgery deterioration	19	8.1	6.4	5.0	11.2	0.2	19.7	
		Stabilization	36	9.7	8.8	6.7	12.7	0.2	32.9	
		Improvement	35	9.1	6.0	7.0	11.2	0.2	20.7	
	Directional CFD deviation from 45°	Surgery deterioration	8	-10.2	7.3	-16.3	-4.1	-24.7	-3.2	0.461
		Non-surgery deterioration	19	-4.4	9.5	-9.0	0.2	-19.7	9.7	
		Stabilization	36	-7.3	11.0	-11.0	-3.5	-32.9	7.5	
		Improvement	35	-5.3	9.6	-8.6	-2.0	-20.7	16.7	
Lumbar	Absolute CFD deviation from 45°	Surgery deterioration	6	14.8	8.1	6.3	23.3	6.1	27.3	0.219
		Non-surgery deterioration	21	11.5	8.7	7.5	15.4	0.3	30.1	
		Stabilization	14	8.1	7.1	4.0	12.2	0.4	26.6	
	Signed_CFDDeviationFrom45	Improvement	6	-14.8	8.1	-23.3	-6.3	-27.3	-6.1	0.292
		Non-surgery deterioration	21	-7.2	12.6	-13.0	-1.5	-30.1	19.1	
		Stabilization	14	-7.4	7.9	-11.9	-2.9	-26.6	3.3	

3.4.6 CFD Angle Ranges (0–30°, 30–60°, 60–90°) and Treatment Outcomes

3.4.6.1 CFD Angle Range Groups & Curve angle changes

To investigate whether specific ranges of *Controlling force Direction* (CFD) are associated with improved radiographic outcomes, the cohort was stratified into three groups based on sagittal-plane CFD: 0–30°, 30–60°, and 60–90°. In the overall cohort (Table 3-11), the majority of patients (N = 206, 77.7%) fell within the 30–60° range, with 46 patients (17.4%) in the 0–30° range and 13 (4.9%) in the 60–90° range. Across all follow-up timepoints, no statistically significant differences in Cobb angle change and PMC Cobb change were observed among the three CFD range groups (all $p > 0.05$) (Table 3-11). Thus, no optimal CFD range for immediate and long-term correction was apparent, with in-brace corrections being achieved across the spectrum of force directions.

Table 3-11. The angle changes in different CFD groups

		0–30°（N =46）		**30–60°（N =206）**		**60–90°（N = 13）**		**Intra-group analysis (Sig.)**
		Mean	SD	Mean	SD	Mean	SD	
Cobb Angle changes (°)	ΔT0T2	-12.8	5.0	-13.2	6.4	-11.4	9.1	0.613
	ΔT0T3	1.4	9.0	0.7	9.8	0.0	9.3	0.878
	ΔT0T4	2.2	9.7	2.4	10.1	0.9	8.5	0.870
PMC Cobb Angle changes (°)	ΔT0T2	-12.4	6.4	-13.3	7.6	-12.3	8.7	0.718
	ΔT0T3	2.6	9.6	0.3	10.3	1.2	9.9	0.373
	ΔT0T4	3.4	9.7	1.8	10.4	0.6	8.7	0.567

Subgroup analysis by curve type

Subgroup analysis by curve type (Table 3-12) showed consistent null findings in thoracic and thoracolumbar curves. In the lumbar subgroup, however, immediate in-brace Cobb correction (T0–T2) differed significantly across CFD ranges ($p = 0.020$), with the 0–30° group achieving a greater mean correction (–14.1° ± 5.6°) than the 30–60° group (–11.6° ± 4.5°). However, it should be noted that the number of lumbar patients with such low CFD angles was relatively small (n=15 with CFD <30°), and this finding was not replicated in other subgroups. Moreover, this difference was not maintained at mid-term or long-term follow-up, and PMC Cobb changes in lumbar curves did not differ significantly between CFD ranges.The isolated lumbar immediate correction advantage in the 0–30° group should be interpreted cautiously, given the small sample size and lack of long-term persistence.

Overall, these results suggest that while the 30–60° range corresponds to the predominant empirical design in the current cohort, it does not consistently confer superior continuous radiographic outcomes.

Table 3-12. The angle changes in different CFD groups by curve type

Curve location		**Timepoints**	**CFD Groups**	**N**	**Mean**	**SD**	**Sig.**
Thoracic	Cobb Angle changes (°)	ΔT0T2	0–30°	17	-12.3	5.7	0.643
			30–60°	99	-12.9	6.2	
			60–90°	10	-11.1	7.5	
		ΔT0T3	0–30°	17	3.8	10.1	0.793
			30–60°	99	2.1	10.0	
			60–90°	10	1.6	9.3	
		ΔT0T4	0–30°	17	4.5	10.2	0.840
			30–60°	99	3.9	10.0	
			60–90°	10	2.2	8.7	
	PMC Cobb Angle changes (°)	ΔT0T2	0–30°	17	-11.0	5.2	0.611
			30–60°	99	-12.8	7.0	
			60–90°	10	-12.5	8.3	
		ΔT0T3	0–30°	17	5.4	10.4	0.289
			30–60°	99	1.2	10.1	
			60–90°	10	1.9	9.8	
		ΔT0T4	0–30°	17	6.2	10.5	0.404
			30–60°	99	2.8	10.2	
			60–90°	10	1.7	9.4	
Thoracolumbar	Cobb Angle changes (°)	ΔT0T2	0–30°	20	-12.7	4.2	0.413
			30–60°	76	-14.1	7.3	
			60–90°	2	-19.0	15.6	
		ΔT0T3	0–30°	20	-0.2	9.2	0.361
			30–60°	76	0.2	10.4	
			60–90°	2	-10.2	1.7	
		ΔT0T4	0–30°	20	1.0	10.5	0.447

			30–60°	76	2.0	10.9	
			60–90°	2	-7.6	4.0	
	PMC Cobb Angle changes (°)	ΔT0T2	0–30°	20	-12.9	5.0	0.739
			30–60°	76	-14.2	8.4	
			60–90°	2	-16.4	12.9	
		ΔT0T3	0–30°	20	1.2	9.3	0.926
			30–60°	76	0.1	11.1	
			60–90°	2	-0.3	17.1	
		ΔT0T4	0–30°	20	2.7	9.1	0.740
			30–60°	76	1.4	11.2	
			60–90°	2	-3.2	7.9	
Lumbar	Cobb Angle changes (°)	ΔT0T2	0–30°	9	-14.1	5.6	0.020
			30–60°	31	-11.6	4.5	
			60–90°	1	0.2	.	
		ΔT0T3	0–30°	9	0.3	5.9	0.402
			30–60°	31	-2.3	6.9	
			60–90°	1	4.4	.	
		ΔT0T4	0–30°	9	0.6	6.8	0.447
			30–60°	31	-1.8	6.6	
			60–90°	1	4.4	.	
	PMC Cobb Angle changes (°)	ΔT0T2	0–30°	9	-14.2	10.4	0.407
			30–60°	31	-12.8	7.7	
			60–90°	1	-2.3	.	
		ΔT0T3	0–30°	9	0.6	8.4	0.701
			30–60°	31	-2.1	8.6	
			60–90°	1	-2.7	.	
		ΔT0T4	0–30°	9	-0.4	8.7	0.967
			30–60°	31	-0.5	8.7	
			60–90°	1	-2.7	.	

3.4.6.2 CFD Angle Ranges and Categorical Outcomes

The relationship between CFD angle ranges and categorical treatment outcomes was assessed using Chi-square analysis. No significant association was found between CFD range and outcome category in the whole cohort (χ^2 p = 0.717) or within any curve type subgroup (all p > 0.05) as shown in Table 3-13.

Subgroup analyses by curve location yielded similar findings. In thoracic, thoracolumbar, and lumbar subgroups, Pearson and Fisher's exact tests consistently indicated non-significant associations between CFD angle and treatment classification (all p > 0.05). Descriptively, patients in the 30–60° group again comprised the majority of each outcome category (e.g., 81.9% of patients in the "Improvement" group), mirroring the overall population distribution. Although the 60–90° group showed numerically higher proportions of improvement (30.8%) compared to its small sample size, the low N (n = 13 overall, and <5 in subgroups) undermines the reliability of this trend.

These findings suggest that, in the absence of alignment-based customization, categorical treatment outcomes are not systematically influenced by the absolute CFD range. The predominance of patients within the range of forces typically applied (roughly 30°–60° posterolateral) likely reflects existing brace design norms rather than an optimal force orientation for all curve types. The data support the hypothesis that force direction alone—without consideration of patient-specific structural alignment—may not sufficiently explain therapeutic variability. This highlights the need for individualized, structure-guided optimization in brace design.

Table 3-13. Distribution of CFD Range Groups and Clinical Outcomes

	CFD Groups	**Surgery deterioration (N, %)**	**Non-surgical deterioration (N, %)**	**Stabilization (N, %)**	**Improvement (N, %)**	**Fisher's Exact Test**
Whole Cohort (N = 265)	0–30°	3, 6.5%	11, 23.9%	23, 50.0%	9, 19.6%	0.764
	30–60°	16, 7.8%	40, 19.4%	91, 44.2%	59, 28.6%	
	60–90°	0, 0.0%	4, 30.8%	5, 38.5%	4, 30.8%	

	CFD Groups	Surgery deterioration (N, %)	Non-surgical deterioration (N, %)	Stabilization (N, %)	Improvement (N, %)	Fisher's Exact Test
Thoracic curve (N = 126)	0–30°	1, 5.9%	5, 29.4%	9, 52.9%	2, 11.8%	0.829
	30–60°	10, 10.1%	21, 21.2%	49, 49.5%	19, 19.2%	
	60–90°	0, 0.0%	4, 40.0%	4, 40.0%	2, 20.0%	
Thoracolumbar curve (N = 98)	0–30°	2, 10.0%	4, 20.0%	9, 45.0%	5, 25.0%	0.688
	30–60°	6, 7.9%	15, 19.7%	27, 35.5%	28, 36.8%	
	60–90°	0, 0.0%	0, 0.0%	0, 0.0%	2, 100.0%	
Lumbar curve (N = 41)	0–30°	0, 0.0%	2, 22.2%	5, 55.6%	2, 22.2%	0.789
	30–60°	0, 0.0%	4, 12.9%	15, 48.4%	12, 38.7%	
	60–90°	0, 0.0%	0, 0.0%	1, 100.0%	0, 0.0%	

3.5 Discussion

This study employed a novel CAD/CAM-based method to quantify the controlling force direction (CFD) in thoracolumbosacral orthosis (TLSO) treatment for adolescent idiopathic scoliosis (AIS), by estimating the resultant vector of surface deformation between the unmodified and orthotist-modified torso models. The aim was to determine whether CFD influences clinical outcomes. Contrary to our initial hypothesis, across the cohort, neither the absolute CFD value nor its deviation from the conventional 45° reference showed significant associations with short-term (in-brace, T2), mid-term (off-brace, T3), or long-term (post-treatment follow-up, T4) changes in coronal Cobb angle, PMC Cobb angle, sagittal alignment, or PMC orientation. Categorical treatment outcomes classified as improved, stable, deteriorated, or requiring surgery were also not significantly different across CFD ranges. The only notable exception was observed in lumbar curves, where more posteriorly oriented CFD showed slightly greater immediate in-brace correction, but this advantage was not maintained at later timepoints.

Our results align with and expand upon previous observations in the literature. Wu et al. found that mid-range posterolateral zones (approximately 22°–67° from posterior) were most effective for controlling coronal curvature while maintaining sagittal alignment [32]. The CFD distribution in our cohort was similarly concentrated within a narrower 30°–60° range. This convergence suggests that current orthotist practice, whether consciously or empirically guided, already favors a biomechanically acceptable force orientation range. The absence of outcome differences across CFD ranges in our study supports the notion that, within this mid-range, minor variations in direction are less critical than ensuring adequate total controlling force and brace fit.

The spine's response to bracing is likely more sensitive to the magnitude and point of application of the net controlling force than to small angular variations within an effective range. Adequate pad pressure may overshadow directional fine-tuning. Prior research has shown that the amount of pressure and strap tightness is directly correlated with in-brace correction [68, 78, 162]. All patients in our series received custom braces that were appropriately snug and fitted; thus, the primary pad forces were likely of sufficient magnitude in every case. For example, Beauséjour *et al.* found that the distribution of interface pressures in different brace regions significantly affected immediate Cobb angle correction and even apical rotation [80]. Several studies demonstrated that higher pad pressures and optimal strap tightness were strongly correlated with greater initial coronal correction and even axial derotation [28, 68, 159]. In our cohort, since all braces were clinician-optimized for pad force (to achieve a decent initial correction), it's possible that the variation in CFD simply did not create a large enough difference in the effective force on the spine to be detectable in outcomes. The spine likely responds primarily to the resultant force vector's magnitude and general direction (posterior vs. anterior). Once the force is roughly directed toward the curve apex (which all our braces did), further adjusting that angle yields diminishing returns compared to adding another 50 N of force or increasing the pad contact area.

It is also worth noting that the braces in this study were all designed by experienced clinicians following modern principles (incorporating 3D considerations like derotation and sagittal profile as much as possible). Thus, the CFD range was inherently limited and truly misdirected forces (e.g., too posterior, which could flatten the torso, or too lateral, which might pinch the ribs) were likely avoided. The lack of "extreme" force directions in our data may partly explain the negligible outcome differences. If one could ethically test very different force directions (for instance, a brace pushing almost directly posterior vs. one pushing directly lateral) on similar patients, larger differences in correction might emerge. Wu's work indirectly supports this: they saw that *extremely posterior* pad forces (their zone 1) were rare and not effective, and *extremely lateral* forces (zone 4) were also uncommon [32]. Essentially, current bracing practice may have already converged on an acceptable mid-range force direction, and our study affirms that within that range, there is no obvious "more optimal" subset.

Another key factors were patient-specific factors: spinal flexibility and curve morphology. Our findings hinted that braces with more posteriorly angled forces gave slightly better initial correction in lumbar curves. This might be because lumbar curves in our sample that accepted a very posterior pad push were inherently more flexible or easier to derotate. Lumbar curves, which tend to have fewer structural constraints from the rib cage, may respond more favorably to posteriorly biased forces, as suggested by our subgroup analysis. Conversely, thoracic curves may require a more complex 3D coupling of lateral and rotational forces to achieve optimal derotation and sagittal preservation. In essence, the relationship between force angle and correction might be confounded by flexibility: more flexible curves both allow more posterior pad placement and correct more easily. Prior studies confirm that flexibility is one of the strongest predictors of in-brace correction [44, 51, 54, 107, 111], potentially confounding any direct relationship between CFD and outcomes. We aslo observed that flexibility, assessed qualitatively via bending x-rays in our study (Substudy 3, Chapter 5), was a better predictor of in-brace correction than CFD. This suggests patient-specific biology (flexibility and growth potential) outweighs the fine details of brace vector mechanics in determining outcomes.

The one potential exception we noted was in certain lumbar curves. Braces with a more directly posterior push (which one might imagine acts more like a translational force on the lumbar vertebrae) had a slightly greater initial straightening effect in that subgroup. Lumbar scoliosis often involves less structural rib deformity and more flexible vertebrae, so a straightforward push may translate to correction efficiently. In contrast, thoracic curves with rib humps might require a component of lateral force to induce spinal derotation and are less amenable to purely posterior pushing. While our subgroup sample was small, it raises the idea that *brace design could perhaps be optimized by curve type*: for example, a lumbar curve might benefit from a pad oriented closer to posterior-anterior, whereas a high thoracic curve might need a pad oriented more laterally or even anteromedially to couple with rib rotation. This hypothesis would need targeted testing, as our overall analysis did not show strong type-specific patterns.

Comparing to other studies, relatively few have explicitly analyzed brace force vectors. Most prior works studied pad forces in terms of pressure magnitude and pressure location [27, 28, 30, 68, 72, 74, 78, 79, 99, 159, 162]. For instance, Linn et al. showed that higher pad pressure correlates with better in-brace correction, leading to devices like smart braces that adjust pressure in real time [170]. Our study contributes novel data by focusing on the *direction* of that force. The negative result (no clear effect) is informative: it suggests that within conventional practice, force direction may not be a critical independent variable. However, this does **not** mean force direction is irrelevant; rather, it might mean that in our cohort there was insufficient variation or that other factors overshadowed it. We cannot exclude that an *inappropriately* directed brace (say, a pad pushing too high or at a wrong angle) would have poorer results – indeed, experienced orthotists likely avoid such scenarios, which is why our data set shows homogeneity around a presumably optimal 45°.

Another subtle point is the 3D nature of scoliosis correction. The Cobb angle is a 2D metric; two braces might achieve similar Cobb correction but differ in how they affect axial rotation or sagittal alignment. A particular force direction might improve one aspect at the expense of another. Wu *et al.* noted that braces with forces in a certain zone managed to avoid kyphosis loss. In our data we did not see a strong link between CFD and kyphosis change, but we did see a general trend that braces overall reduced kyphosis slightly (a common issue in bracing). If force direction were highly suboptimal, one might expect a larger kyphosis reduction (e.g., a pad pushing too posteriorly could flatten the thoracic spine). The absence of such a correlation in our cohort again suggests that none of the braces were grossly misaligned in the sagittal plane perspective. They all applied what could be called a balanced posterolateral push, which moderately affects all planes.

From a clinical standpoint, these findings suggest that within the empirically established posterior-lateral direction used in modern TLSO design, orthotists may have the flexibility to adjust CFD for patient comfort or brace manufacturability without compromising radiographic outcomes. This is particularly relevant when pad orientation must be modified to accommodate torso shape, soft tissue tolerance, or aesthetic preferences. However, for specific curve types—such as flexible lumbar curves—posteriorly oriented forces might offer modest additional benefit in immediate correction, warranting further targeted study. Importantly, our CFD estimation method—based on 3D surface deformation in CAD/CAM models—captures the resultant corrective vector applied to the torso, integrating multiple brace–body contact regions, rather than simply measuring the geometric angle of a single pad. This provides a more holistic representation of how the brace's shape changes translate into directional force application, potentially making it a valuable tool for brace design optimization.

Interpretation and limitations of estimated controlling force direction

A key methodological consideration of this study is that controlling force direction was not directly measured using in-brace force sensors but quantitatively estimated from

CAD/CAM orthotic models. This limitation reflects the retrospective and clinically embedded nature of the cohort, in which direct force-sensing technologies were not routinely available. Nevertheless, the estimated CFD provides meaningful biomechanical insight by capturing relative differences in force orientation across orthoses designed under comparable clinical workflows.

Importantly, the clinical relevance of the estimated CFD is supported indirectly through its association with radiographic outcomes, which remain the gold standard for evaluating orthotic treatment effectiveness in adolescent idiopathic scoliosis. The finding that CFD alone was not significantly associated with outcomes, whereas CFD–PMC alignment demonstrated consistent and clinically interpretable effects, further reinforces that the value of CFD lies not in its absolute magnitude but in its relationship to individual structural orientation. This aligns with the broader biomechanical principle that effective correction depends on force application being appropriately directed relative to deformity geometry rather than applied in a uniform or empirical manner.

Future work should aim to integrate direct in-brace force measurements or sensor-based technologies to further validate and refine the estimation of controlling force direction. Prospective studies combining real-time force sensing with structural alignment metrics may provide additional insight into the dynamic interaction between orthosis design and patient-specific biomechanics.

Limitations and Future Directions

This was a retrospective analysis without experimental manipulation of CFD, so causal inferences remain cautious. The narrow CFD distribution limits the generalizability of null findings to extreme force directions. Our method assumes that surface deformation correlates with underlying spinal force transmission, which, while biomechanically reasonable, has not been directly validated against in-brace force sensor data.

Future research could 1) Combine CFD estimation with real-time force magnitude measurements to explore vector–magnitude interactions; 2) Stratify analyses by flexibility and skeletal maturity to identify patient subgroups that might benefit from specific force orientations; 3) Expand CFD measurement to incorporate secondary pads and strap vectors for a more complete multi-point force model.

3.6 Conclusions

In contemporary CAD/CAM-designed TLSO treatment for AIS, CFD is predominantly concentrated within a 30°–60° posterolateral range. Within this range, small differences in force direction were not associated with significant changes in coronal Cobb angle, PMC parameters, or categorical treatment outcomes. This finding supports the notion that current empirical design practices already operate within an effective biomechanical zone, and that optimizing force magnitude, brace fit, and patient adherence may yield greater clinical benefit than refining CFD alone. For specific curve types—particularly flexible lumbar curves—more posterior force orientations may offer short-term correction advantages, but further evidence is needed to confirm long-term benefits. Future work integrating CFD with individualized three-dimensional structural characteristics, such as PMC orientation, may provide a pathway toward more targeted, patient-specific force vector strategies in scoliosis bracing.

The subsequent substudy (Chapter 2) will delve into this idea by examining the alignment between force direction and each curve's inherent 3D orientation, to explore whether a more nuanced, patient-specific force vector strategy could enhance outcomes.

CHAPTER IV EFFECTS OF STRUCTURAL ALIGNMENT BETWEEN CONTROLLING FORCE DIRECTION AND THE PLANE OF MAXIMUM CURVATURE ON THE BRACE TREATMENT OUTCOMES

4.1 Abstract

Background:

While controlling force application is central to bracing for adolescent idiopathic scoliosis (AIS), its clinical effectiveness likely depends on how well the applied force direction aligns with the patient's underlying curve geometry. This study evaluated the angular relationship between the Controlling force Direction (CFD) and the structural orientation of the curve, defined by the Plane of Maximum Curvature (PMC), and assessed its impact on bracing outcomes.

Methods:

Using the same AIS cohort (N = 265), this study estimated CFD from axial brace slice deformation and PMC orientation from EOS-based radiographs using eight manually defined vertebral landmarks. The absolute CFD–PMC alignment difference and signed difference were computed for each case. Outcomes included Cobb angle, PMC Cobb angle changes at in-brace (T2–T0), off-brace (T3–T0), and follow-up (T4–T0) timepoints, along with treatment classification (Improved, Stable, Progressed, Surgery). Group comparisons were performed across multiple alignment thresholds (absolute CFD–PMC alignment difference ≤10°, 15°, 20°, 25°, 30°). Subgroup analysis will be performed by curve type and PMC Orienation groups. Linear trend and correlation analyses were used to assess alignment-outcome associations.

Results:

The CFD–PMC alignment showed inter-patient variability, with mean absolute CFD–PMC alignment difference of 26.1° ± 13.4°, and mean signed difference of –24.9° ± 16.2°, indicating a systematic posterior offset of CFD relative to PMC. Both of the absolute and signed alignment differences showed no significant relationship with the angle changes and no significant differences among clinical outcome groups. However, in the subgroup analysis, better CFD-PMC alignment is significanly related to greater PMC Cobb corrections in patients with low PMC orientation (<66°) and left lumbar

curves.

Conclusions:

Structural alignment between CFD and PMC orientation was not a significant predictor of brace effectiveness in the overall AIS cohort, as minimizing the angular difference did not consistently translate into better outcomes. However, exploratory subgroup analyses revealed that specific structural patterns, particularly curves with lower PMC orientation and lumbar curve, showed greater 3D correction. These findings support a paradigm shift toward structure-informed orthotic force planning, advocating for personalized vector orientation in brace design workflows.

4.2 Introduction

In Substudy 1 of this thesis, we quantified the controlling force direction (CFD) delivered by CAD/CAM thoracolumbosacral orthoses and investigated whether CFD, taken in isolation, explained clinical outcomes. Across the posterolateral range commonly used in practice, CFD alone showed no robust association with either immediate in-brace correction or longer-term radiographic change, suggesting that force orientation by itself is insufficient to determine treatment effectiveness. These findings suggest that force orientation by itself is insufficient to determine treatment effectiveness, raising the question of whether it is not the absolute CFD, but rather its relationship to the patient's structural deformity, that is more relevant for clinical efficacy. In other words, the plausible explanation may be that the effectiveness of a given force depends on how well it is aligned with the patient's structural deformity.

The concept of the Plane of Maximum Curvature (PMC) has emerged to characterize a curve's spatial orientation [85, 93, 102]. The PMC is the vertical plane between the sagittal (0°) and coronal (90°) planes onto which the projected Cobb angle is maximal [104, 106, 171]. A typical thoracic AIS curve might have a PMC orientation of ~70° (meaning it's 20° off the purely coronal plane), whereas a highly rotated lumbar curve could have a smaller orientation angle (closer to sagittal, indicating the curve is wrapped around the trunk more) [32, 106]. Importantly, the PMC accounts for axial rotation and hypokyphosis, for instance, as thoracic kyphosis is lost, the spine twists and the curve plane rotates away from coronal [96, 103, 172].

From a biomechanical standpoint, one might hypothesize that a brace is most effective when its controlling force is aligned with the curve's PMC. Donzelli *et al.* proposed that Incorporating 3D curve classifications such as PMC into brace design could improve treatment strategies, suggesting that bracing "in the plane of the deformity" is a logical goal [103] . If the brace applies force "in-plane" with the deformity, correction might act more directly on the primary curve. In contrast, a force vector that is off-plane may partially act in directions that do not contribute to reducing the principal curvature or may even induce secondary deformities. For example, when the PMC is oriented toward the sagittal plane, a primarily coronal push may flatten the rib hump or alter vertebral rotation without effectively opening the curve. Conversely, a force vector substantially anterior to the PMC might fail to engage the vertebral column at the apex, dissipating energy into soft tissues and potentially worsening rotation.

Although prior biomechanical modeling and finite element method (FEM) simulations have shown that variations in the location, magnitude, and direction of applied forces substantially affect 3D corrective outcomes [46, 64-66, 72, 82, 89]. But none have explicitly tested the clinical value of aligning the controlling force vector to the PMC. This gap leaves an essential unanswered question: Does force–structure alignment matter for real-world brace outcomes? The role of such alignment may also interact with other patient-specific factors, such as curve stiffness, which will be addressed in a subsequent chapter.

This substudy aims to investigate the relationship between the angular difference $\Delta\theta_{(CFD–PMC)}$, defined as the CFD minus the PMC orientation, and clinical outcomes in AIS bracing. Specifically, the objectives were: (1) Is a smaller $\Delta\theta_{(CFD–PMC)}$ (i.e., better alignment) associated with greater in-brace Cobb angle correction and better long-term outcomes? (2) Does the sign of $\Delta\theta_{(CFD–PMC)}$ (force ahead of vs. behind the curve plane) influence clinical or sagittal-plane changes differently? (3) Do these relationships vary according to the magnitude of the PMC orientation? We hypothesized that closer CFD–PMC alignment would be associated with better treatment ouctomes. To investigate this, we employed the novel CFD measurement technique from Substudy 1 in combination with a method to calculate each curve's PMC orientation, analyzing a large retrospective patient cohort.

4.3 Methods

4.3.1 Study Design and Participants

The cohort selection, eligibility criteria, and shared clinical protocols for this sub-study are described in Sections 3.3.1 & 3.3.2. The sample size for the present analysis reflects the availability of CAD/CAM brace models required for controlling force direction estimation.

This substudy was conducted within the same retrospective cohort of adolescent idiopathic scoliosis (AIS) patients described in Substudy 1, Section 3.3, recruited at a single scoliosis specialty center between 2016 and 2018. Briefly, eligible participants were aged 10–14 years, had a primary coronal Cobb angle of 20°–45°, Risser sign 0–2, and completed brace treatment with available EOS imaging at baseline (T0), first in-brace (T2), end-of-brace (T3), and latest follow-up (T4). The EOS® biplanar X-ray imaging system and the Canfit™ CAD/CAM orthotic fabrication workflow were used for all patients, following identical protocols to those in Substudy 1 (Sections 3.3.4–3.3.8). All braces were designed and fabricated by experienced orthotists according to standardized clinical guidelines. CFD estimation followed the multi-slice vector summation method described in Substudy 1 Section 3.3.7.

4.3.2 Determination of PMC Orientation

For each patient's major curve, the Plane of Maximum Curvature (PMC) orientation was computed using an in-house software tool ("PMC Calculator", C#). The underlying algorithm and its validation were previously developed and reported by Wu et al. (2021), and the PMC Calculator has been adopted in our research group as a standardised measurement tool for PMC-related parameters [106]. In the present thesis, this tool was used as an established measurement platform to derive PMC orientation (and PMC-Cobb when required) for subsequent CFD–PMC alignment analyses.

The workflow was as follows. On standing pre-brace EOS radiographs, the operator identified vertebral landmarks by marking the corner points of the upper-end and lower-end vertebral endplates on both the AP and lateral views. Using EOS imaging geometry, these points were reconstructed into a 3D coordinate system. The software then rotated a candidate vertical plane from 0° (sagittal) to 90° (coronal); at each angle, the 3D vertebral points were projected onto that plane and a projected Cobb angle was computed. The angle yielding the maximal projected Cobb angle was recorded as the PMC orientation. For example, a PMC orientation of 60° indicates that the curve exhibits its maximal Cobb angle when viewed in a plane 60° from the sagittal plane (i.e., 30° off the coronal plane), reflecting the deformity's principal plane. The maximal Cobb angle in that plane was recorded as PMC-Cobb when needed; however, the present thesis primarily focuses on the orientation angle. The interface of the software was shown in the Figure 4-1.

To clarify contribution and workflow, all PMC measurements reported in this thesis were performed by the author following a standardised protocol, and the calculated PMC parameters were exported directly from the software for subsequent CFD–PMC alignment and outcome analyses. Prior work has demonstrated high repeatability of this PMC measurement approach (intraclass correlation coefficient > 0.9) [105, 171], and the same measurement settings were applied consistently across the cohort.

Figure 4-1. User interface of PMC Calculator

4.3.3 Force-Structure Deformity Alignment Parameter: Δθ(CFD–PMC)

For alignment calculations, we expressed CFD and PMC orientations in the same coordinate frame: both as degrees from the sagittal plane (posterior direction as 0°). The key alignment parameter was the angular difference between the net controlling force direction and the patient's structural deformity direction (PMC orientation):

$$\Delta\theta_{\text{CFD-PMC}} = \theta_{\text{CFD}} - \theta_{\text{PMC}}$$

Here, θ_{CFD} is the CFD angle relative to the sagittal plane, and θ_{PMC} is the PMC orientation angle. Positive Δθ values indicate the controlling force is oriented more laterally/anteriorly than the PMC, while negative values indicate a more posterior orientation. For analysis, both signed Δθ and absolute |Δθ| values were calculated.

For example, if a patient's PMC orientation is 70° and their brace CFD is 45°, the difference is –25° (negative, meaning the force was 25° behind the curve plane). If another patient has PMC 55° and CFD 50°, the difference is –5° (slightly behind). If PMC 60° and CFD 75°, the difference is +15° (force ahead of the plane by 15°).

4.3.4 Grouping by Alignment Consistency

To explore potential threshold effects, patients were stratified into alignment-consistent and misaligned groups based on absolute |Δθ| cut-offs (10°, 15°, 20°, 25°, 30°). Subgroup analyses were further conducted according to baseline PMC orientation (<66° vs ≥66°), based on the median value in the cohort.

4.3.5 Outcome Measures

Primary and secondary outcome measures (coronal Cobb change, PMC-Cobb change, and categorical treatment results) were defined identically to Substudy 1 (Section 3.2.8). In this substudy, analyses specifically examined whether Δθ(CFD–PMC) was associated with treatment outcome. Additionally, we tracked changes in sagittal Cobb angles (thoracic kyphosis change) to see if alignment had any association with sagittal profile alterations.

4.3.6 Statistical Analysis

The distribution of PMC orientations was summarized for the entire cohort and compared across curve types using one-way ANOVA, given the established variability of PMC by curve pattern. The distribution of CFD–PMC angular differences ($\Delta\theta_{\text{CFD-PMC}}$) was then examined, including the proportion of patients within specified misalignment thresholds (≤10°, 10–20°, >20°, >30°) and potential trends with curve type or severity.

Associations between $|\Delta\theta_{\text{CFD-PMC}}|$ and Cobb angle changes were evaluated using Pearson's correlation. A negative correlation was hypothesized, indicating that greater misalignment would correspond to reduced correction. Univariate and multivariate linear regression models were constructed, with in-brace Cobb angle reduction as the dependent variable and $|\Delta\theta_{\text{CFD-PMC}}|$ as the primary predictor. Equivalent models were applied to final Cobb angle change as the outcome. All models adjusted for baseline Cobb angle and curve type, given their potential influence on correction magnitude and optimal force orientation.

Stratified subgroup analyses were conducted to explore heterogeneity of the alignment–outcome relationship, including:(a) PMC orientation – Low-PMC (<65°, approximately the lower 50% of orientations) vs High-PMC (≥65°); (b) Curve type. Within each subgroup, correlation analyses were performed, and outcomes between alignment-consistent and misaligned patients were compared using t-tests or two-way ANOVA (e.g., Low-PMC vs High-PMC × Alignment status). Exploratory analyses were also performed for specific curve patterns of clinical interest, such as left lumbar curves with low PMC orientation and left thoracic curves with high rotation.

Statistical significance was set at $p < 0.05$, with subgroup results interpreted cautiously given multiple comparisons. Analyses were performed in SPSS (v26), with regression assumptions (linearity, normality of residuals) verified prior to model interpretation. Where relevant, effect sizes (β coefficients, Cohen's *d*) were reported to indicate the magnitude of associations.

4.4 Results

4.4.1 Curve Structural Orientation Characteristics

The PMC orientation of the major curve varied widely among patients, reflecting diverse 3D deformity patterns. Across the cohort, PMC orientations ranged from approximately 40° up to 85° and the mean PMC orientation was 65.9° ± 15.0°. PMC orientation differs systematically by curve type but is independent of curve magnitude. As shown in Table 4-1, this metric differed significantly by curve type ($p < 0.001$): thoracic curves had the largest mean orientation (71.0° ± 12.8°), thoracolumbar curves were intermediate (63.2° ± 14.6°), and lumbar curves had the smallest mean orientation (56.4° ± 13.9°). No significant correlation was observed between PMC orientation and baseline Cobb magnitude ($r = 0.06$, $p = 0.30$), suggesting that plane orientation is an independent descriptor rather than a proxy for curve size.

These findings indicate that thoracic AIS curves tend to have a more sagittal-plane aligned deformity, whereas lumbar curves exhibit a more laterally oriented (coronal-plane) deformity geometry. Clinically, higher PMC orientations (closer to the coronal plane) are often observed in more rigid thoracic curves and may pose greater challenges for brace correction, whereas lower orientations (more sagittally tilted) are more common in lumbar/thoracolumbar curves and may allow better geometric alignment with conventional pad force directions. These implications are explored further in the Discussion.

Table 4-1. Descriptives of CFD-PMC Alignment Parameters

		N	Mean	SD	Min	Max	Between-Component Variance
Baseline PMC Orientation (°)	Thoracic	126	71.1	12.9	30.0	89.0	0.000
	Thoracolumbar	98	63.3	13.9	32.0	86.0	
	Lumbar	41	56.5	16.8	26.0	88.0	
	Total	265	66.0	14.9	26.0	89.0	
CFD (°)	Thoracic	126	44.3	11.5	12.2	68.2	0.000
	Thoracolumbar	98	38.8	9.9	12.1	61.7	
	Lumbar	41	36.6	10.7	14.9	64.1	
	Total	265	41.1	11.3	12.1	68.2	
	Thoracic	126	-26.8	17.5	-68.8	12.2	0.085

		N	Mean	SD	Min	Max	Between-Component Variance
Signed alignment difference ($\Delta\theta_{(CFD-PMC)}$) (°)	Thoracolumbar	98	-24.6	17.0	-63.8	14.5	
	Lumbar	41	-19.9	18.5	-56.0	21.1	
	Total	265	-24.9	17.6	-68.8	21.1	
Absolute alignment difference $\lvert\Delta\theta_{(CFD-PMC)}\rvert$ (°)	Thoracic	126	27.5	16.3	0.6	68.8	
	Thoracolumbar	98	25.6	15.5	0.4	63.8	
	Lumbar	41	22.9	14.6	1.6	56.0	0.238
	Total	265	26.1	15.8	0.4	68.8	

4.4.2 CFD–PMC Alignment: Structural Consistency and Distribution

4.4.2.1 CFD angle vs PMC Orientation

On average, $\theta_{\text{CFD}} < \theta_{\text{PMC}}$ (controlling forces more sagittal/posterior than the PMC) as shown in Figure 4-2.

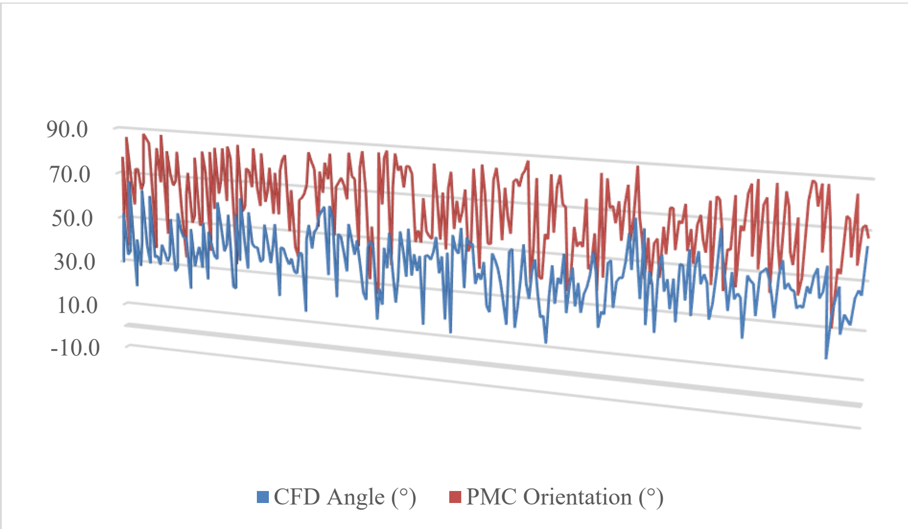

Figure 4-2. CFD angle vs. PMC Orientation

4.4.2.2 Distribution and Proportion of CFD-PMC alignment

To quantify how well the brace's controlling force was aligned with each patient's deformity, we calculated the angular difference between the controlling force direction (CFD) and the PMC orientation. Alignment between the controlling force direction and the structural plane was expressed as $\Delta\theta_{\text{CFD-PMC}}$ (degrees from the sagittal), with $\Delta\theta > 0$ indicating the force is more coronal/anterior than the PMC and $\Delta\theta < 0$ indicating more sagittal/posterior. The absolute alignment difference is $|\Delta\theta_{\text{CFD-PMC}}|$.

As shown in **Error! Reference source not found.**, this CFD–PMC difference also s howed a broad distribution, indicating that many braces were not precisely aligned with the patient's curve plane. $\Delta\theta_{\text{CFD-PMC}}$ ranged from −68.8° to +21.1° with a mean −24.9° ± 17.6° , The absolute difference averaged $|\Delta\theta| = 26.1° \pm 15.8°$, reflecting substantial force–structure mismatch aross the cohort. Additionally, as shown in Figure 4-3, 20.0% of patients achieved ≤10° alignment; 19.6% were ≤20°; 22.6% were 20-30°; and 37.7% exceeded 30°. In other words, only about 20% of patients had very close alignment (≤10° difference). Approximately 39.6% had alignment within 20°; conversely, 60.4% experienced a misalignment greater than 20°.

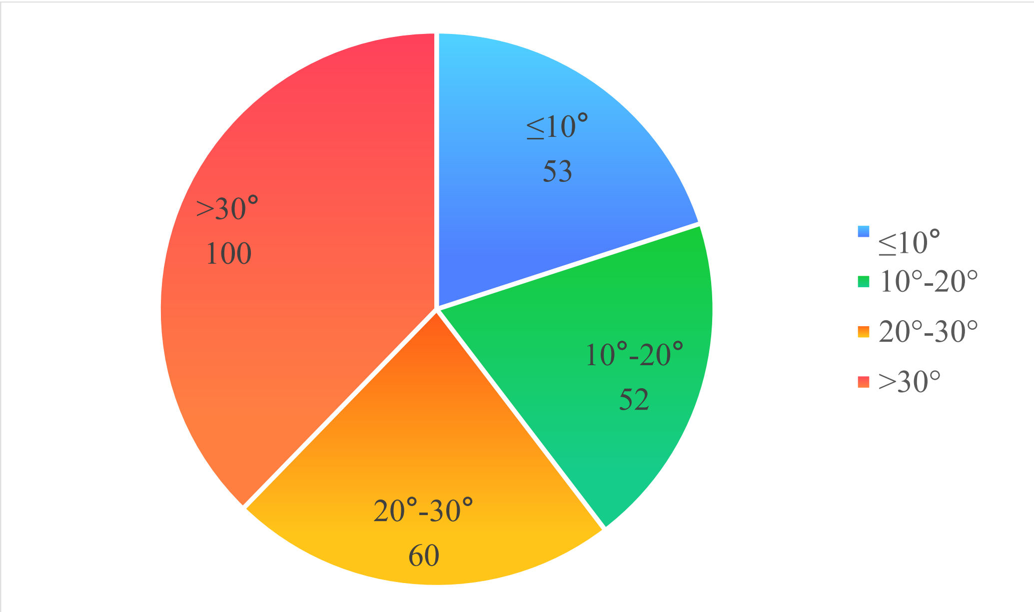

Figure 4-3. Distribution of Absolute alignment difference $|\Delta\theta_{\text{CFD-PMC}}|$

4.4.2.3 Alignment by Curve Type and PMC Orientation

When examining alignment differences by curve type, no statistically significant variation was found. As repoted in Table 4-1, neither $|\Delta\theta|$ ($p = 0.238$) nor $\Delta\theta$ ($p = 0.085$, trend only) differed significantly across curve types, suggesting that misalignment magnitude and direction were not curve-type specific at the cohort level. Thus, the tendency toward misalignment was prevalent in all curve types.

In contrast, alignment *did* differ markedly when considering the intrinsic orientation of the deformity. When stratified at the cohort mean PMC orientation of 66°, high-PMC (≥66°) curves demonstrated significantly greater misalignment than low-PMC (<66°) curves across all major curve types. Across all curve types, high-PMC cases had PMC angles averaging 75.3–78.9°, while corresponding CFD values clustered near 39.1–44.0°. Overall, $|\Delta\theta_{CFD-PMC}|$ averaged 14.5° ± 10.2° in the low-PMC group versus 35.0° ± 13.4° in the high-PMC group ($p < 0.001$), with signed differences showing that high-PMC curves were typically more posteriorly directed relative to the curve plane (mean −34.9° vs −11.9°, $p < 0.001$).

Table 4-2. CFD-PMC Alignment Parameters by PMC Orientation

	PMC orientation group based on 66-degree cut-off	**N**	**Mean**	**SD**	**Sig.**
CFD Angle (°)	PMC orientation < 66° (more sagittal)	115	39.7	11.0	0.076
	PMC orientation ≥ 66° (more coronal)	150	42.1	11.3	
PMC Orientation (°)	PMC orientation < 66° (more sagittal)	115	51.5	9.2	0.000
	PMC orientation ≥ 66° (more coronal)	150	77.1	6.7	
Signed alignment difference ($\Delta\theta_{(CFD-PMC)}$) (°)	PMC orientation < 66° (more sagittal)	115	-11.9	13.2	0.000
	PMC orientation ≥ 66° (more coronal)	150	-34.9	13.4	
Absolute alignment difference $|\Delta\theta_{(CFD-PMC)}|$ (°)	PMC orientation < 66° (more sagittal)	115	14.5	10.2	0.000
	PMC orientation ≥ 66° (more coronal)	150	35.0	13.4	

By curve type, as shown in Table 4-3, thoracic curves with high PMC showed the largest mismatch (mean absolute difference 33.8° ± 14.0° vs 11.2° ± 9.1° in low PMC, $p < 0.001$), and a corresponding signed difference of approximately −33.8° vs −8.8° ($p < 0.001$). Thoracolumbar curves demonstrated a similar pattern (high PMC: 36.3° ± 12.7° vs low PMC: 15.4° ± 12.6°, $p < 0.001$), as did lumbar curves (high PMC: 39.3° ± 10.9°

vs low PMC: 16.8° ± 10.6°, p < 0.001).

Table 4-3. CFD-PMC Alignment Parameters by PMC Orientation and Curve Type

Group Statistics Curve Type	Parameters	PMC orientation < 66° (more sagittal) N	Mean	SD	PMC orientation ≥ 66° (more coronal) N	Mean	SD	Sig.
Thoracic	CFD Angle (°)	35	45.0	10.1	91	44.0	12.1	0.671
	PMC Orientation (°)		53.8	8.1		77.8	6.7	0.000
	Signed alignment difference (°)		-8.8	11.5		-33.8	14.0	0.000
	Absolute alignment difference (°)		11.2	9.1		33.8	14.0	0.000
Thoracolumbar	CFD Angle (°)	50	38.4	9.8	48	39.1	10.2	0.723
	PMC Orientation (°)		51.9	8.9		75.3	6.0	0.000
	Signed alignment difference (°)		-13.5	12.8		-36.1	12.7	0.000
	Absolute alignment difference (°)		15.4	10.3		36.1	12.7	0.000
Lumbar	CFD Angle (°)	30	35.5	11.9	11	39.6	6.1	0.282
	PMC Orientation (°)		48.3	10.3		78.9	8.1	0.000
	Signed alignment difference (°)		-12.8	15.4		-39.3	10.9	0.000
	Absolute alignment difference (°)		16.8	10.6		39.3	10.9	0.000

These findings indicate that braces tended to apply a relatively fixed posterolateral force (39.1–44°) regardless of curve orientation, resulting in good alignment for moderately sagittal-oriented curves (<66°) but substantial misalignment for highly coronal-oriented curves (≥66°).

4.4.3 Correlation of Alignment with Curve Angle changes Across Key Timepoints

As shown in Figure 4-4 and Table 4-4, the degree of CFD–PMC alignment showed no significant correlation with changes in the Cobb angle at any time points. Neither the absolute nor signed alignment difference was significantly related to immediate in-brace Cobb correction (T2–T0) or to Cobb angle change at the end of bracing (T3–T0) and final follow-up (T4–T0) (all $p > 0.1$). In other words, the magnitude of Cobb angle reduction achieved did not appear to depend on how well the brace force was oriented with respect to the deformity plane.

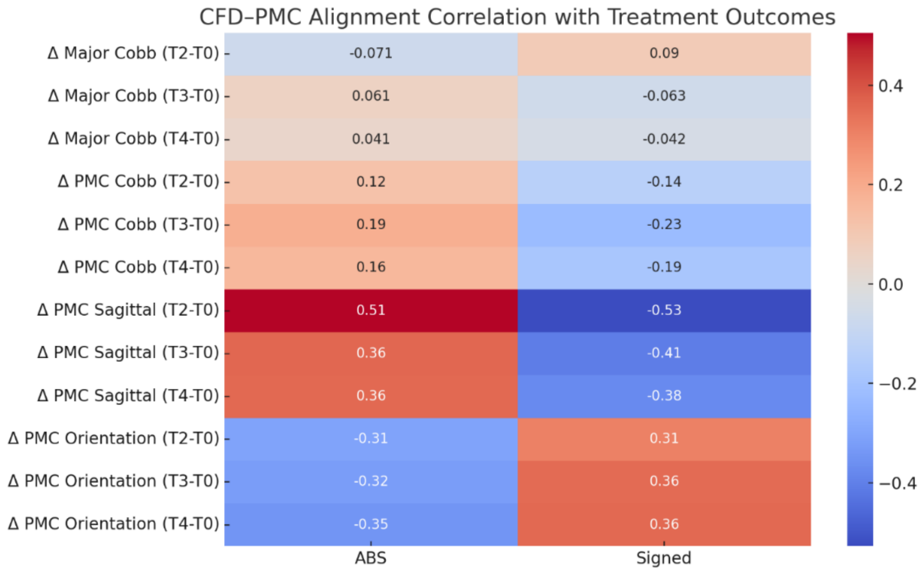

Figure 4-4. Correlation with Alignment Difference and Angle Change Across Treatment Time Points

Table 4-4. Correlation with Alignment Difference and Angle Changes Across Treatment Time Points

				Correlation with Absolute Alignment Difference $\|\Delta\theta_{(CFD-PMC)}\|$		**Correlation with Signed Alignment Difference $\Delta\theta_{(CFD-PMC)}$**	
	Time Points	Mean	SD	Pearson Correlation (r)	Sig.	Pearson Correlation (r)	Sig.
Coronal Cobb angle changes (°)	ΔT0T2	-13.0	6.3	-0.071	0.248	0.090	0.143
	ΔT0T3	0.8	9.6	0.061	0.321	-0.063	0.310
	ΔT0T4	2.3	9.9	0.041	0.506	-0.042	0.506
PMC Cobb angle changes (°)	ΔT0T2	-13.1	7.5	0.124	**0.045**	-0.137	**0.026**
	ΔT0T3	0.8	10.1	0.189	**0.002**	-0.228	**0.000**
	ΔT0T4	2.0	10.2	0.162	**0.008**	-0.186	**0.002**
PMC Sagittal angle changes (°)	ΔT0T2	-4.0	8.8	0.506	**0.000**	-0.528	**0.000**
	ΔT0T3	-1.1	9.2	0.361	**0.000**	-0.409	**0.000**
	ΔT0T4	-0.5	9.1	0.358	**0.000**	-0.378	**0.000**

PMC	ΔT0T2	-5.9	17.3	-0.306	**0.000**	0.308	**0.000**
Orientation	ΔT0T3	1.1	13.9	-0.324	**0.000**	0.356	**0.000**
changes (°)	ΔT0T4	1.1	13.7	-0.348	**0.000**	0.357	**0.000**

In contrast, 3D structural outcomes demonstrated significant, albeit moderate, associations with alignment. A larger misalignment (higher $|\Delta\theta_{(CFD-PMC)}|$) was associated with less improvement (or greater loss) in overall curve magnitude as captured by the 3D PMC Cobb angle. This relationship was weak but significant at all timepoints ($r \approx 0.12–0.19$, $p < 0.01$ for ΔPMC Cobb at T2, T3, T4), implying that patients whose braces were poorly aligned tended to show smaller reductions (or slight increases) in the true 3D curve size. Conversely, the signed alignment difference correlated negatively with 3D curve changes ($r \approx –0.14$ to $–0.23$, all $p < 0.05$), suggesting that when the controlling force was oriented relatively more posteriorly (i.e. behind the deformity plane), better 3D curve improvement was achieved.

The strongest alignment-outcome correlations were observed for changes in the PMC sagittal angle, which reflects the anterior-posterior tilt of the curvature plane. Larger absolute misalignment was moderately correlated with smaller PMC sagittal angles post-treatment ($r = 0.36–0.51$ across timepoints, $p < 0.001$). Similarly, the signed difference showed a strong negative correlation with sagittal plane changes ($r = –0.53$ to $–0.38$, $p < 0.001$), indicating that when braces were oriented more posteriorly relative to the curve, the structural curvature underwent significantly greater flattening of its sagittal tilt (i.e. a larger reduction in the PMC sagittal angle). In practical terms, anterior–posterior alignment seemed to substantially influence how much the spine's curvature straightened or "flattened" in the sagittal plane during treatment.

Alignment was also significantly related to transverse-plane structural changes. Both metrics of misalignment correlated with changes in PMC orientation (the rotation of the curve's plane over time). Notably, absolute misalignment had a moderate negative correlation with PMC orientation change ($r \approx –0.32$, $p < 0.001$), while the signed difference correlated positively ($r \approx +0.33$, $p < 0.001$). These trends indicate that better alignment (smaller $|\Delta\theta_{(CFD-PMC)}|$, or $\Delta\theta_{(CFD-PMC)}$ nearer to zero/posterior) was associated with less unintended transverse-plane rotation of the curve. In poorly aligned cases, the PMC orientation tended to shift more during bracing, whereas well-aligned cases maintained a more consistent structural orientation.

Overall, these correlation results suggest that while coronal Cobb angle correction was insensitive to force–structure alignment, the 3D characteristics of the curve (particularly its sagittal tilt and transverse orientation) were significantly affected. Braces aligned closer to the patient's PMC plane produced more favorable 3D remodeling (greater sagittal flattening and stability of the curve's rotational position), even if the frontal Cobb change was similar.

4.4.4 CFD–PMC Alignment Cut-off Thresholds on Multiple Treatment Outcomes

To further exprole the clinical relevance of alignment, this study performed outcome comparisons between "well-aligned" and "misaligned" groups at various alignment difference thresholds (Absolute Alignment Difference ≤ 10°, 15°, 20°, 25°, 30° versus those above each threshold). This study compared changes in various outcome measures across the "better aligned" and "misaligned" groups, and the outcomes included traditional coronal Cobb angle, 3D PMC Cobb angle, PMC sagittal angle, and PMC orientation across three timepoints (T2, T3, T4).

4.4.4.1 Alignment Thresholds and Coronal Cobb Angle

As shown in Table 4-5, coronal Cobb outcomes showed no meaningful group differences at any cut-off. For example, at a 20° alignment threshold the in-brace Cobb reduction averaged –12° in well-aligned patients vs. –13° in misaligned patients ($p = 0.45$), and the long-term Cobb change was ~+1° (slight worsening) in aligned vs. +3° in misaligned ($p = 0.07$); these slight differences were not statistically significant. This consistent null finding (all $p > 0.05$ across thresholds) reinforces that an adequately aligned brace force does not necessarily yield superior Cobb angle correction in isolation.

Table 4-5. Coronal Cobb Angle Change Under Different Cut-off Thresholds Across Treatment

Time Points

	Cut-off	Better aligned (N)	Better aligned (°)	Better aligned SD	Misaligned (N)	Misaligned (°)	Misaligned (SD)	Mean Difference (°)	p-value
ΔCobb Angle (T2 - T0)	10°	53	-12.5	7.8	212	-13.2	5.9	-0.7	0.481
	15°	79	-12.4	7.0	186	-13.3	6.0	-0.9	0.280
	20°	105	-12.7	6.6	160	-13.3	6.2	-0.7	0.448
	25°	132	-12.4	6.7	133	-13.6	5.9	-1.2	0.123
	30°	164	-12.7	6.8	101	-13.5	5.6	-0.7	0.357
ΔCobb Angle (T3 - T0)	10°	53	1.0	9.1	212	0.8	9.8	-0.2	0.902
	15°	79	0.1	8.6	186	1.1	10.1	1.1	0.309
	20°	105	-0.6	8.3	160	1.7	10.4	1.5	0.054
	25°	132	0.2	9.2	133	1.4	10.0	1.3	0.281
	30°	164	0.2	9.0	101	1.7	10.7	1.5	0.216
ΔCobb Angle (T4 - T0)	10°	53	2.6	8.9	212	2.2	10.2	-0.5	0.763
	15°	79	1.7	8.4	186	2.5	10.5	0.9	0.376
	20°	105	0.9	8.3	160	3.2	10.8	1.2	0.074
	25°	132	1.8	9.3	133	2.8	10.6	1.0	0.417
	30°	164	1.8	9.2	101	3.0	11.0	1.2	0.350

4.4.4.2 Alignment Thresholds and 3D structural outcomes

In contrast, **3D structural outcomes differed significantly based on alignment**, especially beyond a misalignment of 15–20°.

PMC Cobb angle (3D curve magnitude)

As shown in Table 4-6, no significant group difference was seen at the very strict 10° cut-off, but at moderate and higher misalignment thresholds the differences became clear. At the 20° threshold, for instance, patients with better alignment showed on average a slight continued improvement (a further decrease) in PMC Cobb angle by the end of brace treatment, whereas misaligned cases had a net worsening of the 3D curvature. Specifically, from baseline to the off-brace timepoint (T3), the well-aligned group's PMC Cobb angle changed by approximately –2.1° (indicating further curve reduction), compared to an average +2.6° increase in the misaligned group ($p < 0.001$, see Table Table 4-6). By final follow-up (T4), this gap had widened: misaligned patients had a larger net gain in PMC Cobb (i.e. more curve progression), while aligned patients maintained better curve control (group differences at thresholds ≥ 20° remained significant, $p < 0.05$). These results demonstrate a dose–response style effect, where beyond 15–20° of mismatch the 3D curve magnitude outcome was notably worse. In essence, braces that were aligned within about 15° of the patient's deformity plane tended to prevent 3D curve worsening, whereas larger misalignments were associated with 3D curve progression despite treatment.

Table 4-6. PMC Cobb Angle Change Under Different Cut-off Thresholds Across Treatment Time Points

	Cut-off	Better aligned (N)	Better aligned (°)	Better aligned SD	Misaligned (N)	Misaligned (°)	Misaligned (SD)	Mean Difference (°)	p-value
Δ PMC Cobb angle (T2-T0)	10°	53	-14.7	10.1	212	-12.7	6.6	2.0	0.08
	15°	79	-13.9	9.7	186	-12.8	6.3	1.1	0.472
	20°	105	-14.0	8.8	160	-12.5	6.4	2.1	0.112
	25°	132	-13.8	8.5	133	-12.5	6.2	1.3	0.155
	30°	164	-13.9	8.2	101	-11.8	6.0	2.1	**0.025**
ΔPMC Cobb angle (T3-T0)	10°	53	-1.6	10.4	212	1.4	10.0	3.0	0.054
	15°	79	-1.9	9.8	186	1.9	10.1	3.8	0.368
	20°	105	-2.1	9.5	160	2.6	10.1	3.4	**< 0.001**
	25°	132	-1.0	10.1	133	2.5	9.9	3.6	**0.004**
	30°	164	-0.5	9.6	101	2.9	10.7	3.4	**0.008**
ΔPMC Cobb angle (T4-T0)	10°	53	-0.1	10.3	212	2.6	10.1	2.7	0.085
	15°	79	-0.2	9.9	186	3.0	10.2	3.2	**0.005**
	20°	105	-0.4	9.4	160	3.7	10.3	3.2	**0.001**
	25°	132	0.6	10.0	133	3.5	10.1	2.9	**0.021**
	30°	164	0.8	9.6	101	4.0	10.8	3.2	**0.012**

PMC sagittal angle

Alignment was associated with PMC sagittal angle, defined as the angulation of the major curve when the PMC is projected onto the sagittal plane, rather than on the traditional thoracic kyphosis measured with T4/T5-7T12. As reported in Table 4-7, across all tested cut-offs from 10° through 30°, the better-aligned group showed significantly greater reductions in PMC sagittal angle than the misaligned group at every follow-up interval (all $p < 0.001$). For example, at a 20° cut-off, the initial in-brace change in PMC sagittal angle was –8.9° in the aligned group versus –0.9° in the misaligned group (T2–T0, $p < 0.001$). This indicates that well-aligned braces produced a substantial change in the sagittal projection of the curve's plane immediately, whereas misaligned braces achieved minimal change. This pattern persisted over time: by brace removal, aligned patients still had a net decrease of ~5°, whereas misaligned patients had a mean increase of +1–2°, indicating a shift toward a more sagittally oriented PMC plane (T3–T0, $p < 0.001$ at the 20° threshold). The same divergence was evident at final follow-up (T4–T0, $p < 0.001$), suggesting that sustained sagittal-plane changes of the PMC projection were strongly linked to good force alignment.

Table 4-7. PMC Sagittal Angle Change Under Different Cut-off Thresholds Across Treatment Time Points

	Cut-off	Better aligned (N)	Better aligned (°)	Better aligned SD	Misaligned (N)	Misaligned (°)	Misaligned (SD)	Mean Difference (°)	p-value
ΔPMC Sagittal angle (T2 - T0)	10°	53	-11.3	9.8	212	-2.2	7.5	9.1	< 0.001
	15°	79	-9.6	9.7	186	-1.7	7.1	8.0	0.018
	20°	105	-8.9	9.1	160	-0.9	6.9	7.9	< 0.001
	25°	132	-8.0	8.8	133	-0.2	6.8	7.8	< 0.001
	30°	164	-7.0	8.6	101	0.8	6.5	7.9	< 0.001
ΔPMC Sagittal angle (T3 - T0)	10°	53	-7.2	10.1	212	0.4	8.3	7.7	< 0.001
	15°	79	-6.0	10.0	186	1.0	8.0	6.9	< 0.001
	20°	105	-5.0	10.1	160	1.5	7.6	5.6	< 0.001
	25°	132	-4.1	10.0	133	1.9	7.3	5.9	< 0.001
	30°	164	-3.2	9.5	101	2.4	7.5	5.6	< 0.001
ΔPMC Sagittal angle (T4 - T0)	10°	53	-6.1	9.9	212	0.8	8.3	6.9	< 0.001
	15°	79	-4.6	9.9	186	1.2	8.2	5.8	< 0.001
	20°	105	-4.0	9.7	160	1.7	7.9	5.8	< 0.001
	25°	132	-3.2	9.8	133	2.1	7.5	5.3	< 0.001
	30°	164	-2.8	9.1	101	3.1	7.8	5.8	< 0.001

PMC orientation

Similarly, force–structure alignment significantly influenced the change in the PMC orientation angle (Table 4-8). At all alignment thresholds, the misaligned group demonstrated a greater reduction in PMC orientation, indicating that their curve's plane rotated more toward the sagittal plane (i.e. lost transverse-plane derotation) during treatment. By contrast, well-aligned patients showed only small changes or even slight increases in PMC orientation, suggesting better maintenance of the original transverse-plane alignment. For example, at a 20° cut-off, the mean change in PMC orientation immediately in-brace was –1.1° for aligned patients versus –9.0° for misaligned ($p < 0.001$). Over longer follow-up, aligned cases actually showed a small rebound *increase* in PMC orientation angle (returning closer to baseline, +5–6° by post-treatment assessments), whereas misaligned cases had continued net decreases (–2° to –9° range; all $p < 0.01$). This resulted in starkly different trajectories: well-aligned braces kept the deformity's plane relatively stable or slightly more coronal, while poorly aligned braces were associated with the spine's curvature plane progressively rotating **away** from the brace force (toward the sagittal direction). These group comparisons underscore that a brace force aimed in the correct plane is critical for controlling 3D aspects of the deformity, even if the frontal Cobb angle outcomes appear similar.

Table 4-8. PMC Orientation Change Under Different Cut-off Thresholds Across Treatment Time Points

	Cut-off	Better aligned (N)	Better aligned (°)	Better aligned SD	Misaligned (N)	Misaligned (°)	Misaligned (SD)	Mean Difference (°)	p-value
ΔPMC Orientation (T2 - T0)	10°	53	1.9	18.0	212	-7.8	16.6	-9.7	< 0.001
	15°	79	-0.5	17.2	186	-8.2	16.9	-7.7	< 0.001
	20°	105	-1.1	17.0	160	-9.0	16.8	-9.1	< 0.001
	25°	132	-1.7	17.0	133	-10.1	16.6	-8.4	< 0.001
	30°	164	-2.4	17.0	101	-11.5	16.4	-9.1	< 0.001
ΔPMC Orientation (T3 - T0)	10°	53	9.9	13.1	212	-1.2	13.2	-11.1	< 0.001
	15°	79	7.4	13.6	186	-1.6	13.1	-9.0	0.001
	20°	105	5.9	14.4	160	-2.1	12.6	-7.5	< 0.001
	25°	132	5.1	14.3	133	-3.0	12.2	-8.1	< 0.001
	30°	164	3.9	14.1	101	-3.6	12.1	-7.5	< 0.001
ΔPMC Orientation (T4 - T0)	10°	53	9.1	12.5	212	-0.9	13.3	-10.0	< 0.001
	15°	79	6.5	13.2	186	-1.2	13.3	-7.7	< 0.001
	20°	105	5.6	13.6	160	-1.9	13.0	-8.6	< 0.001
	25°	132	5.0	13.6	133	-2.9	12.7	-7.9	< 0.001
	30°	164	4.4	13.1	101	-4.3	13.0	-8.6	< 0.001

4.4.5 Comparison of Alignment Across Different Clinical Outcomes

4.4.5.1 Alignment Difference Across Different Categorized Clinical Outcomes

To determine whether alignment between CFD and PMC orientation was associated with categorical treatment outcomes, both signed and absolute alignment differences were compared across four clinical groups as defined in Chapter III, Section. 3.3.9: surgical deterioration, non-surgical deterioration, stabilization, and improvement.

As shown in Table 4-9, mean signed alignment difference ranged from –28.8° in the surgery deterioration group to –24.0° in the improvement group. However, the differences across groups were not statistically significant ($p = 0.747$). The mean values for all groups were negative, reflecting a consistent tendency for controlling forces to be directed posterior to the PMC orientation, regardless of clinical outcome.

Similarly, the absolute alignment difference showed no significant variation across clinical categories ($p = 0.847$). Mean absolute alignment difference ranged narrowly from 25.3° (improvement group) to 28.8° (surgery deterioration group), suggesting that misalignment was common and broadly distributed across all outcome groups.

These null findings are consistent with earlier continuous-outcome analyses, where CFD–PMC alignment showed no significant association with long-term Cobb angle change. Because the categorical Tx classification (per SRS/SOSORT criteria) is defined using a ≥ 5° Cobb angle change threshold, the absence of significant Cobb differences inherently limits the potential for alignment to influence categorical outcomes.

Table 4-9. Signed and Absolute Alignment Differences Across Clinical Outcomes

	Categorical Clinical Outcomes	N	Mean	SD	Min	Max	Sig.
Signed Alignment Difference	Surgery deterioration	19	-28.8	12.9	-51.7	-5.9	0.747
	Non-surgery deterioration	55	-25.6	19.4	-68.8	8.9	
	Stabilization	119	-24.6	17.6	-63.8	21.1	
	Improvement	72	-24.0	17.3	-52.2	15.6	
	Total	265	-24.9	17.6	-68.8	21.1	
Absolute Alignment Difference	Surgery deterioration	19	28.8	12.9	5.9	51.7	0.847
	Non-surgery deterioration	55	26.6	17.8	0.6	68.8	
	Stabilization	119	25.9	15.6	0.4	63.8	
	Improvement	72	25.3	15.3	1.0	52.2	
	Total	265	26.1	15.8	0.4	68.8	

4.4.5.2 Alignment Thresholds Across Categorized Clinical Outcomes

When outcomes were examined under various absolute alignment thresholds (10°, 15°, 20°, 25°, 30°), no statistically significant differences in outcome category distribution were detected for any cut-off (all $p > 0.3$). For example, at the 20° threshold, the proportion of patients with surgical deterioration was similar in the poorly aligned group (9.4%) and the well-aligned group (3.8%), and the distribution across all outcome categories did not differ significantly ($p = 0.323$). This pattern held across all tested thresholds (Table 4-10).

Table 4-10. Distribution of Clinical Outcomes under Different PMC-CFD Alignment Cut-Off

Thresholds

Cut off thresholds	$\lvert\Delta\theta_{\text{CFD-PMC}}\rvert$	N	Surgery deterioration (N)	Non-surgical deterioration (N)	Stabilization (N)	Improvement (N)	Sig.
10°	> 10°	212	16	40	99	57	0.442
	≤ 10°	53	3	15	20	15	
15°	> 15°	186	15	38	84	49	0.825
	≤ 15°	79	4	17	35	23	
20°	> 20°	160	15	34	71	40	0.323
	≤ 20°	105	4	21	48	32	
25°	> 25°	133	13	28	58	34	0.421
	≤ 25°	132	6	27	61	38	
30°	> 30°	101	10	23	41	27	0.443
	≤ 30°	164	9	32	78	45	

In summary, these findings are consistent with earlier results showing no significant association between CFD–PMC alignment and changes in coronal Cobb angle. Since the categorical treatment outcomes (improvement, stability, deterioration, surgery) were defined entirely by Cobb angle change thresholds (≥5° progression or final Cobb >50° for surgery), a lack of correlation with Cobb angle inevitably translates into a lack of correlation with these outcome categories. In other words, the classification system is structurally tied to a parameter that alignment did not significantly influence. This does not imply that alignment has no clinical relevance; rather, its measurable impact in this study was more evident in three-dimensional structural metrics (PMC Cobb, sagittal angle, orientation) that are not directly incorporated into the categorical definition. In addition, the clinical outcomes were affected by multiple determinants, including long-term adherence, skeletal maturity, and curve progression risk, which are not directly controlled for in this analysis. These findings suggest that CFD–PMC alignment plays a crucial role in structural remodeling; however, the categorical resolution and long-term confounders hinder its translation into treatment-based classifications. As a result, potential biomechanical benefits of better alignment may be under-represented in such classification frameworks, which prioritize coronal curve magnitude over 3D deformation.

4.4.6 Subgroup Analysis by Curve Type and PMC Orientation

As shown in Table 4-11, direct group comparisons by alignment cut-off threshold of 20° (aligned vs. misaligned) underscored the pattern: when PMC Orientation < 66°, aligned patients had markedly better 3D corrections. For example, aligned thoracic curves showed significantly greater reductions in PMC Cobb and sagittal angles ($p<0.02$), and aligned thoracolumbar curves had much larger coronal and sagittal improvements (e.g. ~–15.7° vs –9.3° major Cobb, $p<0.005$). Aligned lumbar curves also trended toward better PMC sagittal correction ($p\approx0.06$). In contrast, among PMC ≥ 66° patients, Cobb changes did not differ by alignment; the only significant differences were in thoracic curves' sagittal parameters (better kyphotic corrections in aligned cases, $p<0.05$). These findings indicate that force–structure alignment most strongly predicts 3D structural improvement in more sagittal deformities (PMC Orientation < 66°), especially in lumbar curves, whereas the effect diminishes in highly coronal curves.

Table 4-11. Subgroup Analysis of Treatment Outcomes by Curve Type and PMC in Aligned and Misaligned Groups

PMC Orientation	**Curve Type**	**Angle Changes Across Timepoints**		**Aligned Group: $\lvert\Delta\theta_{CFD\text{-}PMC}\rvert \le 20°$**			**Misaligned Group $\lvert\Delta\theta_{CFD\text{-}PMC}\rvert > 20°$**			**Mean Differences**	**Sig.**
				N	**Mean**	**SD**	**N**	**Mean**	**SD**		
PMC Orientation < 66° (more sagittal)	Thoracic	Coronal Cobb angle changes (°)	ΔT0T2	29	-12.3	6.5	6	-9.0	4.4	-3.4	0.232
			ΔT0T3		2.2	8.6		11.3	12.3	-9.1	0.035
			ΔT0T4		4.2	8.9		11.6	12.6	-7.4	0.095
		PMC Cobb angle changes (°)	ΔT0T2		-13.3	8.5		-9.7	3.0	-3.7	0.311
			ΔT0T3		-0.3	9.5		8.9	12.5	-9.2	0.049
			ΔT0T4		1.7	10.4		10.2	11.8	-8.5	0.085
		PMC Sagittal angle changes (°)	ΔT0T2		-8.0	9.6		-4.2	3.9	-3.8	0.354
			ΔT0T3		-6.1	9.7		-3.9	4.3	-2.2	0.591
			ΔT0T4		-5.0	10.3		-2.3	4.5	-2.7	0.538
		PMC Orientation changes (°)	ΔT0T2		-1.4	18.4		-7.3	15.7	6.0	0.467
			ΔT0T3		10.9	12.5		14.7	7.3	-3.8	0.480
			ΔT0T4		9.7	12.4		12.5	9.2	-2.8	0.609
	Thoracolumbar		ΔT0T2	36	-13.4	7.6	14	-11.1	5.7	-2.3	0.312
			ΔT0T3		-2.2	8.9		3.4	13.2	-5.6	0.090

PMC Orientation	Curve Type	Angle Changes Across Timepoints		Aligned Group: $\lvert\Delta\theta_{CFD\text{-}PMC}\rvert \leq 20°$			Misaligned Group $\lvert\Delta\theta_{CFD\text{-}PMC}\rvert > 20°$			Mean Differences	Sig.
				N	Mean	SD	N	Mean	SD		
		Coronal Cobb angle changes (°)	ΔT0T4		-0.3	8.5		4.6	14.4	-4.9	0.144
		PMC Cobb angle changes (°)	ΔT0T2		-15.4	9.8		-13.9	7.0	-1.5	0.605
			ΔT0T3		-4.7	10.1		3.7	10.5	-8.4	0.012
			ΔT0T4		-2.0	10.0		3.0	11.5	-5.0	0.137
		PMC Sagittal angle changes (°)	ΔT0T2		-12.4	8.9		-8.8	8.0	-3.6	0.192
			ΔT0T3		-8.0	8.2		-1.0	11.2	-7.0	0.018
			ΔT0T4		-5.9	9.0		-2.8	9.1	-3.1	0.285
		PMC Orientation changes (°)	ΔT0T2		2.3	19.5		4.1	15.8	-1.8	0.760
			ΔT0T3		7.4	13.5		1.9	16.8	5.5	0.235
			ΔT0T4		6.9	13.4		4.2	15.9	2.7	0.543
	Lumbar	Coronal Cobb angle changes (°)	ΔT0T2	22	-11.2	4.7	8	-12.0	6.8	0.9	0.696
			ΔT0T3		-3.3	5.2		1.6	5.4	-4.9	0.034
			ΔT0T4		-2.9	5.2		3.0	6.5	-5.9	0.016
		PMC Cobb angle changes (°)	ΔT0T2		-13.3	9.4		-12.5	7.4	-0.7	0.845
			ΔT0T3		-4.3	8.4		2.7	3.8	-7.0	0.033
			ΔT0T4		-3.2	7.4		5.9	8.7	-9.1	0.009
		PMC Sagittal angle changes (°)	ΔT0T2		-9.0	9.2		-7.0	7.9	-2.0	0.588
			ΔT0T3		-4.2	11.4		0.1	8.6	-4.2	0.350
			ΔT0T4		-2.9	10.5		4.1	15.1	-7.0	0.165
		PMC Orientation changes (°)	ΔT0T2		-1.3	10.4		2.3	17.3	-3.6	0.496
			ΔT0T3		1.9	15.0		1.9	13.2	0.0	0.996
			ΔT0T4		0.5	15.0		-2.1	18.2	2.6	0.691
PMC Orientation ≥ 66° (more coronal)	Thoracic	Coronal Cobb angle changes (°)	ΔT0T2	13	-11.1	4.9	78	-13.4	6.3	2.2	0.225
			ΔT0T3		3.7	7.6		1.4	10.3	2.3	0.451
			ΔT0T4		4.2	6.7		3.1	10.4	1.1	0.709
		PMC Cobb angle changes (°)	ΔT0T2		-11.6	5.1		-12.6	6.6	1.0	0.614
			ΔT0T3		3.5	6.3		1.8	10.5	1.7	0.577
			ΔT0T4		2.7	7.0		3.3	10.4	-0.6	0.844
			ΔT0T2		-3.2	5.6		0.7	5.1	-3.8	0.015
			ΔT0T3		-1.4	5.5		1.0	5.9	-2.4	0.170

PMC Orientation	Curve Type	Angle Changes Across Timepoints		Aligned Group: $\lvert\Delta\theta_{CFD\text{-}PMC}\rvert \leq 20°$			Misaligned Group $\lvert\Delta\theta_{CFD\text{-}PMC}\rvert > 20°$			Mean Differences	Sig.
				N	Mean	SD	N	Mean	SD		
		PMC Sagittal angle changes (°)	ΔT0T4		-2.7	5.4		0.9	6.0	-3.6	0.044
		PMC Orientation changes (°)	ΔT0T2		-3.6	16.2		-12.0	16.7	8.3	0.097
			ΔT0T3		3.8	9.9		-1.9	9.6	5.7	0.049
			ΔT0T4		5.7	8.5		-0.6	9.3	6.3	0.026
	Thoracolumbar	Coronal Cobb angle changes (°)	ΔT0T2	5	-19.7	7.7	43	-14.6	6.3	-5.1	0.101
			ΔT0T3		-4.4	8.3		1.0	9.9	-5.4	0.246
			ΔT0T4		-0.8	11.3		2.6	11.0	-3.4	0.521
		PMC Cobb angle changes (°)	ΔT0T2		-17.7	8.2		-12.4	5.9	-5.3	0.074
			ΔT0T3		2.2	10.8		3.3	10.0	-1.1	0.820
			ΔT0T4		2.1	10.3		4.1	10.5	-2.0	0.691
		PMC Sagittal angle changes (°)	ΔT0T2		-2.7	3.3		0.0	6.3	-2.7	0.348
			ΔT0T3		9.5	15.7		3.4	8.7	6.1	0.182
			ΔT0T4		6.0	11.2		3.9	8.7	2.1	0.627
		PMC Orientation changes (°)	ΔT0T2		-16.8	7.6		-10.3	14.6	-6.5	0.338
			ΔT0T3		-11.8	22.9		-5.4	14.2	-6.4	0.375
			ΔT0T4		-5.8	17.0		-6.1	14.8	0.3	0.970
	Lumbar	Coronal Cobb angle changes (°)	ΔT0T2	0	.	.	11	-13.2	4.8		
			ΔT0T3		.	.		-0.2	9.1		
			ΔT0T4		.	.		-0.6	8.1		
		PMC Cobb angle changes (°)	ΔT0T2		.	.		-12.3	7.0		
			ΔT0T3		.	.		1.0	9.2		
			ΔT0T4		.	.		0.3	8.3		
		PMC Sagittal angle changes (°)	ΔT0T2		.	.		0.9	10.1		
			ΔT0T3		.	.		4.2	6.6		
			ΔT0T4		.	.		5.6	6.6		
		PMC Orientation changes (°)	ΔT0T2		.	.		-9.0	19.1		
			ΔT0T3		.	.		-7.7	13.2		
			ΔT0T4		.	.		-10.5	11.7		

4.5 Discussion

This study is, to our knowledge, the first to quantitatively investigate the relationship between controlling force–structure alignment and three-dimensional (3D) curve correction in brace treatment for adolescent idiopathic scoliosis (AIS). Using patient-specific measurements of the plane of maximum curvature (PMC) and an automated method to estimate controlling force direction (CFD) from CAD/CAM brace models, we examined whether closer alignment between these vectors was associated with better orthotic treatment outcomes.

In the overall AIS cohort, this study found no significant association between CFD–PMC alignment and either coronal or PMC Cobb angle changes. These findings suggest that within the current TLSO, posterolateral controlling force can halt progression in most patients, even when forces are not perfectly "in-plane" with the deformity. An observation was the narrow range of applied force vectors: most braces clustered around a ~45° posterolateral direction regardless of patient-specific anatomy. This reflects the empirical nature of current orthotic practice, where force application is guided by tradition and orthotist experience rather than individualized 3D alignment measures [9, 82]. Additionlly, previous studies reported that the posterolateral corrective frce significantly reduced both coronal and PMC Cobb angles [32]. Our results echo these findings: braces that applied laterally-directed pushes reduced the magnitude of the scoliotic curve on average. However, it is also plausible that the relevance of alignment depends on other biomechanical factors, particularly the intrinsic flexibility of the curve. In a pliant spine, corrective loads may be effective even if applied off-axis, whereas in a rigid curve, off-axis forces may dissipate rather than reach the apex. This possibility was not directly tested in the present analysis but will be further examined in next Chapter.

This study stratified patients by the initial orientation of the plane of maximum curvature (PMC) to see if spine geometry influenced brace response. At the subgroup level, there was no strong dependence of coronal correction on PMC orientation: both patients with relatively sagittal (low-angle) PMCs and those with more frontal (high-angle) PMCs experienced similar Cobb reductions. This is consistent with prior findings that braces do not appreciably reorient the PMC [64]. In our analysis, PMC orientation remained statistically unchanged after bracing across all subgroups. Wu *et al.* (2024) similarly reported that PMC orientation did not significantly change over time for any force direction group. The implication is that the innate 3D orientation of the scoliotic curve is not easily altered by external bracing forces; instead, the brace primarily reduces the angle of curvature within that plane. Interestingly, we observed a slight increase in PMC orientation (rotation toward the sagittal plane) in a subset of patients with forces analogous to Wu *et al.*'s "zone 2" group, though this change was small. This minor difference may reflect the way certain force vectors interact with the rib cage and torso geometry, but overall it reinforces that bracing mainly corrects angle magnitude rather than twist orientation [64].

This study also examined outcomes stratified by curve type (thoracic-dominant vs. thoracolumbar/lumbar curves). At the cohort level, all curve types benefited from coronal correction, but the magnitude of improvement varied. Thoracic curves showed substantial lateral reduction, while lumbar curves often require special attention to pelvic alignment [173]. Our lumbar-dominant subgroup had modest coronal improvements, similar to trends reported in finite-element studies [62, 167, 173]. For instance, Li *et al.* (2023) modeled a Lenke-5 case and found that 3D forces applied to the pelvis can markedly improve both lumbar curve and pelvic tilt [100]. In our study, we did not systematically target the pelvis, and lumbar curves responded primarily when the force direction had a superior-inferior component. This suggests that thoracolumbar curves may require vertically oriented pads to control sacral obliquity, an idea supported by Li *et al.*'s finding that forces along the coronal (Z) axis were crucial for correcting pelvic tilt [100]. In contrast, thoracic curves in our cohort were effectively addressed by lateral pad pressure consistent with the classic three-point correction, matching the 3D correction principles. Overall, curve-type stratification revealed expected trends: both subgroups achieved coronal correction, lumbar curves likely need supplemental pelvic-pad design to optimize 3D alignment, a consideration for future brace customization.

A consistent theme of our study and related research is the paramount importance of force direction. Braces work by applying pressure in three dimensions, and small changes in force orientation can have large effects on outcomes. Our analysis mirrors Guan *et al.*'s computational results: using a patient-specific finite-element model, Guan *et al.* (2020) optimized 3D controlling forces and found that the best point of force application lay on the convex side at the location of maximal vertebral displacement [174]. In other words, the most effective push is where the spine deviates most. In clinical terms, this suggests that pads should be aimed not just laterally but also along the plane of maximum curvature. Wu *et al.* (2024) categorized forces into quadrants and showed that posterolateral forces (zone 3) achieved good lateral correction without worsening sagittal balance[32]. We similarly found that posterolaterally-oriented pads produced strong coronal correction with minimal kyphosis flattening. By contrast, purely sagittal-plane forces (Wu's zone 1) or purely coronal-plane forces (zone 4) were rare and less effective in our dataset. Clin *et al.* (2010) further quantified this: they showed that increasing strap tension – which effectively changes the force vector magnitude in the coronal plane – improved coronal curve correction[175]. These findings emphasize that a brace must deliver "pushes" from the right angle. In practice, this means that the orthotist should align the corrective pads to the curve apex and the trunk geometry. Modern braces often use a "shift/push" strategy (as with Boston 3D braces) combining translation and lateral force; our data suggest that such multi-axis forces are indeed most potent. In summary, careful consideration of force direction, informed by 3D measurements like the PMC and patient-specific anatomy, is critical to optimizing brace performance.

The insights from our cohort and subgroup analyses point directly toward personalized brace design. Traditional brace fabrication relies on standard templates or artisan plaster-modification, but modern techniques can tailor geometry and force application to each patient's 3D anatomy. In this spirit, Kardash *et al.* (2022) developed a fully computational brace design methodology that automatically optimizes brace shape for each individual. Their system uses a patient-specific trunk model and a differentiable simulation of the brace–body interaction, then searches for brace geometry that maximizes correction while maintaining comfort. In silico, their optimized Boston braces improved clinical metrics by roughly 45% over initial designs [176]. Our results underscore the value of this approach: by quantifying how force direction and pad placement affect multi-planar correction, we provide data that such algorithms could incorporate. For example, an optimization routine could use our findings to adjust pad height or strap tension to direct forces into the most effective zones. Similarly, Visser *et al.* (2012) described a CAD-based brace optimization that adjusts translational and rotational correction factors to balance curve reduction against patient comfort [177]. These personalized design strategies are highly relevant because our subgroup results indicate that even within a single brace concept, some patients might benefit from different pad orientations. In practice, a computer-aided system could take pre-brace imaging, classify the patient's PMC orientation and curve type, and then position corrective pads accordingly – for example, placing anterolateral pads for high-angle PMCs or pelvic extensions for lumbar curves. In short, our work provides empirical backing for the personalized paradigms described by Kardash *et al.* and others: effective bracing should no longer be one-size-fits-all, but rather customized in 3D to the individual's spine and trunk.

Looking ahead, the future of scoliosis bracing lies in force-based optimization. This will likely involve routine use of patient-specific FEM in clinical workflows, assisted by machine learning or differentiable simulations to speed optimization (as in Kardash *et al.*) [176]. We also foresee more adaptive brace designs: for example, dynamic pads that can adjust force vectors over time as the spine grows or stiffens [170]. Finally, our study suggests that measuring 3D spine parameters (Cobb angles in multiple planes, PMC orientation) before and after bracing should become standard, so that feedback on force direction efficacy can be systematically gathered. By combining clinical data with advanced modeling, the community can iteratively refine how braces apply forces to the body, ultimately improving 3D correction while minimizing side effects. In sum, our work emphasizes that understanding and aligning controlling forces with the individual patient's spinal geometry is crucial – and that future research and design should build on this principle to create the next generation of optimized scoliosis braces.

4.6 Conclusion

In this AIS cohort, controlling force direction (CFD)–PMC alignment showed no significant association with treatment outcomes in the overall analysis, particularly for coronal Cobb change, where aligned and misaligned braces performed no significant differences. However, specific structural subgroups demonstrated notable or trend-level benefits from better alignment. In particular, patients with low PMC orientation and lumbar curves achieved greater 3D correction and better maintenance of correction when the CFD-PMC aligns better. These findings indicate that while routine bracing has effects on patients with AIS, precise alignment in most cases, targeted force alignment may offer additional benefit in patients especially with lower PMC orientation.

This study provides insight on how to integrate patient-specific structural parameters, such as PMC orientation and curve type, into brace design, optimizing force direction for those subgroups most likely to benefit. Future work should validate these subgroup effects in prospective trials, explore interaction with other biomechanical determinants (e.g., compliance, spinal flexibility), and develop design tools that incorporate real-time feedback on force magnitude and direction. By focusing on individualized 3D force alignment where it matters most, brace treatment for AIS could become both more precise and effective, translating biomechanical insights into tangible clinical improvements.

CHAPTER V THE RELATIONSHIP BETWEEN SUPINE SPINAL FLEXIBILITY AND BRACE TREATMENT OUTCOMES IN ADOLESCENT IDIOPATHIC SCOLIOSIS

5.1 Abstract

Background: While controlling force–structure alignment has been investigated as a determinant of brace effectiveness in adolescent idiopathic scoliosis, patient-specific structural responsiveness may play an equally critical role. Supine radiographs provide a practical way to quantify spinal flexibility, reflecting the intrinsic capacity of a curve to correct under passive unloading. However, the prognostic value of supine flexibility for long-term brace outcomes has not been fully validated in large cohorts. This study aimed to determine the relationship between supine spinal flexibility and orthotic treatment success, and to explore its potential interaction with controlling force–structure alignment.

Methods: A total of 328 AIS patients prescribed full-time thoracolumbosacral orthoses (TLSO) were included. Baseline standing (T0) and supine (T1) radiographs were obtained, and flexibility was calculated as the percentage Cobb reduction related to the baseline Cobb angle. Controlling force direction was estimated from CAD/CAM brace models and compared with the plane of maximum curvature derived from radiographs. Based on findings from a companion substudy, alignment was classified using an absolute CFD–PMC difference threshold of 20°, with ≤20° defined as aligned and >20° as misaligned. Patients were followed at in-brace (T2), end of treatment (T3), and post-brace follow-up (T4). Outcomes included continuous Cobb angle changes and categorical classifications (Improved, Stable, Deteriorated, Surgery). Multivariable regression and subgroup analyses were performed to evaluate associations between flexibility, alignment, and outcomes.

Results: The mean baseline Cobb angle was 31°±5°, with mean supine flexibility of 26%±15%. Greater flexibility strongly predicted better brace correction and favorable long-term outcomes ($p < 0.001$). Multivariate regression confirmed flexibility as an independent predictor of success (OR 0.72 per 10% increase, 95% CI 0.60–0.86, $p < 0.001$). Patients with flexibility ≥30% showed markedly lower progression than those

<30% (10% vs 35%, $p < 0.001$). Thoracic curves were stiffer and more likely to progress than thoracolumbar/lumbar curves (flexibility 25% vs 40%, progression 32% vs 10%, both $p < 0.001$). Stratified analyses suggested that the influence of CFD–PMC alignment was most evident in low-flexibility curves, particularly thoracolumbar curves, where alignment reduced surgical deterioration.

Conclusion: Supine spinal flexibility is a powerful prognostic indicator in AIS bracing, with higher flexibility predicting superior correction and lower progression risk. While CFD–PMC alignment was not broadly predictive in the whole cohort, its apparent protective effect in stiff thoracolumbar curves highlights that force direction becomes particularly critical when intrinsic correction potential is limited. These findings suggest that brace effectiveness depends not only on how much the spine can yield under unloading, but also on whether corrective vectors are aligned with the structural orientation, especially in rigid curves. Integrating flexibility assessment with force–structure alignment may therefore enhance individualized brace planning and facilitate early identification of patients at high risk for treatment failure.

5.2 Introduction

The preceding chapter examined how controlling force direction and its alignment with curve structure (CFD–PMC) relate to outcomes in AIS bracing. Those analyses indicated that mechanical parameters of the brace, while important, do not by themselves explain the full variability in clinical response. This chapter shifts the focus to a patient factor that is measurable before treatment, which is spinal flexibility on a pre-brace supine radiograph, and evaluates how that supine flexibility relates to both the initial in-brace correction and longer-term outcomes.

Spinal flexibility can be assessed in several ways, including active standing side-bending radiographs, fulcrum-bending radiographs, traction films (manual or table-based), relaxed prone or supine films, and, less commonly, hanging radiographs or positional imaging with ultrasound/EOS/X-ray [51, 55, 86, 108-113, 115, 117, 178, 179]. Active side-bending depends on patient effort, discomfort, and examiner instruction and can overestimate flexibility (apparent values >100%), which weakens its link to in-brace performance. Fulcrum-bending [86, 110, 178] and traction &

suspension [109, 111, 113, 115, 120] require additional equipment and are difficult to standardize across routine follow-up. By contrast, relaxed prone/supine imaging captures passive, gravity-unloaded straightening, is quick and reproducible, and shows the strongest correlation with the first in-brace correction reported in the literature [44, 51, 53-55, 108, 116, 121, 122]. For these reasons and because it was feasible and uniformly available in our cohort, this study used the pre-brace supine radiograph as the flexibility measure.

Supine flexibility in this context means the curve's capacity to straighten passively under gravity when the patient is lying down, typically expressed as the percentage reduction in Cobb angle from standing to supine. Supine imaging is simple, requires no active effort, and captures the component of the deformity that can be corrected without muscular compensation. Prior work shows that the Cobb angle on a supine film correlates well with the first in-brace Cobb angle [44, 54, 124], whereas aggressive side-bending views can overestimate "flexibility" and may be less informative for brace performance [55]. For example, in a cohort of 105 AIS patients, Cheung *et al.* found a high correlation ($r = 0.74$) between supine flexibility and immediate in-brace Cobb correction, and noted that the spine's inherent flexibility governed the brace's corrective effect [44]. A more flexible curve will allow greater brace-induced straightening, whereas a stiff curve will resist correction. These findings support the use of simple supine (or prone) radiographs as effective predictors of how much correction a well-fitted brace can immediately achieve for a given curve.

Despite these advances, several gaps and controversies remain regarding flexibility and bracing outcomes. Most prior analyses emphasize either the initial in-brace result and limited track multiple timepoints to describe how flexibility relates to the entire treatment course, including post-weaning follow-up [51]. Moreover, the interaction between curve pattern, three-dimensional alignment, and flexibility remains incompletely defined. Finally, although the previous chapter showed that CFD–PMC alignment is not universally decisive, there are biomechanical reasons to suspect that alignment may matter most when a curve has limited capacity to straighten passively, an interaction that has not been thoroughly tested.

To address these gaps, the present study analyzes a large, single-protocol cohort of braced AIS patients with standardized imaging across the whole treatment period. The current study aims to (i) quantify the association between baseline supine flexibility and radiographic outcomes at key milestones (T2 in-brace, T3 end of bracing, T4 post-weaning); (ii) evaluate how supine flexibility relates to clinically defined outcomes (improvement, stabilization, deterioration, surgery) and its predictive performance using logistic models and ROC analyses; and (iii) examine whether these relationships differ by curve type and by structural–mechanical alignmen.

5.3 Methods

5.3.1 Study Design and Participants

This sub-study was conducted within the shared retrospective cohort described in Chapter 3. The effective sample size differed from other sub-studies due to the availability of pre-brace supine radiographs required for flexibility assessment.

A total of 328 adolescents with idiopathic scoliosis who underwent standardized CAD/CAM-based thoracolumbosacral orthosis treatment were included in this analysis. All patients were managed under the same clinical protocol and followed with radiographic assessments at predefined time points. Detailed cohort definition, inclusion, and exclusion criteria are provided in Sections 3.3.

5.3.2 Imaging protocol and timepoints

Biplanar EOS radiographs were obtained at up to five timepoints: T0 (standing baseline prior to brace), T1 (pre-fabrication supine radiograph to quantify intrinsic flexibility), T2 (first in-brace standing radiograph, typically 1–3 months after initiation), T3 (off-brace radiograph at brace discontinuation due to maturity, progression, or failure), and T4 (latest off-brace follow-up after discontinuation)

5.3.3 Definition of Supine Flexibility

Supine spinal flexibility was quantified using a standard formula that compares the Cobb angle in standing (T0) versus supine (T1) positions:

$$\text{Flexibility Rate (\%)} = \frac{T0_{Cobb} - T1_{Cobb}}{\mathrm{T0}_{Cobb}} * 100\%$$

This value reflects the inherent passive reducibility of the curve under gravity unloading, with higher positive values indicating greater flexibility. Flexibility was analyzed as a continuous variable and later categorized into subgroups and ROC analyses.

5.3.4 Outcome Measures

Radiographic outcomes were computed as changes in the coronal and PMC Cobb angle relative to T0 at T2, T3, and T4 (ΔT2 = T2–T0; ΔT3 = T3–T0; ΔT4 = T4–T0), with positive values indicating progression and negative values indicating improvement. Categorical outcomes at T3 and T4 were defined as Improvement (≥5° decrease), Stabilization (<5° absolute change), Deterioration (≥5° increase), and Surgical deterioration (Cobb ≥50° or surgery/recommendation for surgery documented) due to different brace discontinuation contexts (e.g., skeletal maturity vs. treatment failure).

5.3.5 PMC-CFD Alignment Grouping

The structural–mechanical alignment was classified a priori using the absolute CFD–PMC angular difference: aligned ≤20°; misaligned >20° (based on companion substudy evidence in 4.4.6).

5.3.6 Statistical Analysis

We summarized baseline characteristics and flexibility distributions overall and by curve type. Pearson correlations assessed associations between flexibility and continuous outcomes (ΔCobb and correction rates at T2–T4; ΔPMC Cobb at T2–T4). Group differences across curve types, outcome categories, and selected covariates were evaluated with one-way ANOVA and Bonferroni-adjusted post-hoc tests. To evaluate predictive performance, receiver operating characteristic (ROC) analyses estimated area under the curve (AUC) and Youden-optimized thresholds. Logistic regression models—first univariate, then multivariable, adjusting for baseline Cobb, curve type, Risser sign, and compliance—estimated the association between flexibility (continuous and dichotomized) and deterioration or surgical deterioration. Effect modification by flexibility for the relationship between alignment status and outcomes was explored with stratified analyses (low flexibility ≤30% vs high flexibility >30%); curve-type-specific strata were examined secondarily. Two-tailed $p<0.05$ was considered statistically significant.

5.4 Results

5.4.1 Study Population Description

As illustrated in Table 5-1, among 328 patients (mean age 12.4 ± 1.1 years; 85.1% female), skeletal maturity at initiation was predominantly low (Risser 0 in 52.7%). Baseline major-curve Cobb averaged 30.3° ± 5.5°. Curve types comprised 159 thoracic (48.5%), 116 thoracolumbar (35.4%), and 53 lumbar (16.2%). Mean bracing duration (T0–T3) was 2.5 ± 0.7 years; 233 patients (71.0%) had additional off-brace follow-up (T4), averaging 1.1 ± 0.6 years beyond weaning. Subjective and objective wear times averaged 13.3 ± 5.2 and 13.6 ± 5.2 hours/day, respectively. A BMI subset (n=102) had a mean BMI of 17.2 ± 2.0 kg/m².

Table 5-1. Participants Characteristics

Characteristics	N	Mean	SD
Age (years)	328	12.4	1.1
Female	279		
Male	49		
Risser Sign 0	173		
Risser Sign 1	72		
Risser Sign 2	83		
Curve type - Thoracic	159		
Curve type - Thoracolumbar	116		
Curve type - Lumbar	53		
Treatment Duration (T0-T3) (days)	328	906.5	271.7
Treatment Duration (T0-T3) (years)	328	2.5	0.7
Follow-up duration (T3-T4) (days)	233	404.6	217.3
Follow-up duration (T3-T4) (years)	233	1.1	0.6
T0 Cobb Angle (°)	328	30.3	5.5
T1 Cobb Angle (°)	328	21.1	6.1
T2 Cobb Angle (°)	328	17.4	7.1
T3 Cobb Angle (°)	328	31.1	11.0
T4 Cobb Angle (°)	233	31.7	10.1
T0_PMC Cobb Angle (°)	327	34.0	7.5
T2_PMC Cobb Angle (°)	327	20.9	8.3
T3_PMC Cobb Angle (°)	327	34.6	10.8
T4_PMC Cobb Angle (°)	233	35.6	10.3
Change in Cobb Angle (T1 - T0) (°)	328	-9.2	4.8
Change in Cobb Angle (T2 - T0) (°)	328	-12.9	6.4
Change in Cobb Angle (T3 - T0) (°)	328	0.7	9.7
Change in Cobb Angle (T4 - T0) (°)	233	1.6	9.1
Change in PMC Cobb angle (T2 - T0) (°)	327	-13.1	7.6
Change in PMC Cobb angle (T3 - T0) (°)	327	0.6	10.0
Change in PMC Cobb angle (T4 - T0) (°)	233	1.6	9.2
Flexibility Rate (%)	328	30.5%	15.6%
CorrectionRate_T2 (%)	328	42.8	20.3
CorrectionRate_T3 (%)	328	-2.8	32.5

CorrectionRate_T4 (%)	233	-5.9	31.7
BMI (kg/m2)	102	17.2	2.0
WHO BAZ_BMI-for-age Z-score	102	-0.6	1.0
BMI categories Underweight	4		
BMI categories - Normal	92		
BMI categories Overweight	6		
Subjective Compliance (hrs/day)	328	13.3	5.2
Objective Compliance (hrs/day)	279	13.6	5.2

5.4.2 Correlation Between Supine Flexibility and Demographic Factors

Supine flexibility averaged 30.5% ± 15.6% overall. As shown in Table 5-2, tt differed by curve type (ANOVA p<0.001), being lowest in thoracic curves (25.1% ± 14.9%) and higher in thoracolumbar (36.1% ± 15.8%) and lumbar curves (34.2% ± 11.7%); post-hoc contrasts confirmed thoracic vs thoracolumbar (mean difference −11.0%, p<0.001) and thoracic vs lumbar (−9.0%, p<0.001), with no difference between thoracolumbar and lumbar (p=1.000). No significant flexibility differences were observed between males (27.4 ± 14.2%) and females (31.0 ± 15.8%) ($p = 0.135$), although males exhibited slightly lower flexibility on average.

Table 5-2. Supine Flexibility by Risser Sign, Curve Type, Gender, and BMI Groups

		N	**Mean**	**SD**	**Sig.**
Risser Sign (N = 328)	Risser Sign 0	173	30.8	15.6	0.891
	Risser Sign 1	72	30.4	15.5	
	Risser Sign 2	83	29.8	16.0	
Curve type (N = 328)	Thoracic	159	25.1	14.9	0.000
	Thoracolumbar	116	36.1	15.8	
	Lumbar	53	34.2	11.7	
Gender (N = 328)	F	279	31.0	15.8	0.135
	M	49	27.4	14.2	
BMI categories (N =102)	Underweight	4	34.5	8.7	0.762
	Normal weight	92	30.6	13.7	
	Overweight	6	33.7	16.2	

As shown in Table 5-3, a weak but statistically significant negative correlation was found between flexibility and age ($r = -0.184$, $p = 0.001$), while no significant correlation was observed with Risser sign categories ($p = 0.891$). No significant associations were found with BMI ($r = -0.004$, $p = 0.970$), or BMI-for-age Z-score (WHO BAZ; $r = 0.067$, $p = 0.502$). Similarly, flexibility was not significantly different among patients with different BMI categories ($p = 0.762$), including underweight

(34.5 ± 8.7%), normal weight (30.6 ± 13.7%), and overweight individuals (33.7 ± 16.2%).

Table 5-3. Correlation between Supine Flexibility and Demographic Factors

Factors	Pearson Correlation (r)	Sig.
Age (years)	-0.184	0.001
BMI (kg/m2)	-0.004	0.970
BMI-for-age Z-score	0.067	0.502
Baseline Cobb Angle (°)	-0.020	0.719
Baseline PMC Cobb Angle (°)	0.002	0.967

5.4.3 Correlation Between Flexibility and Curve Correction

Greater supine flexibility is associated not only with better immediate correction but also with improved structural responses at later treatment stages. As shown in Table 5-4, supine flexibility showed moderate negative correlations with curve changes at in-brace (T2) (r = –0.425), off-brace (T3) (r = –0.310), and post-treatment follow-up (T4) (r = –0.365), all statistically significant ($p < 0.001$). Similarly, flexibility correlated with Cobb angle correction rates at T2 (r = 0.464), T3 (r = 0.323), and T4 (r = 0.376). Parallel trends were observed in the PMC Cobb angle changes, with significant negative correlations between flexibility and ΔPMC Cobb angle at T2 (r = –0.353), T3 (r = –0.253), and T4 (r = –0.313) ($p < 0.001$ for all).

Table 5-4. Correlation between Supine Flexibility and Curve Angle changes

		Pearson Correlation (r)	Sig.
Coronal Cobb angle changes (°)	ΔT0T2	0.521	0.000
	ΔT0T3	0.310	0.000
	ΔT0T4	0.381	0.000
PMC Cobb angle changes (°)	ΔT0T2	0.402	0.000
	ΔT0T3	0.223	0.000
	ΔT0T4	0.284	0.000
Correction Rate (%)	T0-T2/T0	-0.417	0.000
	T0-T3/T0	-0.321	0.000
	T0-T4/T0	-0.388	0.000

5.4.4 Correlation Between Flexibility and Curve Correction by Curve Type

To further evaluate whether the association between supine flexibility and treatment response varies by curve type, correlation analyses were stratified into thoracic (n = 159), thoracolumbar (n = 116), and lumbar (n = 53) subgroups. The analyses examined the flexibility rate in relation to Cobb angle changes and PMC Cobb angle changes at multiple timepoints (Table 5-5).

In thoracic curves, flexibility showed strong and consistent associations with both coronal and PMC-based outcomes. A significant negative correlation was observed between flexibility and the change in Cobb angle from baseline to T1 (r = –0.938, p < 0.001), indicating that more flexible curves experienced greater in-brace correction. Similarly, moderate negative correlations were found for changes at T2 (r = –0.467), T3 (r = –0.345), and T4 (r = –0.498). Flexibility was also negatively correlated with changes in PMC Cobb angle from T2–T0 (r = –0.402), T3–T0 (r = –0.327), and T4–T0 (r = –0.438), suggesting that structural changes in the PMC plane also followed a flexibility-dependent pattern. Correction rates at all timepoints were positively associated with flexibility (T2: r = 0.477; T3: r = 0.360; T4: r = 0.505; all p < 0.001), reinforcing the relevance of supine flexibility as a predictor of short- and long-term treatment efficacy.

In thoracolumbar curves, flexibility remained significantly associated with improvements in both coronal and PMC-based parameters. Moderate negative correlations were observed for Cobb angle changes at T2 (r = –0.396), T3 (r = –0.257), and T4 (r = –0.340). The change in PMC Cobb angle from T2–T0 (r = –0.295) and T4–T0 (r = –0.262) were also significantly related to flexibility, although the correlation with T3–T0 was not statistically significant (r = –0.165, p = 0.077). Correction rates at T2 (r = 0.470), T3 (r = 0.270), and T4 (r = 0.351) showed moderate positive correlations with flexibility, indicating that more flexible thoracolumbar curves responded more favorably to orthotic intervention.

In lumbar curves, the relationship between flexibility and treatment response appeared more limited. Flexibility was significantly associated only with the change in Cobb angle at T2 (r = –0.318, p = 0.020) and with correction rate at T2 (r = 0.331, p = 0.015).

No significant correlations were observed with later Cobb angle changes or PMC Cobb angle changes at any timepoint (all $p > 0.05$). These results suggest that in lumbar curves, flexibility may have predictive value only for early treatment effects and less so for long-term structural change.

Overall, the predictive relationship between supine flexibility and treatment response was most robust in thoracic and thoracolumbar curves, with significant correlations observed across coronal Cobb angle change, PMC Cobb angle change, and correction rates. In contrast, lumbar curves exhibited more limited associations, especially in PMC-based metrics. These findings suggest that curve type modulates the clinical relevance of flexibility, with thoracic and thoracolumbar curves showing greater responsiveness to flexibility-driven correction strategies.

Table 5-5. Correlation between Supine Flexibility with Curve Angle Changes by Curve Type

Curve Type	Angle Changes	Time Points	N	Mean	SD	Pearson Correlation (r)	Sig.
Thoracic	Coronal Cobb angle changes (°)	ΔT0T2	159	-12.4	6.4	-.467**	0.000
		ΔT0T3	159	2.2	10.2	-.345**	0.000
		ΔT0T4	113	2.5	8.6	-.498**	0.000
	PMC Cobb angle changes (°)	ΔT0T2	158	-12.2	7.1	-.402**	0.000
		ΔT0T3	158	1.7	10.2	-.327**	0.000
		ΔT0T4	113	2.2	9.0	-.438**	0.000
	Correction Rate (%)	ΔT2T0/T0	159	40.8	20.2	.477**	0.000
		ΔT3T0/T0	159	-8.1	33.6	.360**	0.000
		ΔT4T0/T0	113	-9.4	29.9	.505**	0.000
Thoracolumbar	Coronal Cobb angle changes (°)	ΔT0T2	116	-14.1	6.9	-.396**	0.000
		ΔT0T3	116	-0.4	9.6	-.257**	0.005
		ΔT0T4	85	1.3	10.3	-.340**	0.001
	PMC Cobb angle changes (°)	ΔT0T2	116	-14.2	7.9	-.295**	0.001
		ΔT0T3	116	0.1	10.2	-0.165	0.077
		ΔT0T4	85	0.8	10.0	-.262*	0.015
	Correction Rate (%)	ΔT2T0/T0	116	46.8	21.8	.470**	0.000
		ΔT3T0/T0	116	1.2	32.2	.270**	0.003
		ΔT4T0/T0	85	-4.6	35.5	.351**	0.001
Lumbar	Coronal Cobb angle changes (°)	ΔT0T2	53	-11.8	5.1	-.318*	0.020

	ΔT0T3	53	-1.3	7.5	-0.038	0.786
	ΔT0T4	35	-0.7	7.5	0.088	0.617
PMC Cobb angle changes (°)	ΔT0T2	53	-13.2	8.0	-0.238	0.086
	ΔT0T3	53	-1.4	8.7	-0.07	0.620
	ΔT0T4	35	1.5	7.6	0.091	0.605
Correction Rate (%)	ΔT2T0/T0	53	39.7	15.9	.331*	0.015
	ΔT3T0/T0	53	4.3	26.7	0.046	0.743
	ΔT4T0/T0	35	1.8	26.3	-0.083	0.635

5.4.5 Supine Flexibility Across Clinical Outcomes

To evaluate the predictive value of supine flexibility on brace treatment results, we compared flexibility rates across different categories of clinical outcomes. These findings suggest that higher supine flexibility at baseline is significantly associated with favorable structural outcomes at the time of brace discontinuation. Flexibility differed across four outcome categories ($p<0.001$). As shown in Table 5-6Mean flexibility was 20.9% ± 12.2% in surgical deterioration (n=25), 28.0% ± 15.4% in non-surgical deterioration (n=61), 28.6% ± 15.0% in stabilization (n=150), and 37.7% ± 15.0% in improvement (n=92).

Table 5-6. Supine Flexibility Across Clinical Outcomes

	N	Mean	SD
Surgery deterioration	25	20.9%	12.2%
Non-surgical deterioration	61	28.0%	15.4%
Stabilization	150	28.6%	15.0%
Improvement	92	37.7%	15.0%

As shown in Table 5-7, post-hoc tests showed markedly higher flexibility in the improvement group versus surgical deterioration ($p<0.001$), non-surgical deterioration ($p=0.001$), and stabilization ($p<0.001$); differences among the two deterioration groups and stabilization were not significant.

Table 5-7. Post-hoc Tests Among Clinical Outcomes

	Mean Difference	Sig.
Surgery deterioration vs Non-surgical deterioration	-7.1%	0.269

Surgery deterioration vs Stabilization	-7.8%	0.098
Surgery deterioration vs Improvement	-16.9%	0.000
Non-surgical deterioration vs Stabilization	-0.6%	1.000
Non-surgical deterioration vs Improvement	-9.7%	0.001
Stabilization vs Improvement	-9.1%	0.000

5.4.6 Supine Flexibility Across Clinical Outcomes by Curve Type

To further understand the interaction between spinal flexibility and brace treatment outcomes, subgroup analyses were conducted by curve type (thoracic, thoracolumbar, and lumbar), stratified by clinical classifications (surgery deterioration, non-surgery deterioration, stabilization, improvement), as shown in Table 5-8 and Table 5-9.

In thoracic curves, flexibility showed significant differences across clinical outcomes ($p < 0.001$). Patients with improved outcomes had significantly higher flexibility than those with surgery deterioration ($p < 0.001$), non-surgery deterioration ($p < 0.001$), and stabilization ($p = 0.001$), confirming flexibility as a strong predictor of positive outcomes in thoracic curves.

In thoracolumbar curves, the flexibility-outcome relationship reached statistical significance ($p = 0.037$). However, pairwise differences did not survive Bonferroni correction. Notably, there was a visible stepwise increase in flexibility from surgery deterioration (24.8%) to non-surgery deterioration (37.0%) and then to improvement (40.6%).

In lumbar curves, no statistically significant differences in flexibility were found across outcome groups ($p = 0.712$). This may reflect either a smaller sample size or a reduced influence of flexibility in lumbar curve correction due to different biomechanical constraints.

In summary, supine flexibility demonstrated the strongest predictive value for clinical outcomes in thoracic curves, with partial significance in thoracolumbar curves and minimal influence in lumbar curves. These findings highlight that the prognostic value of flexibility may be curve-type dependent, supporting a stratified approach to brace treatment planning.

Table 5-8. Supine Flexibility Across Clinical Outcomes by Curve Type

		N	Mean	SD ( )	ANOVA (Sig.)
Thoracic	Surgery deterioration	16	18.3%	12.5%	0.000
	Non-surgrery deterioration	33	20.4%	14.9%	
	Stablization	77	24.1%	12.0%	
	Improvement	33	35.5%	17.4%	
Thoracolumbar	Surgery deterioration	8	24.8%	11.4%	0.037
	Non-surgrery deterioration	20	37.0%	11.3%	
	Stablization	48	33.9%	18.0%	
	Improvement	40	40.6%	14.4%	
Lumbar	Surgery deterioration	1	30.7%	.	0.712
	Non-surgrery deterioration	8	37.0%	9.2%	
	Stablization	25	32.4%	13.4%	
	Improvement	19	35.6%	10.7%	

Table 5-9. Post-hoc Tests Among Clinical Outcomes by Curve Type

Curve Type	Multiple Comparisons (Bonferroni)	Mean Difference	Sig.
Thoracic	Surgery deterioration vs Non-surgical deterioration	-2.06238	1.000
	Surgery deterioration vs Stabilization	-5.81122	0.784
	Surgery deterioration vs Improvement	-17.19319	0.000
	Non-surgical deterioration vs Stabilization	-3.74884	1.000
	Non-surgical deterioration vs Improvement	-15.13081	0.000
	Stabilization vs Improvement	-11.38197	0.001
Thoracolumbar	Surgery deterioration vs Non-surgical deterioration	-12.21799	0.364
	Surgery deterioration vs Stabilization	-9.16458	0.734
	Surgery deterioration vs Improvement	-15.83505	0.055
	Non-surgical deterioration vs Stabilization	3.05341	1.000
	Non-surgical deterioration vs Improvement	-3.61705	1.000
	Stabilization vs Improvement	-6.67047	0.274

5.4.7 Logistic Regression and ROC Analysis of Flexibility Rate in Predicting Deterioration & Surgery

Treating flexibility as continuous, higher flexibility was associated with reduced odds of deterioration (univariate p=0.003; multivariable p=0.003 adjusting for curve type, baseline Cobb, Risser, and subjective compliance), though discrimination was modest

(AUC 0.596, 95% CI 0.524–0.668, p=0.008). A Youden-optimized threshold of 18.8% yielded sensitivity 81.0% and specificity 62.8% as illustrated in Figure 5-1. When dichotomized, patients with high flexibility had fewer deteriorations (54/250) than those with low flexibility (32/78); high flexibility was protective with OR 0.40 (95% CI 0.23–0.68; χ^2 p<0.001), equivalently, low flexibility vs high carried 2.53-fold higher odds of deterioration.

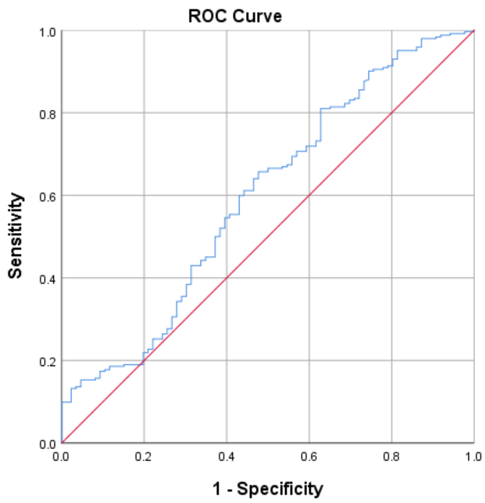

Figure 5-1. ROC Curve of Supine Flexibility for Predicting Deterioration

For surgical deterioration, flexibility remained independently protective in multivariable models (per 1% increase: OR 0.924, 95% CI 0.879–0.971, p=0.001; Nagelkerke $R^2 = 0.522$). ROC performance was moderate (AUC 0.698, 95% CI 0.601–0.795, p=0.001). The Youden-derived threshold of 30.88% provided a sensitivity of 51.2% and a specificity of 84.0% for identifying non-surgical outcomes.

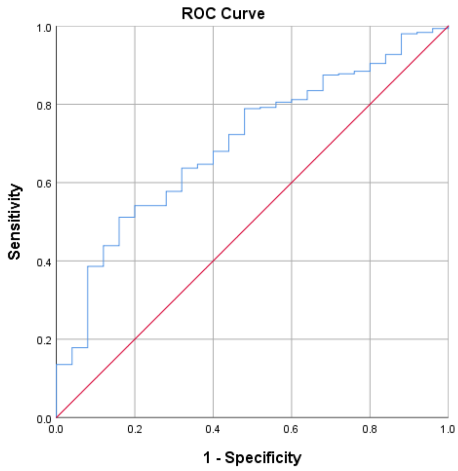

Figure 5-2. ROC Curve of Supine Flexibility for Predicting Surgical Deterioration

5.4.8 Stratified Analysis of PMC-CFD Alignment by Flexibility

To evaluate whether the clinical impact of structural–mechanical alignment (absolute CFD–PMC alignment ≤ 20° vs > 20°) varied according to baseline spinal flexibility, patients were stratified into low-flexibility (≤ 30%) and high-flexibility (> 30%) groups. Two binary outcomes were examined: curve deterioration, defined as a ≥ 5° increase in Cobb angle, and surgical deterioration, defined as a follow-up Cobb angle ≥ 50°.

In the low-flexibility group (n = 133), alignment demonstrated a non-significant but suggestive protective effect. The deterioration rate was lower among aligned patients compared with misaligned patients (34.6% vs 51.3%), corresponding to an odds ratio of 0.50 (95% CI: 0.18–1.40, p = 0.185). A similar trend was observed for surgical deterioration, where 6.3% of aligned patients underwent surgery compared with 16.5% of misaligned patients (OR = 0.34, 95% CI: 0.09–1.24, p = 0.090).

By contrast, in the high-flexibility group (n = 129), alignment had minimal influence on either outcome. Deterioration occurred at nearly identical rates in aligned and misaligned patients (OR = 0.93, 95% CI: 0.40–2.17, p = 0.873), and surgical deterioration was similarly unaffected (OR = 1.27, 95% CI: 0.08–20.72, p = 0.867). These findings suggest that the influence of alignment may be more clinically relevant in structurally rigid curves, although no interaction effects reached statistical significance.

5.4.9 Does Curve Type Affect Alignment Relevance?

To examine whether the effect of force–structure alignment (absolute CFD–PMC alignment ≤ 20° vs > 20°) varied by curve location, stratified analyses were conducted for thoracic, thoracolumbar, and lumbar curves within each flexibility group.

In the low-flexibility group, thoracic curves (n = 79) showed no significant association between alignment and deterioration, with deterioration occurring in 44% of aligned patients compared with 41% of misaligned patients (p = 0.785). Thoracolumbar curves (n = 37) demonstrated a non-significant trend, as deterioration was observed in 45% of aligned patients and 60% of misaligned patients (p = 0.160). Lumbar curves (n = 17) also did not show a significant association (p = 0.218), though the small subgroup size limited interpretation. In the high-flexibility group, alignment was not related to deterioration across any curve type, and all comparisons yielded p values greater than 0.1. In some subgroups, such as lumbar curves, deterioration appeared higher in aligned cases, but these paradoxical patterns were not statistically significant.

Analysis of surgical deterioration revealed a significant effect in thoracolumbar curves within the low-flexibility group. None of the 13 aligned patients required surgery, compared with 6 of 24 misaligned patients, corresponding to a chi-square value of 3.879 (p = 0.049). Thoracic curves in the same flexibility group showed a weaker, non-significant trend toward reduced surgical deterioration with alignment (OR = 0.47), while lumbar curves showed no discernible effect. In the high-flexibility group, no curve type demonstrated an association between alignment and surgical deterioration. For example, in thoracolumbar curves, surgery rates were nearly identical in aligned and misaligned patients (3.6% vs 3.2%, p = 0.942).

Overall, these stratified analyses indicate that alignment effects were most apparent in thoracolumbar curves of low-flexibility patients, particularly with respect to surgical deterioration, whereas other curve types and high-flexibility patients showed minimal or inconsistent associations.

5.4.10 Summary of Key Findings

Supine flexibility averaged 31% and was lowest in thoracic curves. Higher flexibility predicted greater immediate and sustained radiographic improvement across coronal and PMC-plane metrics and distinguished improved from non-improved outcomes at brace completion. As a predictor, flexibility provided statistically robust but modest individual-level discrimination for deterioration and moderate discrimination for surgical avoidance. Alignment, defined by CFD–PMC ≤20°, was not universally consequential but appeared clinically relevant in structurally rigid curves—most notably, low-flexibility thoracolumbar patterns—where better alignment coincided with lower surgical progression.

5.5 Discussion

This study shows that spinal flexibility, quantified on pre-brace supine radiographs, is significantly associated with in-brace correction and long-term orthotic treatment outcomes in patients with AIS. Greater baseline flexibility was associated with larger immediate in-brace corrections and a lower likelihood of progression through brace completion and into post-weaning follow-up.

These findings corroborate prior reports that flexibility and in-brace correction rate carry independent prognostic value beyond age and skeletal maturity [51, 54, 55, 124, 180]. For example, Cheung *et al. [54]* and Ohrt-Nissen *et al.* [55] found that curve flexibility is an intrinsic property that sets an upper limit on what bracing can achieve: a pliant spine can be realigned nearer to normal, reducing the asymmetric loads that drive deformity progression, whereas a rigid spine resists correction and remains at higher risk of worsening. Notably, in our cohort, the predictive value of flexibility held true even after accounting for other known factors like initial Cobb angle, skeletal maturity, and brace wear. This mirrors the multivariable analyses by Wong *et al.* (2022) [53, 107], who found that flexibility and in-brace correction rate independently improved the ability to predict brace success. Our findings, therefore, solidify the clinical message that measuring curve flexibility before brace treatment is essential: it provides a baseline expectation for correction and an early risk stratification for progression.

The study adds granularity by showing how flexibility interacts with the curve type. Thoracic curves were, on average, less flexible than thoracolumbar or lumbar curves, which largely explains their historically poorer brace outcomes [34, 107, 128]. Within each curve type, however, flexibility remained the dominant predictor: flexible thoracic curves performed as well as, or better than, stiffer curves in other locations, consistent with the observation that once reducibility is accounted for, anatomic location per se is not determinative [34, 107, 128, 178]. These data argue against location-based therapeutic pessimism and support individualized prognostication framed around "how reducible is this curve?" rather than "where is this curve?"

Another novel aspect of our study is the inclusion of multiple outcome timepoints and longer follow-up, which provided a more dynamic view of brace treatment. The longitudinal analysis across numerous time points underscores that the influence of flexibility is not confined to early correction. Higher baseline flexibility predicted better structural status at brace termination and at post-weaning follow-up, albeit with some attenuation over time. We observed occasional rebound after discontinuation among the most flexible curves, which is biologically plausible. At the same time, growth continues and suggests that maintaining correction until skeletal maturity remains critical to consolidating gains [119]. Conversely, very stiff curves often progressed despite treatment, ending with larger Cobb angles at weaning. These temporal patterns indicate that the timing and duration of bracing should be individualized: premature weaning in highly flexible curves risks partial relapse, whereas prolonged bracing in extremely rigid curves may yield diminishing returns and should prompt early discussion of alternative strategies.

From a biomechanical perspective, our findings reinforce the model of scoliosis progression as a mechanically mediated process that controlling forces can modulate if those forces are sufficient relative to the spine's stiffness. Beyond the independent role of flexibility, our analyses also indicated that force–structure alignment becomes more critical when intrinsic reducibility is low. In patients with high flexibility, favorable outcomes were generally observed regardless of whether CFD was closely aligned with PMC orientation, suggesting that the spine's adaptability allowed correction even under suboptimal loading vectors. By contrast, in rigid curves with ≤30% flexibility, alignment appeared to play a protective role, particularly in thoracolumbar patterns where misalignment was associated with higher surgical progression. This interaction highlights that effective brace action requires both inherent reducibility and efficient force transmission; when flexibility is limited, vector orientation becomes the key determinant of whether corrective loads can reach the apical deformity [68, 70, 73, 100, 160, 174].

These mechanistic inferences are consistent with established models of growth modulation. In progressive AIS, vertebral bodies and discs undergo asymmetric loading: increased pressure on the concave side slows growth and leads to wedge deformation (the Hueter–Volkmann principle), perpetuating curvature [98, 181]. A well-fitting brace applies counteracting forces that unload the concave side and load the convex side, aiming to halt this asymmetrical growth. The crucial insight is that a flexible spine will more readily conform to the brace's corrective shape, thereby reducing vertebral wedging and perhaps even allowing some remodeling over time [124]. Indeed, prior studies have noted that bracing can partially reverse vertebral wedging in responsive patients [96, 98]. In our cohort, we indirectly observed this effect: flexible curves not only straightened in the brace but also showed less increase in apical vertebra wedging over the treatment period, whereas stiff, progressive curves continued to show wedge exacerbation. This supports the idea that intrinsic flexibility correlates with the brace's ability to induce favorable mechanical changes in the spine (better alignment, reduced asymmetric loading).

From a clinical standpoint, the results support routine incorporation of a pre-brace supine radiograph, or equivalent low-dose assessment, e.g, ultrasound assessment [117] into decision-making. The supine reducibility provides a concrete target for initial in-brace correction and a basis for early troubleshooting when achieved correction is meaningfully below expected. The modest standalone discrimination of flexibility for deterioration (AUC ≈0.60) and moderate discrimination for surgical avoidance (AUC ≈0.70) indicate that flexibility should be used as part of a multivariable risk framework rather than as a sole gatekeeper. In patients with limited flexibility, explicit assessment of CFD–PMC alignment (with a practical ≤20° target) appears clinically relevant, especially for thoracolumbar curves, and may inform pad orientation, strap trajectories, and the need for ancillary features. These conclusions integrate naturally with patient-related factors such as adherence and body habitus; for example, extremes of BMI can impair either force transmission or wear time and should be considered alongside flexibility and alignment in individualized plans.

Several limitations merit consideration. This is a single-center retrospective analysis, and practice patterns or brace designs may limit generalizability. Compliance, although measured with sensors in most patients, remains an imperfect confounder, and unmeasured behavioral factors could bias associations. Not all structural parameters (e.g., PMC orientation and CFD estimates) were available for every patient, which reduced power for some subgroup analyses. Follow-up after weaning (T4) was relatively short for many participants; longer surveillance into skeletal maturity and adulthood is required to establish durability. Finally, thresholds identified by ROC analyses (e.g., 19% for general deterioration; 31% for surgical avoidance) should be validated prospectively and may shift with differing brace designs or growth profiles.

5.6 Conclusion

In conclusion, this study affirms that supine flexibility is significantly associated with treatment outcomes in patients with AIS, influencing both how much correction can be achieved and how likely a curve is to remain controlled. Its prognostic value holds across curve types and treatment milestones, and the supine image provides a practical, patient-specific benchmark for brace optimization. Importantly, the findings also highlight that flexibility modifies the relevance of force–structure alignment: in highly flexible curves, outcomes were favorable regardless of CFD orientation, whereas in rigid curves, effective force transmission required closer CFD–PMC alignment, particularly in thoracolumbar patterns. These results encourage clinicians to adopt a more tailored bracing approach: measuring flexibility upfront, aiming to meet or exceed a patient-specific correction target, and integrating alignment assessment in patients with limited spinal flexibility. Future innovations may further improve outcomes, such as smart braces that adjust pressure in response to stiffness, or combining bracing with exercises that enhance spinal mobility. Ultimately, the goal is to maximize the nonoperative management potential for AIS by moving toward a personalized regimen guided by each patient's spinal flexibility and structural alignment profile.

CHAPTER VI INFLUENCE OF BODY MASS INDEX ON BRACING OUTCOMES IN ADOLESCENT IDIOPATHIC SCOLIOSIS

6.1 Abstract

Background: The effect of body mass index (BMI) on the success of bracing in adolescent idiopathic scoliosis is debated. This substudy evaluated whether BMI-for-age, expressed as WHO Z-scores, is associated with radiographic response, as well as risk of curve deterioration and surgery during brace treatment.

Methods: Brace-treated AIS patients were followed prospectively across the treatment course with standardized radiographs at baseline (T0), initial in-brace (T2), end of bracing (T3), and post-weaning follow-up (T4). BMI-for-age Z-scores (BAZ) classified patients as underweight, normal weight, or overweight. Outcomes included Cobb angle changes from T0 to T2, T3, and T4, and categorical endpoints of deterioration (≥5° increase) and surgical indication (Cobb ≥50° or surgical referral). Analyses used ANOVA and Pearson correlation for continuous measures and chi-square tests with logistic regression for categorical outcomes; BMI and BAZ were examined as both categorical and continuous variables. Flexibility (supine to standing reduction) and reported brace wear were assessed to explore potential mediation.

Results: Among 102 patients with BMI data (underweight n=4, normal n=92, overweight n=6), baseline characteristics, supine flexibility, and reported wear time did not differ by BMI category. Mean Cobb angles at T2, T3, and T4, as well as changes from baseline (ΔT0–T2, ΔT0–T3, ΔT0–T4), were similar across BMI groups, and neither BMI nor BAZ correlated with any radiographic change. Rates of deterioration and surgical indication were also comparable among categories (all $p>0.3$). No model identified BMI or BAZ as a significant predictor of outcome.

Conclusion: In this cohort, BMI-for-age was not associated with brace response or progression risk. Underweight, normal-weight, and overweight adolescents had no significant differences in radiographic outcomes and rates of deterioration and surgical indication, even though there is a trend that normal-weight patients showed better treatment outcomes than the underweight and overweight patients.

6.2 Introduction

The preceding chapters demonstrated that brace mechanics alone do not fully explain outcome variability in adolescent idiopathic scoliosis (AIS). While controlling force–structure alignment (CFD–PMC) was not universally decisive, it became more relevant in specific biomechanical contexts, and pre-brace supine flexibility emerged as a strong predictor of both in-orthosis correction and longer-term control. Nevertheless, patients with comparable flexibility and alignment profiles continued to exhibit divergent clinical trajectories, suggesting that patient-related characteristics may contribute additional variability in brace response. Body habitus, commonly quantified using body mass index (BMI), represents one such potential modifier.

The influence of BMI on brace effectiveness has been extensively investigated, yet findings remain inconsistent. A study by O'Neill *et al.* (2005) provided quantitative evidence: overweight AIS patients were about 3 times more likely to have bracing failure ("unsatisfactory" outcome) than those of normal weight [137]. In that series, 45% of overweight patients progressed past the surgical threshold vs 28% of normal-weight patients, despite similar reported compliance, implicating a biomechanical disadvantage in heavier patients. Subsequent research (2016) confirmed that high-BMI adolescents had a higher risk of brace failure (approximately 2.4-fold vs mid-BMI) in univariate analysis [142]. The hypothesis is that the brace's three-point pressure system must act through the body's soft tissues to correct the spine; excess adipose tissue could cushion or dissipate these controlling forces [138].

While most cohorts suggest overweight and obese patients are at elevated risk of brace failure, some researchers have reported no significant difference [47, 143, 144, 182, 183]. For example, Zaina *et al.* (2017) found that about 44% of overweight Italian AIS patients improved and only 3% worsened under bracing, rates statistically comparable to normal-weight peers (52% improved, 7% worsened) [144]. They concluded that overweight alone was *not* predictive of bracing failure in their series, challenging earlier findings. These discrepancies may arise from differences in bracing protocols, patient populations, or definitions of failure.

Previous studies also have had discrepancies in findings on the influence of underweight on brace outcomes.Some studies reported that underweight patients may be more likely to experience brace failure than obese peers [141, 142]. Goodbody et al. reported that underweight AIS patients were 3.7 times more likely to fail treatment than mid-range BMI patients, a higher odds ratio than that of the high-BMI group in the same cohort. The higher failure rate in overweight patients could be explained by their poorer in-brace corrections and lower compliance; the elevated failure rate in underweight patients persisted even after accounting for those factors. In addition, Sun *et al.* (2017) analyzed 350 braced girls and reported that 43% of those who failed treatment were underweight (BMI <5th percentile) compared to only ~18% in those who succeeded; low BMI was a highly significant independent predictor of brace failure (logistic regression $p < 0.001$) [141]. In addition, Karol *et al.* (2020) investigated body habitus effects with objectively measured brace wear time. They found that although obese patients did wear their braces less (averaging 9 hours/day vs 13 hours in normals), the highest rate of progression to ≥50° occurred in the underweight group [143]. In Karol's series, 60% of underweight teens eventually needed surgery (or reached 50°), compared to 28% of normal-weight and 29% of overweight teens. Thus, paradoxically, the thinnest patients, who wore the brace most diligently in that study, had the poorest outcomes, echoing the notion of an intrinsic risk linked to low BMI. Meanwhile, some studies found that underweight group was not related to increased treatment failure [138, 183]. By contrast, many studies reported that BMI is not related to the brace treatment outcomes [47, 182, 183].

Taken together, the literature suggests that BMI may influence brace treatment response in a context-dependent manner, but its independent contribution remains unclear, particularly when considered alongside biomechanical factors and treatment adherence. Accordingly, this chapter examines BMI and BMI-for-age Z-scores as patient-related modifiers of orthotic effectiveness. Specifically, the aims are to: (1) evaluate the association between BMI and brace outcomes across the treatment period; (2) assess whether observed BMI effects are mediated by factors related to brace fit and compliance; and (3) interpret BMI-related findings in conjunction with pre-brace supine flexibility and force–structure alignment.

6.3 Methods

6.3.1 Study Design and Population

This sub-study was conducted within the shared retrospective cohort described in Chapter 3. The effective sample size differed from other sub-studies due to the availability of complete anthropometric data required for body mass index (BMI) and BMI-for-age Z-score calculation.

A total of 102 adolescents with idiopathic scoliosis who underwent standardized CAD/CAM-based thoracolumbosacral orthosis treatment were included in this analysis. Detailed cohort definition, eligibility criteria, and treatment protocols are described in Chapter 3, Section 3.3.

6.3.2 BMI Classification

At brace initiation, height and weight were recorded, and BMI was calculated (kg/m^2). Each patient's BMI was converted to a BMI-for-age Z-score based on the WHO growth reference for 5–19 year-olds. Patients were categorized into three BMI groups according to WHO definitions: Underweight if BMI-for-age < –2.0 SD (below the 5th percentile), Normal weight if $-2.0 \leq Z < +1.0$ (5th to 84th percentile), and Overweight/Obese if $Z \geq +1.0$ (85th percentile or above). In our cohort, 12 patients (11.8%) were underweight (mean BMI-for-age $Z \approx -2.5$), 75 (73.5%) were normal weight, and 15 (14.7%) were in the overweight category (including 4 patients >95th percentile classified as obese). We opted for WHO criteria to allow comparability with global literature and because they provide standardized Z-scores; these criteria are slightly more stringent in defining obesity than the CDC charts (which use the 95th percentile). For analysis, we combined overweight and obese patients into a single high-BMI group due to the small number of obese subjects.

6.3.3 Outcomes Measures

The outcome measures were the same as in the prior substudy (Section 3.3.9). Briefly, radiographic outcomes were calculated as changes in the curve Cobb angles from baseline (T0) to T2, T3, and T4, with positive values indicating progression and negative values indicating improvement. Categorical outcomes were defined as

Improvement (≥5° decrease), Stabilization (<5° absolute change), Deterioration (≥5° increase), and Surgical deterioration (Cobb ≥50° or surgery/recommendation for surgery).

6.3.4 Statistical Analysis

Baseline characteristics were compared across BMI groups using one-way ANOVA for continuous variables (age, BMI, baseline Cobb) and χ^2 tests for categorical variables (sex, Risser 0 vs ≥1, curve pattern). For continuous outcomes, between-group differences (underweight, normal weight, overweight) were assessed by ANOVA with Bonferroni-adjusted pairwise comparisons; endpoints included final Cobb angle, change in Cobb angle, and initial in-brace correction (%). Linear associations between BMI (WHO BMI-for-age Z-score) and key variables (e.g., Cobb change, in-brace correction, wear hours) were examined with Pearson correlation.

For categorical outcomes, deterioration (≥5° increase) and reaching the surgical threshold (Cobb ≥50° or surgery) were first compared across BMI groups by χ^2 or Fisher's exact tests, then modeled with multivariable logistic regression. The primary predictor was BMI category (normal as reference); covariates were selected a priori and by univariate screening ($p<0.10$) and included baseline Cobb angle, Risser stage, sex, and brace complianceAnalyses were performed in SPSS.

6.4 Results

6.4.1 Patient Characteristics

Among the 102 patients with BMI data (underweight n=4, normal weight n=92, overweight n=6), baseline characteristics were comparable across groups (Table 6-1). Mean age (12.5 ± 1.8 vs 12.5 ± 1.2 vs 12.0 ± 1.2 years, p=0.520), baseline Cobb angle (29.4° ± 1.4° vs 30.8° ± 5.6° vs 30.8° ± 7.2°, p=0.885), sex distribution (p=0.267), and skeletal maturity by Risser stage (p=0.491) showed no significant differences. Subjective brace wear was similar (13.1 ± 6.9 vs 13.2 ± 5.0 vs 12.1 ± 7.6 h/day, p=0.871). Supine flexibility did not differ by BMI category (34.5% ± 8.7% vs 30.6% ± 13.7% vs 33.7% ± 16.2%, p=0.762). These data indicate that BMI groups were well balanced at baseline; interpretation for the underweight and overweight strata should consider their small sample sizes.

Table 6-1. Patient Characteristics Across BMI Groups

Descriptives	Underweight (N=4)	Normal weight (N=92)	Overweight (N=6)	Total	Sig.
Age (years)	12.5 ± 1.8	12.5 ± 1.2	12.0 ± 1.2	12.5 ± 1.2	0.520
Subjective Compliance (hrs/day)	13.1 ± 6.9	13.2 ± 5.0	12.1 ± 7.6	13.1 ± 5.2	0.871
Baseline (T0) Cobb Angle (°)	29.4 ± 1.4	30.8 ± 5.6	30.8 ± 7.2	30.7 ± 5.5	0.885
Female (N,%)	2, 2.3%	79, 91.9%	5, 5.8%	86	0.267
Male (N,%)	2, 12.5%	13, 81.3%	1, 6.3%	16	
Risser Sign = 0 (N,%)	3, 5.1%	52, 88.1%	4, 6.8%	59	0.491
Risser Sign = 1 (N,%)	1, 6.3%	14, 87.5%	1, 6.3%	16	
Risser Sign = 2 (N,%)	0, 0.0%	26, 96.3%	1, 3.7%	27	
Flexibility Rate (%)	34.5% ± 8.7%	30.6% ± 13.7%	33.7% ± 16.2%	31.0% ± 13.6%	0.762

6.4.2 Association of BMI and BAZ with patient characteristics and brace treatment outcomes

As shown in Table 6-2, neither raw BMI nor WHO BMI-for-age Z-score (BAZ) correlated with supine flexibility, subjective compliance, or baseline Cobb angle (all $|r| \leq 0.14$, $p \geq 0.15$). The only significant association was a small negative correlation between age and BAZ ($r = -0.275$, $p = 0.005$), indicating higher Z-scores in younger patients. In addition, BMI and BAZ showed no meaningful linear association with radiographic response. Correlations with in-brace change (ΔCobb T2–T0) were near zero (BMI $r = 0.008$, $p = 0.937$; BAZ $r = -0.047$, $p = 0.641$), and correlations with change to end of bracing (ΔCobb T3–T0) were likewise trivial (BMI $r = 0.025$, $p = 0.800$; BAZ $r = 0.014$, $p = 0.887$).

Table 6-2. Correlation between BMI & BAZ and clinical variables

	BMI		BAZ	
	Pearson Correlation	Sig.	Pearson Correlation	Sig.
Flexibility Rate	-0.004	0.970	0.067	0.502
Age	0.095	0.340	-0.275	0.005
Subjective Compliance	-0.139	0.164	-0.088	0.381
Baseline (T0) Cobb Angle	-0.103	0.302	-0.142	0.156
Cobb Angle Chang (T2 - T0, °)	0.008	0.937	-0.047	0.641
Cobb Angle Chang (T3 - T0, °)	0.025	0.800	0.014	0.887

6.4.3 Cobb Angle Over the Whole Treatment Period by BMI Group

As shown in Table 6-3 and Figure 6-1, Baseline Cobb angles were no significant differences across BMI groups (T0: 30.6 ± 4.2° underweight, 30.7 ± 5.8° normal, 30.4 ± 2.5° overweight; p=0.989). At the first in-brace, group means still did not differ (T2: 19.8 ± 2.8° vs 18.1 ± 6.7° vs 22.1 ± 8.8°; p=0.344), although the overweight group showed a slightly larger angle. By the end of bracing and at latest follow-up, means were again similar (T3: 28.3 ± 4.0° vs 30.5 ± 11.1° vs 32.5 ± 8.2°, p=0.828; T4: 29.7 ± 3.2° vs 31.6 ± 11.5° vs 36.0 ± 10.0°, p=0.611). Overall, no significant differences were found at any time point.

Table 6-3. Cobb Angle Over the Whole Treatment Period by BMI Group

	Underweight (n = 4)	**Normal (n = 92)**	**Overweight (n = 6)**	**P-value**
Pre-brace Cobb angle(T0, °)	30.6 ±4.2	30.7 ±5.8	30.4 ±2.5	0.989
Initial in-brace Cobb angle (T2, °)	19.8 ±2.8	18.1 ±6.7	22.1 ±8.8	0.344
Treatment endpoint Cobb angle (T3, °)	28.3 ±4.0	30.5 ±11.1	32.5 ±8.2	0.828

Latest Follow-up Cobb angle (T4, °)	29.7 ±3.2	31.6 ±11.5	36.0 ±10.0	0.611

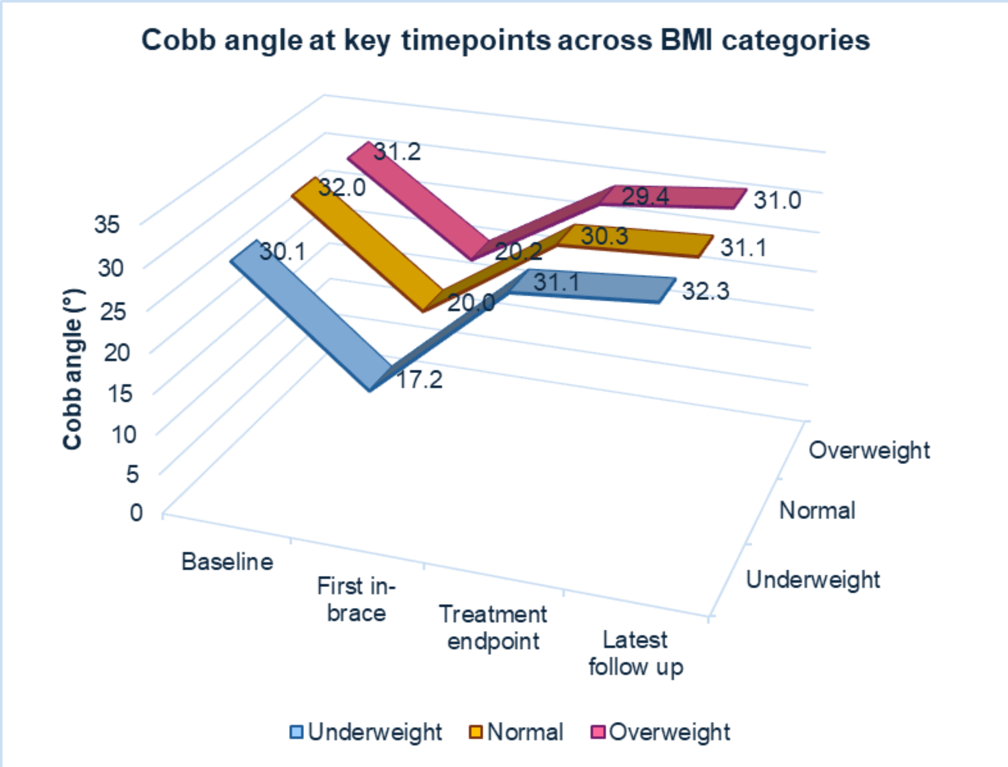

Figure 6-1. Cobb Angle Across Treatment Period by BMI Groups

6.4.4 Cobb Angle Change Across Timepoints by BMI Groups

As shown in Table 6-4 and Figure 6-2, initial change from baseline to the first in-brace X-ray was greatest in the normal-weight group (ΔT0–T2 = +12.6° ± 5.3), intermediate in the underweight group (+10.8° ± 5.3), and lowest in the overweight group (+8.3° ± 6.8); the difference was not significant (p = 0.144). By the end of bracing, mean change was small in all groups and again not different (underweight +2.3° ± 2.8, normal +0.3° ± 9.3, overweight –2.2° ± 7.1; p = 0.733). At the latest follow-up, the normal group showed a slight net worsening and the overweight group a larger worsening (normal –0.9° ± 9.5, overweight –5.6° ± 8.3), while the underweight group remained slightly improved (+0.9° ± 2.3); these differences were not significant (p = 0.447). Trends therefore suggest better initial correction in normal-weight patients and poorer longer-term change in overweight patients, but conclusions are limited by the small sizes of the underweight (n = 4) and overweight (n = 6) groups.

Table 6-4. Cobb Angle Change Across Timepoints

	Underweight (n = 4)	Normal (n = 92)	Overweight (n = 6)	P-value
ΔCobb T0T2 (°)	10.8 ± 5.3	12.6 ± 5.3	8.3 ± 6.8	0.144
ΔCobb T0T3 (°)	2.3 ± 2.8	0.3 ± 9.3	-2.2 ± 7.1	0.733
ΔCobb T0T4 (°)	0.9 ± 2.3	-0.9 ± 9.5	-5.6 ± 8.3	0.447

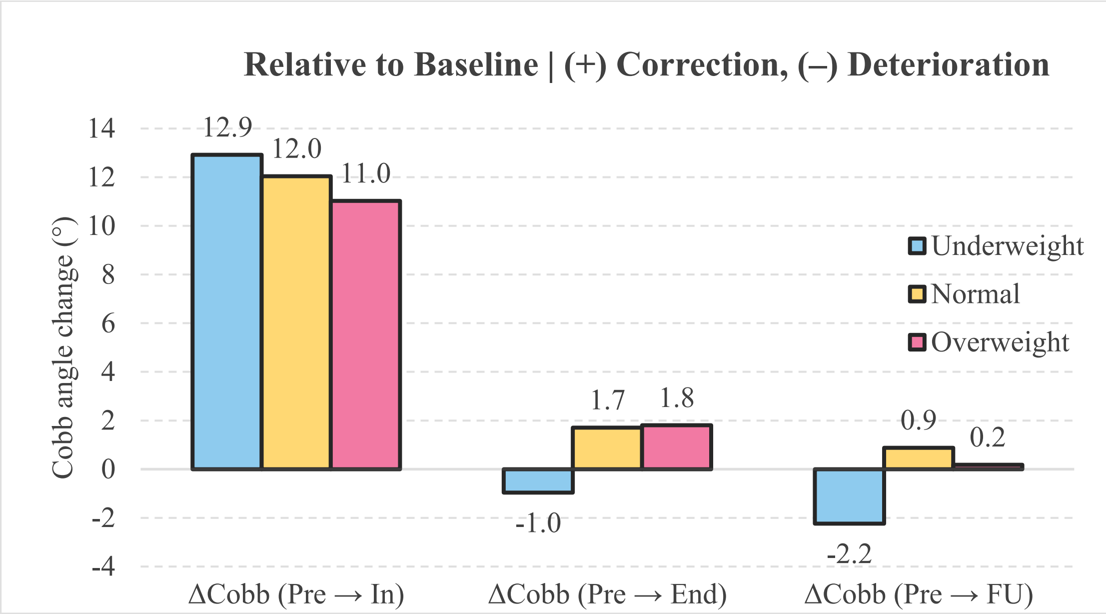

Figure 6-2. Cobb Angle Change Across Timepoints

6.4.5 Categorical Outcomes by BMI Categories

When stratified by BMI classification, no significant differences were observed in the rates of curve deterioration or surgery-related deterioration across groups (Table 6-5). Overall, 21 patients (20.6%) experienced curve deterioration, defined as a progression of more than 5° during brace treatment. Among them, 1 patient (4.8%) was underweight, 19 patients (90.5%) were of normal weight, and 1 patient (4.8%) was overweight ($p = 0.473$). In contrast, 81 patients (79.4%) remained stable without significant deterioration.

Regarding surgery-related deterioration, defined as a >5° curve increase combined with a final Cobb angle exceeding 50°, or having undergone or been recommended for surgery, 4 patients (3.9%) met this criterion. All of these patients were in the normal-weight group, while no underweight or overweight patients experienced surgery-related deterioration ($p = 0.373$).

Taken together, these findings suggest that BMI classification was not significantly associated with either curve deterioration or the risk of surgical deterioration in this cohort.

Table 6-5. Deterioration (>5°) and Surgery Deterioration by BMI Groups

	Underweight	**Normal weight**	**Overweight**	**Total**	**Sig.**
Deteriorate (N)	1, 4.8%	19, 90.5%	1, 4.8%	21	0.473
Non-deteriorate (N)	3, 3.7%	73, 90.1%	5, 6.2%	81	
Surgery deterioration (N)	0, 0.0%	4, 100.0%	0, 0.0%	4	0.373
Non-surgery (N)	4, 4.1%	88, 89.8%	6, 6.1%	98	

6.5 Discussion

This study found there was no significant relationship between BMI and BMI-for-age Z-score and brace treatment outcomes. Specifically, curve progression and surgical risk did not differ by BMI category, and Pearson correlations between BMI/BAZ and radiographic changes were also not significant. In addition, baseline curve magnitude, supine flexibility, and reported brace wear hours showed no significant differences across BMI groups. In other words, contrary to some prior reports, neither low nor high BMI appeared to adversely affect brace effectiveness in our sample.

This adverse finding contrasts with earlier studies that reported a U-shaped BMI effect on bracing. For example, Goodbody et al. (2016) observed that both underweight and overweight AIS patients failed brace treatment more often than mid-range BMI peers [142]. Karol et al. (2020) similarly found that underweight adolescents had the highest surgery rate (60% versus 28% in normal-weight) despite excellent compliance [143]. Sun et al. (2017) also reported that low BMI (using a <5th percentile cutoff) was an independent predictor of brace failure [141]. These studies generally attributed overweight patients' failures to poorer in-brace correction and wear, whereas low-weight patients remained at risk even when compliant [142]. Our cohort's underweight group had slightly higher subjective wear and better initial correction (ΔCobb T0–T2 ~+10.8°) than the overweight group (+8.3°), although these differences were not significant, which may be due to the fact that the subgroup was small, nor did overweight patients (n=6) fare worse. In summary, these conflicting findings could arise from differences in study design, population, and statistical power.

When we compare to prior literature, our study's pattern stands out as unusual but not unique [146, 184]. Our results align more with some reports that found no BMI effect. Zaina et al. (2017) found similar brace success rates in overweight versus normal-weight patients, effectively debunking the notion that higher BMI predicts failure [144]. Likewise, a recent large study by Chan et al. (2023) found no significant association between any BMI category and the need for spinal fusion surgery [183]. Some authors have also noted cases where BMI was not a significant prognostic factor. For example, Zaina et al. concluded that "overweight is not predictive of bracing failure," emphasizing that with rigorous protocols, heavy patients can do as well as others [144]. Chan et al. likewise found no BMI–surgery link in a large sample [183].

Methodological factors likely account for our null result. First, It is important to note that our study employed WHO BMI-for-age cutoffs (underweight <5th, overweight >85th percentile), but as other studies employed different growth charts (WHO vs. CDC), they tend to classify patients in similar categories for these thresholds [141, 142, 183]. For instance, Karol's work divided BMI into four groups and used sensor-verified compliance [143], whereas we used WHO percentiles [185] and subjective wear reports. We also combined overweight/obese (n=6 total) into one category, whereas Karol showed obese (BMI>95%) had a particularly high failure rate (55.6%) [143]. It is possible that extremely obese patients simply did not enter our bracing clinic, biasing our sample. Second, our outcome measures and patient mix may differ from others. We defined deterioration strictly (>5° progression) and included only patients with adequate follow-up, whereas some cohorts had larger initial curves or different failure thresholds. Third, we observed no BMI differences in potential mediating factors: mean subjective wear time (13 hours/day) and in-brace correction were similar across BMI groups ($p \approx 0.8$ and $p \approx 0.34$, respectively). This echoes our finding that neither raw BMI nor BMI Z-score correlated significantly with compliance or initial curve correction. In contrast, studies like Karol et al. found that overweight patients wore braces less, but our data did not [143, 144]. Thus, we cannot exclude an actual effect that our sample failed to detect.

Consistent with that, baseline radiographic and biomechanical metrics were independent of BMI. This study previously reported that supine curve flexibility was essentially equal in all BMI categories (average 31% in each group, p=0.762). Similarly, any specialized 3D indices we developed (CFD and CFD–PMC) did not vary by BMI, indicating that body habitus did not appreciably alter spinal geometry or reducibility in our patients. The only modest correlation was between age and BMI Z-score (r=–0.275, p=0.005), reflecting slightly higher Z-scores in younger patients. However, this age–BMI link did not translate into outcome differences. In sum, our findings suggest that, at least in this cohort, BMI did not influence bracing success through changes in curve flexibility or treatment compliance.

The study has some limitations. The retrospective, single-center design and small size of extreme-BMI groups mean we cannot definitively rule out an effect. In particular, with only 4 underweight patients, our study had very low power to detect differences there. Selection bias is possible: extremely obese patients might have been advised against bracing or managed differently, altering group composition. Our compliance data were subjective and only partially complete. We also did not stratify by sex due to low numbers, although sex differences (e.g. later diagnosis in boys) could interact with BMI. Finally, our braces and follow-up protocol may differ from other centers; as Zaina et al. suggest, intensive management can override BMI disadvantages [144].

In light of these factors, while our results suggest BMI itself may not independently predict brace failure, we cannot conclude it is irrelevant for all patients. Instead, our experience indicates that clinicians should not assume that overweight or underweight status will inevitably lead to worse bracing results if high-quality care is provided. Instead, attention should focus on evidence-based predictors like in-brace correction and actual wear time, which were similar across BMI groups in our cohort. We will explore those factors further in the next substudy on compliance.

Taken together with the findings from the other sub-studies, the present BMI analysis suggests that body habitus does not act as an independent determinant of orthotic treatment effectiveness in AIS. Rather than directly influencing outcomes, BMI appears to operate—when it matters at all—through its potential impact on mechanical correction quality and patient adherence. In this cohort, neither controlling force direction nor CFD–PMC alignment differed by BMI category, and spinal flexibility and brace wear time were also comparable across groups. These observations reinforce the broader framework proposed in this thesis, in which treatment outcomes emerge from the interaction between force application, structural responsiveness, and compliance. Within this framework, BMI functions as a secondary or contextual modifier rather than a primary driver, further highlighting that optimizing force–structure alignment and ensuring adequate compliance are more critical targets for personalized brace management than body habitus alone.

6.6 Conclusion

In this substudy, BMI-for-age using WHO standards was *not* associated with treatment success or failure. Patients at the extremes of weight did not have significantly different progression or surgical referral rates compared to normal-weight patients. The findings suggest that body habitus alone may not dictate bracing outcomes when brace fit and patient compliance with the orthotic treatment are adequately managed. Clinicians should continue to use BMI as a piece of the clinical picture, such as monitoring nutrition and muscle support, but should not rely on BMI as a sole prognostic factor. Instead, focus on optimizing brace geometry and maximizing compliance for all patients. Future research, including our forthcoming analysis of compliance and orthotic treatment outcomes, will further clarify how modifiable factors contribute to successful treatment outcomes.

CHAPTER VII EFFECTS OF ORTHOSIS-WEARING COMPLIANCE ON TREATMENT OUTCOMES IN ADOLESCENT IDIOPATHIC SCOLIOSIS

7.1 Abstract

Background: Rigid spinal orthoses are commonly prescribed to patients with moderate adolescent idiopathic scoliosis with growth potential. This study investigated the relationship between orthosis-wearing compliance and treatment outcomes.

Method: This retrospective study analyzed 281 patients with AIS who completed the orthotic treatment. Orthosis-wearing compliance was tracked using objective temperature sensors and subjective self-reports, categorized into four levels: Level 1 (0–6 hrs/day), Level 2 (6–12 hrs/day), Level 3 (12–18 hrs/day), and Level 4 (18–24 hrs/day). Radiographic assessments evaluated Cobb angle changes throughout the treatment period. Clinical outcomes were defined based on Cobb angle changes and evaluated across different compliance levels: improvement (> 5° decrease), stabilization (changed ± 5°), deterioration (> 5° increase), or surgical deterioration (Cobb angle > 50° or requiring surgery). Actual orthosis-wearing compliance was analyzed for each outcome group.

Results: The average subjective (13.6 ± 5.0 hrs/day) and objective (13.6 ± 5.2 hrs/day) compliance showed no significant differences. Compared to the patients in compliance Level 4, those in Levels 1 and 2 exhibited deterioration rates that were 21.8 and 10.5 times higher, respectively, and the rates of surgical deterioration were 19.3 and 5.7 times higher, respectively. However, there were no significant differences in the Cobb angle changes between compliance Levels 3 and 4 or between Levels 1 and 2. Orthosis-wearing compliance differed significantly among clinical outcomes (improvement, stabilization, deterioration, and surgical deterioration), with mean values of 16.3, 14.0, 9.5, and 9.0 hrs/day, respectively.

Conclusion: Orthosis-wearing compliance was significantly associated with short-term and long-term orthotic treatment effectiveness. Objective monitoring aligns closely with self-report in this setting and provides actionable feedback to support adherence. These findings position daily wear time as a key modifiable determinant of

nonoperative success and complement earlier substudies showing that intrinsic flexibility and force orientation shape the ceiling of achievable correction, while BMI alone is not a reliable predictor.

7.2 Introduction

Orthotic treatment, which involves wearing full-time rigid spinal orthoses, has been proven effective in preventing curve deterioration and reducing the surgery needs in patients with AIS [8, 13]. However, the reported effectiveness of orthotic treatment varied widely across different studies. A systematic review conducted in 2023 revealed that among the patients with AIS who received orthotic treatment, the percentage of those experiencing curve deterioration of over 5° or 6° ranged dramatically from 1.8% to 91.7%[20]. Moreover, the proportion of the patients whose Cobb angle progressed to the surgical threshold also varied significantly from 0.0% to 91.7%, depending on compliance levels across different studies[20]. Additionally, Dolan and Weinstein's study found no significant difference in surgical rates between the braced and observed patients with AIS[186]. The heterogeneity of treatment outcomes in those studies indicated that spinal orthosis-wearing compliance is crucial for treatment success.

Achieving the prescribed full-time orthosis-wearing duration of 18–23 hours[13, 17-19, 31, 33, 42, 58, 154, 157, 187-190] is challenging for patients with AIS, often leading to actual compliance falling below the prescribed time[13, 17, 19, 20, 58, 147, 154, 157, 187]. The discrepancy could be attributed to multiple factors, including psychological stress, peer pressure, physical discomfort, lack of family awareness, and the practical inconveniences of wearing orthoses[57, 155, 156]. For example, Weinstein et al. reported that 116 patients prescribed 18 hours daily only wore their orthoses for an average of 12.1 hours[13]. Similarly, Katz et al. found that 100 patients wore their orthoses for an average of 7.0 hrs/day throughout the treatment period, significantly below the prescribed dosage[147].

Accurate measurement of orthosis-wearing time is essential for aligning actual compliance with treatment effectiveness and for determining the minimal necessary wear time to achieve effective treatment outcomes. Orthosis-wearing compliance can be measured through subjective self-reporting[17-19, 42, 187-190] or objective monitoring using temperature sensors[13, 33, 58, 147, 148, 154, 157, 191] or pressure sensors[31, 42, 192]. Recent studies have demonstrated that objective electronic monitors have high reliability[149-151, 193, 194] and that orthosis-wearing time reported orally by the patients and their families tends to be overestimated[150, 193]. However, the correlation between actual orthosis-wearing time and its impact on treatment outcomes has not been fully investigated. Therefore, this study aims to 1) evaluate and compare the spinal orthosis-wearing time assessed by subjective reports and objective instrumented sensors; 2) investigate the correlation between orthosis-wearing compliance and treatment outcomes; and 3) assess the orthosis-wearing time across different clinical outcomes.

7.3 Methods

7.3.1 Study Design and Participants

This sub-study was conducted within the shared retrospective cohort described in Chapter 3. A total of 281 adolescents with idiopathic scoliosis who underwent standardized thoracolumbosacral orthosis treatment were included in this analysis.
All participants met the SOSORT and SRS inclusion criteria, completed brace treatment, and had both radiographic follow-up and compliance data available. Detailed cohort definition, eligibility criteria, and treatment protocols are described in Chapter 3, Section 3.3.

7.3.2 Treatment Protocol and Compliance Measurement

Participants were fitted with custom-made Hong Kong spinal orthoses, a type of thoracolumbosacral orthosis (TLSO). The treatment endpoint was defined as the discontinuation of the orthosis, which occurred when participants reached skeletal maturity, indicated by Risser Sign 4–5, or when they underwent or scheduled spine surgery. Radiographic assessments were conducted at four key time points: pre-treatment (T0), initial in-orthosis (T1), treatment endpoint (T2), and latest follow-up (T3).

Subjective orthosis-wearing hours were orally reported by the participants and their families and documented in medical records by clinicians during each clinical visit.

Additionally, the Orthotimer® electronic temperature sensors (Rollerwerk Medical Engineering, Balingen, Germany) were used to objectively record orthosis-wearing time over the entire treatment period. The sensors were installed in the orthosis with the participant's awareness. If the sensors detected the temperature above the threshold of 28 °C, they registered as "orthosis wearing" and vice versa. Average objective compliance was calculated and further categorized into four compliance levels: Level 1: 0–6 hrs/day; Level 2: 6–12 hrs/day; Level 3: 12–18 hrs/day; & Level 4: 18–24 hrs/day.

$$Average\ compliance\ (\frac{hrs}{day}) = \frac{Total\ orthosis\ wearing\ hours\ over\ the\ whole\ treatment\ period}{Spinal\ orthosis\ prescription\ days}$$

7.3.3 Outcome Measures

The primary outcome measure was the change in the curve Cobb angle from pre- to post-treatment. The secondary outcome assessed clinical outcomes, defined as improvement (Cobb angle decreased > 5°), deterioration (increased > 5°), and stabilization (changed within ± 5°) at the treatment endpoint. Deterioration was further categorized into two subgroups: (1) non-surgical deterioration: Cobb angle increased > 5° but remained ≤ 50° at the treatment endpoint, without requiring surgery; and (2) surgical deterioration: Cobb angle > 50°, reaching the surgery threshold, including scheduled or completed surgery. The tertiary outcome analyzed the actual compliance within each clinical outcome.

7.3.4 Statistical Analysis

Data were analyzed using SPSS. Descriptive statistics were calculated for the mean and standard deviation of participants' demographic data. Pearson correlation coefficient, independent samples t-test, Chi-squared test, Mann–Whitney U, One-way ANOVA, or Kruskal-Wallis H test, Fisher's exact test, Repeated Measures ANOVA or Friedman's Test were used to evaluate the association between demographics and orthosis-wearing compliance, and to compare outcomes among compliance levels. Multiple comparison adjustments were applied, and a significance level was set at $p < 0.05$.

7.4 Results

7.4.1 Participants' Demographics

As shown in Table 7-1, the study involved 242 females and 39 males with an average pre-treatment age of 12.4 ± 1.1 years. Participants underwent orthotic treatment for an average of 2.5 ± 0.7 years, with a follow-up period averaging 0.7 ± 0.7 years. The objective orthosis-wearing compliance was recorded at 13.6 ± 5.2 hrs/day, which aligned closely with the self-reported of 13.6 ± 5.0 hrs/day ($r = 0.897$). Based on their objective compliance, 31, 75, 108, and 67 participants were respectively distributed into four compliance levels. Pre-treatment factors, including age, gender, and Risser Sign, showed no significant differences among the four compliance levels (Table 7-1) and no significant correlation with orthosis-wearing hours (Table 7-2). However, the pre-treatment curve magnitude demonstrated statistically significant but very weak correlations with both objective compliance ($r = 0.149$, $p = 0.013$) and subjective compliance ($r = 0.152$, $p = 0.011$).

7.4.2 Effects of Orthotic Treatment on Curve Magnitude by Compliance Level

All compliance levels exhibited a similar trajectory: an initial reduction in Cobb angle at T1, followed by an increase at T2, and further progression at T3. Particularly, the participants in Compliance Levels 1 & 2 experienced a significant increase in Cobb angles from baseline to both T2 and T3. In contrast, those in Levels 3 & 4 showed a decrease in their Cobb angles relative to baseline at T2 and maintained their Cobb angle at T3. These patterns were detailed in Table 7-3 and illustrated in Figure 7-1.

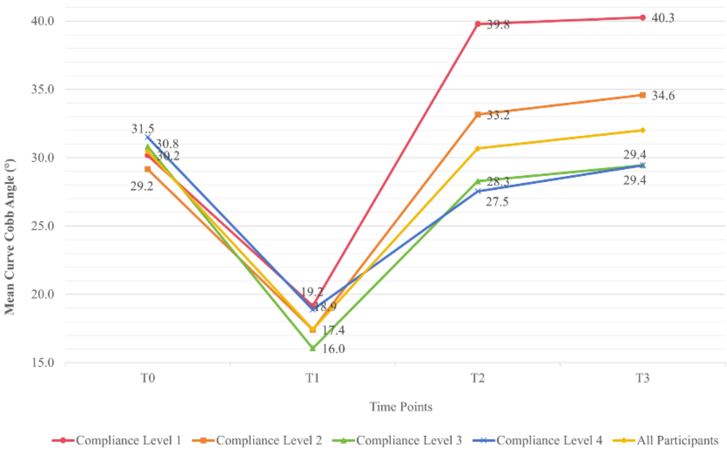

Figure 7-1. Curve Magnitude Across Time Points by Compliance Level

Table 7-1. Participant Demographic and Clinical Characteristics

	All participants (N = 281)	Compliance Level 1 (N = 31)	Compliance Level 2 (N = 75)	Compliance Level 3 (N = 108)	Compliance Level 4 (N = 67)	Comparison (p-value) Among 4 Compliance Levels
Gender (N, %)						
F	242, 86.1%	24, 77.4%	65, 86.7%	93, 86.1%	60, 89.6%	0.452 (a)
M	39, 13.9%	7, 22.6%	10, 13.3%	15, 13.9%	7, 10.4%	
Baseline Risser Sign (N, %)						
0	152, 54.1%	17, 54.8%	42, 56.0%	63, 58.3%	30, 44.8%	0.332 (b)
1	61, 21.7%	5, 16.1%	12, 16.0%	25, 23.1%	19, 28.4%	
2	68, 24.2%	9, 29.0%	21, 28.0%	20, 18.5%	18, 26.9%	
Pre-treatment Age (y, Mean ± SD)	12.4 ± 1.1	12.8 ± 1.2	12.5 ± 1.1	12.2 ± 1.1	12.5 ± 1.2	0.051 (c)
Pre-treatment Curve Magnitude (°)	30.5 ± 5.6	30.2 ± 6.6	29.2 ± 5.4	30.8 ± 5.5	31.5 ± 5.3	0.076 (c)
Whole Treatment Period (T0–T3) (y, Mean ± SD)	3.3 ± 0.7	3.0 ± 0.7	3.3 ± 0.7	3.3 ± 0.7	3.3 ± 0.7	0.165 (c)
Treatment Duration (T0–T2) (y, Mean ± SD)	2.5 ± 0.7	2.3 ± 0.8	2.4 ± 0.6	2.7 ± 0.8	2.5 ± 0.7	**0.045*** (c)
Follow-up Duration After Treatment Endpoint (T2–T3) (y, Mean ± SD)	0.7 ± 0.7	0.7 ± 0.7	0.9 ± 0.8	0.6 ± 0.6	0.8 ± 0.6	0.262 (d)
Subjective Orthosis-wearing Compliance (hrs/day)	13.6 ± 5.0	5.9 ± 3.5	9.8 ± 2.5	15.0 ± 2.8	19.0 ± 1.7	**0.000*** (d)
Objective Orthosis-Wearing Compliance (hrs/day)	13.6 ± 5.2	4.1 ± 1.5	9.8 ± 1.7	15.1 ± 1.8	20.0 ± 1.4	**0.000*** (d)

Abbreviations: F: female; M: male; y: year; SD: standard deviation. Statistical methods: a = Fisher's Exact Test; b = Chi-Square Test; c = ANOVA; d = Kruskal-Wallis Test; An asterisk (*) indicates a statistical significance level at $p < 0.05$.

Table 7-2. Association of Factors with Objective and Subjective Orthosis-Wearing Compliance

Factors		Objective Compliance (hrs/day)	p-value (objective)	Subjective Compliance (hrs/day）	p-value (subjective)
Gender	Female	13.8 ± 5.2	p = 0.199 (e)	13.7 ± 5.0	p = 0.199 (e)
	Male	12.8 ± 5.5		12.8 ± 5.2	
Baseline Risser Sign	0	13.4 ± 5.2	p = 0.296 (c)	13.2 ± 5.0	p = 0.296 (c)
	1	14.6 ± 4.8		14.7 ± 4.5	
	2	13.4 ± 5.5		13.4 ± 5.3	
Pre-treatment Age		/	r = -0.07, p = 0.240 (f)	/	r = -0.092, p = 0.126 (f)
Pre-treatment Curve Magnitude (°)		/	**r = 0.149, p = 0.013 (c)***	/	**r = 0.152, p = 0.011 (c)***
Whole Treatment Period (T0–T3)		/	r = 0.096, p = 0.110 (f)	/	r = 0.095, p = 0.111 (f)
Treatment Duration (T0–T2)		/	r = 0.109, p = 0.069 (f)	/	**r = 0.137, p = 0.022 (f)***
Follow-up Duration After Treatment Endpoint (T2–T3)		/	r = -0.002, p = 0.742 (f)	/	r = -0.051, p = 0.393 (f)
Subjective Orthosis-Wearing Compliance		/	**r = 0.897, p = 000 (f)***	/	/

Statistical methods: e = Independent t-test; c = ANOVA; f = Pearson correlation; A slash (/) indicates not applicable.

Table 7-3. Curve Magnitude Across Whole Treatment Period

Compliance Levels	Curve Cobb Angle (°, M ± SD)				Comparison (p-value) Among 4 Time Points (g)	Post Hoc Test p-value (h)					
	T0	T1	T2	T3		T0 vs. T1	T0 vs. T2	T0 vs. T3	T1 vs. T2	T1 vs. T3	T2 vs. T3
All Participants	30.5 ± 5.6	17.4 ± 6.9	30.7 ± 10.9	32.0 ± 11.2	**0.000**	**0.000↓**	1.000→	0.051→	**0.000↑**	**0.000↑**	**0.000↑**
Level 1	30.2 ± 6.6	19.2 ± 7.9	39.8 ± 15.7	40.3 ± 15.3	**0.000**	**0.000↓**	**0.001↑**	**0.000↑**	**0.000↑**	**0.000↑**	0.925→
Level 2	29.2 ± 5.4	17.4 ± 6.1	33.2 ± 10.5	34.6 ± 11.4	**0.000**	**0.000↓**	**0.002↑**	**0.000↑**	**0.000↑**	**0.000↑**	**0.010↑**
Level 3	30.8 ± 5.5	16.0 ± 7.0	28.3 ± 9.2	29.4 ± 9.3	**0.000**	**0.000↓**	**0.005↓**	0.392→	**0.000↑**	**0.000↑**	**0.001↑**
Level 4	31.5 ± 5.3	18.9 ± 6.9	27.5 ± 8.0	29.4 ± 9.3	**0.000**	**0.000↓**	**0.000↓**	0.179→	**0.000↑**	**0.000↑**	**0.000↑**

Statistical methods: g = Repeated Measures ANOVA; h: p values were adjusted using Bonferroni correction for multiple comparisons; ↑ indicates a significant increase ($p < 0.05$); ↓ indicates a significant decrease ($p < 0.05$); → indicates no significant change ($p \geq 0.05$).

7.4.3 Cobb Angle Changes Across Time Points

The Cobb angle changes at the four time points for different compliance levels were presented in Table 7-4& Figure 7-2. Initial in-orthosis curve corrections from T0 to T1 across the four compliance levels were 11.0°, 11.8°, 14.8°, and 12.6°, respectively, with Level 3 showing a significantly higher correction than Levels 1 ($p = 0.021$) and 2 ($p = 0.009$). From T0 to T2, Levels 1 and 2 exhibited respective curve deteriorations of 9.6° and 4.0°, which significantly differed from Levels 3 and 4, which improved by 2.5° and 4.0°. Similarly, from T0 to T3, Levels 1 and 2 deteriorated by 10.1° and 5.4°, while Levels 3 and 4 improved by 1.4° and 2.1°. Across both time periods, no significant differences were observed between Levels 1 and 2 nor between Levels 3 and 4.

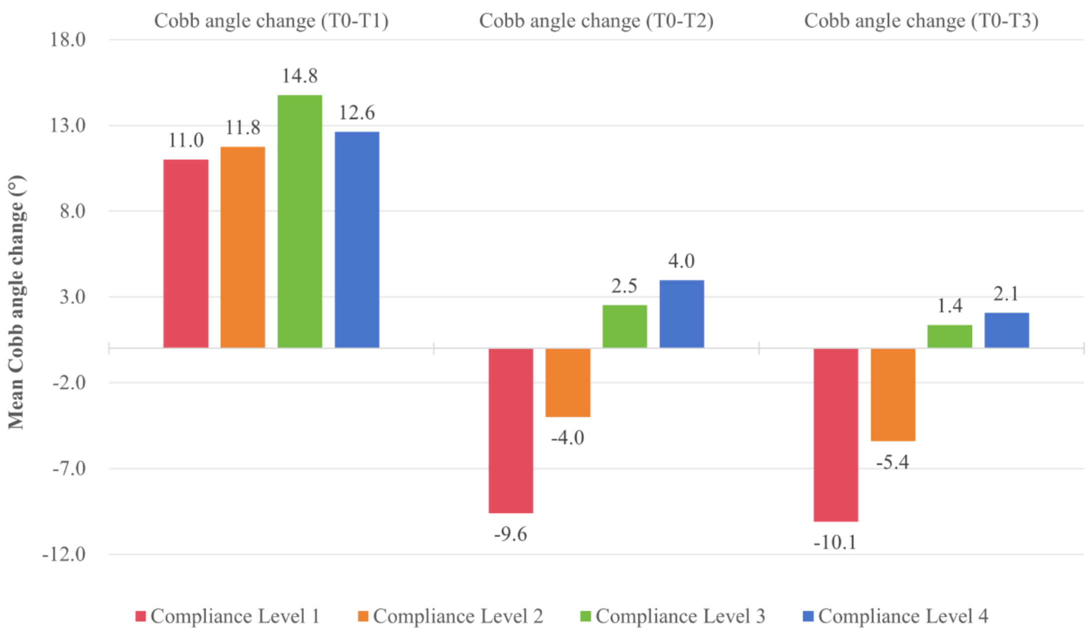

Figure 7-2. Mean Cobb Angle Changes by Compliance Level

7.4.4 Clinical Outcomes Across Different Compliance Levels

The distribution of clinical outcomes across compliance levels was summarized in Table 7-5and Figure 7-3. Improvement rates, defined as the percentage of participants whose Cobb angle decreased > 5°, were 3.2%, 13.3%, 39.8%, and 41.8% from Levels 1 to 4. Compared to Level 1, Levels 3 & 4 showed a significantly higher likelihood of improvement, with odds ratios (OR) of 19.8 and 21.5, respectively.

Deterioration rates from Levels 1 to 4 were 58.1%, 40.0%, 12.0%, and 6.0%, respectively. Levels 1 and 2 had significantly higher risks of deterioration than Level 4, with ORs of 21.8 and 10.5, respectively. No significant differences were observed between Levels 1 & 2, nor between Levels 3 & 4 in the improvement and deterioration rates.

The rates of surgical deterioration were 22.6%, 8.0%, 2.8%, and 1.5% from Levels 1 to 4. Level 1 demonstrated a significantly higher need for surgery than Levels 2, 3, and 4, with ORs of 3.4, 10.2, and 19.3, respectively.

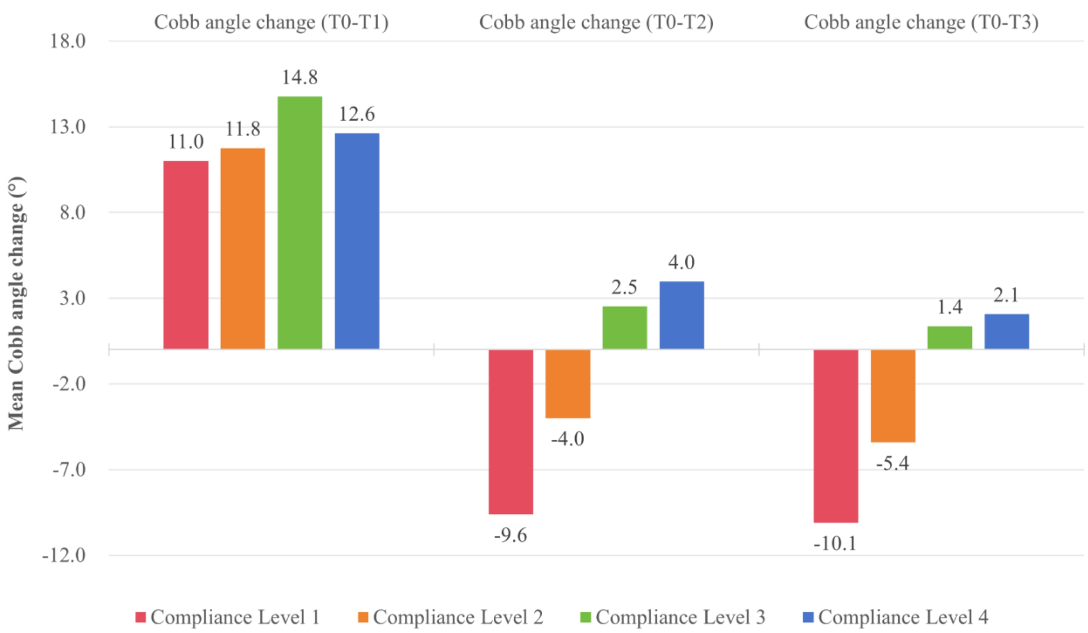

Figure 7-3. Distribution of Clinical Outcomes Across Different Compliance Levels

Table 7-4. Curve Cobb Angle Change Under Different Compliance Levels

	Compliance Levels	N	Mean ± SD	95% Confidence Interval	Tests of Normality	Test of Homogeneity of Variances	Comparison (p-value) Among 4 Compliance Levels	Post-hoc Analysis p-value					
								Levels 1 vs. 2	Levels 1 vs. 3	Levels 1 vs. 4	Levels 2 vs. 3	Levels 2 vs. 4	Levels 3 vs. 4
Cobb Angle Change (T0–T1)	1	31	11.0 ± 7.0	(8.5, 13.6)	Y	Y	**0.002*** (c)	1	**0.021***	1	**0.009***	1	0.174
	2	75	11.8 ± 6.2	(10.3, 13.2)	Y	Y							
	3	108	14.8 ± 6.3	(13.6, 16.0)	Y	Y							
	4	67	12.6 ± 5.9	(11.2, 14.1)	Y	Y							
	Total	281	13.0 ± 6.4	(12.3, 13.8)			/						
Cobb Angle Change (T0–T2)	1	31	-9.6 ± 12.4	(-14.2, -5.1)	N	N	**0.000*** (d)	0.13	**0.000***	**0.000***	**0.000***	**0.000***	1
	2	75	-4.0 ± 9.0	(-6.1, -1.9)	Y	N							
	3	108	2.5 ± 7.6	(1.1, 4.0)	N	N							
	4	67	4.0 ± 6.2	(2.5, 5.5)	Y	N							
	Total	281	-0.2 ± 9.5	(-1.3, 0.9)			/						
Cobb Angle Change (T0–T3)	1	31	-10.1 ± 12.1	(-14.5, -5.6)	N	Y	**0.000*** (d)	0.256	**0.000***	**0.000***	**0.000***	**0.000***	1
	2	75	-5.4 ± 9.8	(-7.7, -3.2)	N	Y							
	3	108	1.4 ± 7.6	(-0.1, 2.8)	Y	Y							
	4	67	2.1 ± 7.6	(0.2, 3.9)	Y	Y							
	Total	281	-1.5 ± 9.8	(-2.7, -0.4)			/						

Abbreviations: Y: Yes; N: No. Statistical methods: c = ANOVA; d = Kruskal-Wallis Test.

Table 7-5. Distribution and Odds Ratios for Clinical Outcomes Across Compliance Levels

Clinical Outcomes	Level 1 (N, %)	Level 2 (N, %)	Level 3 (N, %)	Level 4 (N, %)	Levels Comparison	Sig.	OR	95% CI (Lower - Upper)
Improvement	1, 3.2%	10, 13.3%	43, 39.8%	28, 41.8%	1 vs. 2	0.154	4.6	(0.6, 37.7)
					1 vs. 3	**0.004***	19.8	(2.6, 151.0)
					1 vs. 4	**0.003***	21.5	(2.8, 167.4)
					2 vs. 3	**0.000***	4.3	(2.0, 9.3)
					2 vs. 4	**0.000***	4.7	(2.0, 10.6)
					3 vs. 4	0.796	1.1	(0.6, 2.0)
Stabilization	12, 38.7%	35, 46.7%	52, 48.1%	35, 52.2%	1 vs. 2	0.454	1.4	(0.6, 3.3)
					1 vs. 3	0.354	1.5	(0.7, 3.3)
					1 vs. 4	0.215	1.7	(0.7, 4.1)
					2 vs. 3	0.844	1.1	(0.6, 1.9)
					2 vs. 4	0.508	1.3	(0.6, 2.4)
					3 vs. 4	0.599	1.2	(0.6, 2.2)
Deterioration	18, 58.1%	30, 40.0%	13, 12.0%	4, 6.0%	1 vs. 2	0.092	2.1	(0.9, 4.9)
					1 vs. 3	**0.000***	10.1	(4.0, 25.4)
					1 vs. 4	**0.000***	21.8	(6.3, 75.1)
					2 vs. 3	**0.000***	4.9	(2.3, 10.2)
					2 vs. 4	**0.000***	10.5	(3.5, 31.9)
					3 vs. 4	0.196	2.2	(0.7, 6.9)
	11, 35.5%	24, 32.0%	10, 9.3%	3, 4.5%	1 vs. 2	0.729	1.2	(0.5, 2.8)

Clinical Outcomes	Level 1 (N, %)	Level 2 (N, %)	Level 3 (N, %)	Level 4 (N, %)	Levels Comparison	Sig.	OR	95% CI (Lower - Upper)
Non-surgical Deterioration					1 vs. 3	**0.001***	5.4	(2.0, 14.4)
					1 vs. 4	**0.000***	11.7	(3.0, 46.3)
					2 vs. 3	**0.000***	4.6	(2.0, 10.4)
					2 vs. 4	**0.000***	10.0	(2.9, 35.2)
					3 vs. 4	0.251	2.2	(0.6, 8.2)
Surgical Deterioration	7, 22.6%	6, 8.0%	3, 2.8%	1, 1.5%	1 vs. 2	**0.045***	3.4	(1.0, 11.0)
					1 vs. 3	**0.001***	10.2	(2.5, 42.4)
					1 vs. 4	**0.007***	19.3	(2.3, 164.7)
					2 vs. 3	0.124	3.0	(0.7, 12.6)
					2 vs. 4	0.110	5.7	(0.7, 49.0)
					3 vs. 4	0.586	1.9	(0.2, 18.5)
Total (N)	31, 100.0%	75, 100.0%	108, 100.0%	67, 100.0%	/			

Notes: OR: Odds ratio for the comparison of outcomes between compliance levels; Deterioration: Cobb angle increase > 5°; Non-surgical Deterioration: Cobb angle increase exceeding 5° but remained ≤50° at the endpoint, managed without surgery; Surgical Deterioration: Cobb angle increased >5°, with a final angle >50°, or requiring surgical intervention.

7.4.5 Compliance Across Clinical Outcome Groups

Clinical outcomes and corresponding average subjective and objective orthosis-wearing hours were summarized in Table 7-6and Figure 7-4. The objective compliance significantly differed among the groups: the deterioration group (9.5 ± 4.6 hrs/day), the stabilization group (14.0 ± 5.1 hrs/day), and the improvement group (16.3 ± 3.6 hrs/day). The deterioration and stabilization groups had significantly lower compliance than the improvement group, while the improvement and stabilization groups demonstrated higher compliance than the deterioration group.

Delving deeper into the deterioration group, the surgical deterioration group had the lowest average objective orthosis-wearing time of 9.0 ± 5.2 hrs/day, while those with non-surgical deterioration averaged 9.6 ± 4.4 hrs/day, with no significant difference between the two subgroups. Both subgroups exhibited lower compliance than those in the stabilization and improvement groups. Furthermore, the non-surgical cohort who did not require surgery and Cobb angle ≤50° averaged 13.9 ± 5.1 hrs/day. Subjective compliance followed a similar trend.

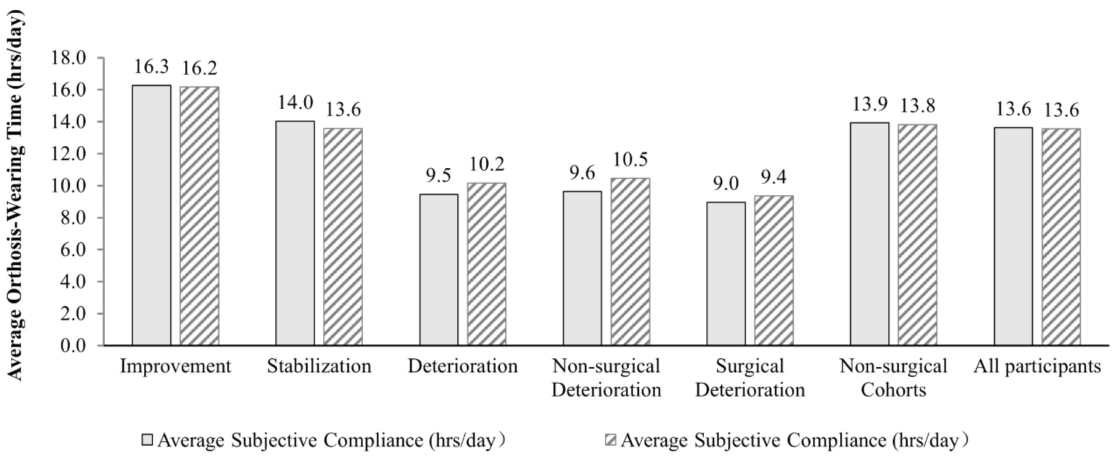

Figure 7-4. Average Orthosis-Wearing Time for Different Clinical Outcomes

Table 7-6. Orthosis-Wearing Compliance Across Different Clinical Outcomes

	Clinical Outcomes	N	Mean ± SD	Multiple Comparisons	Sig.
Average Objective Compliance (hrs/day)	Improvement	82	16.3 ± 3.6	Improvement vs. Stabilization	**0.001***
	Stabilization	134	14.0 ± 5.1	Improvement vs. Deterioration	**0.000***
	Deterioration	65	9.5 ± 4.6	Stabilization vs. Deterioration	**0.000***
	Non-surgical Deterioration	48	9.6 ± 4.4	Non-surgical Deterioration vs. Improvement	**0.000***
	Surgical Deterioration	17	9.0 ± 5.2	Non-surgical Deterioration vs. Stabilization	**0.000***
	Non-surgical Cohorts	264	13.9 ± 5.1	Non-surgical Deterioration vs. Surgical Deterioration	0.962
	All participants	281	13.6 ± 5.2	Surgical Deterioration vs. Improvement	**0.000***
	/	/	/	Surgical Deterioration vs. Stabilization	**0.005***
	/	/	/	Surgical Deterioration vs. Non-surgical Cohorts	**0.000***
Average Subjective Compliance (hrs/day)	Improvement	82	16.2 ± 3.5	Improvement vs. Stabilization	**0.000***
	Stabilization	134	13.6 ± 5.0	Improvement vs. Deterioration	**0.000***
	Deterioration	65	10.2 ± 4.6	Stabilization vs. Deterioration	**0.000***
	Non-surgical Deterioration	48	10.5 ± 4.7	Non-surgical Deterioration vs. Improvement	**0.000***
	Surgical Deterioration	17	9.4 ± 4.5	Non-surgical Deterioration vs. Stabilization	**0.001***
	Non-surgical Cohorts	264	13.8 ± 4.9	Non-surgical Deterioration vs. Surgical Deterioration	0.832
	All participants	281	13.6 ± 5.0	Surgical Deterioration vs. Improvement	**0.000***
	/	/	/	Surgical Deterioration vs. Stabilization	**0.009***
	/	/	/	Surgical Deterioration vs. Non-surgical Cohorts	**0.000***

Notes: Non-surgical Cohorts: All patients who didn't require surgery and Cobb angle ≤ 50° at treatment endpoint.

7.5 Discussion

The present study comprehensively investigated the curve magnitude and Cobb angle changes throughout the treatment period, compared clinical outcomes across different compliance levels, and assessed the orthosis-wearing compliance for each clinical outcome group.

This study showed significant consistency between objective and subjective measurements, aligning with Chan's findings where both self-reports and objective force sensors recorded an average orthosis-wearing compliance of 10.7 hrs/day for 14 patients[42]. However, some studies found that self-reports may overestimate compliance compared to objective compliance monitoring devices due to social desirability, recall bias, or participants' lack of awareness about their actual wearing behaviors[150, 193, 194]. This overestimation may be mitigated in the current study by the Hawthorne effect[195]Participants were aware that the embedded thermal sensors were monitoring their compliance, likely leading them to report more accurately.

Therefore, electronic monitors could be considered a valuable complement to orthotic treatment, not only for their high reliability but also for their potential to enhance compliance, ultimately impacting the treatment outcomes[56, 58, 60]. For example, Miller et al. found that patients in the sensor–monitored group had a significantly higher compliance rate of 85.7% compared to 56.5% in the non-monitored group[60]. Furthermore, Karol et al. reported that patients informed about the monitoring and consistently counseled by their physician had significantly higher compliance than the non-monitored & non-counseled group (15.0 vs. 12.5 hrs/day) and experienced significantly lower surgery rates (25% vs. 36%), demonstrating the potential of monitoring to influence the compliance and treatment outcomes positively[58].

The curve magnitude in all four compliance levels demonstrated the trend of initial in-orthosis correction followed by curve deterioration at subsequent time points, aligning with existing studies[18, 196-200]. Luhmann et al. investigated the natural history of curve changes and found that spinal curves tend to continue progressing after orthosis weaning[201], but the velocity and intensity of the curve progression are not related to the treatment compliance[17, 18, 201].

In the current study, despite curve progression after orthosis weaning in all compliance levels, those with compliance of less than 12 hrs/day experienced significant curve deterioration at both orthosis weaning and the latest follow-up relative to baseline, while those with more than 12 hrs/day compliance showed a decrease at orthosis weaning and remained stable at the latest follow-up. This suggests that daily wearing an orthosis for over 12 hours may yield lasting benefits for spinal curvature control, even after orthosis discontinuation. The enduring effects likely result from the sustained and consistent pressure applied by the orthosis in high compliance groups, which helps maintain spinal structure and prevent further curve deterioration.

This study demonstrated that higher orthosis-wearing compliance was closely associated with better initial and long-term curve corrections. These findings are consistent with Wiley et al.'s results, highlighting significant differences in curve correction among compliance levels (18–23, 12–18, and 0–12 hrs/day) in both initial in-orthosis assessments and long-term follow-ups[189].

Higher initial correction not only supports the perceived effectiveness of the treatment but also reinforces the importance of compliance, motivating patients to continue wearing orthoses as prescribed. For instance, Linder et al. reported that high compliance during the orthosis adaption period is related to compliance at the following treatment stages[154]. Therefore, achieving better initial corrections may create a positive feedback loop that promotes higher compliance throughout the treatment process and significantly improves long-term treatment outcomes.

The participants who wore orthoses over 12 hrs/day had significantly higher improvement rates, lower deterioration rates, and lower rates of required surgery than those with below 12 hrs/day compliance. Moreover, no significant differences in deterioration or surgery rates were observed between the compliance levels of 0–6 hrs/day and 6–12 hrs/day, nor between 12–18 hrs/day and 18–24 hrs/day.

These findings indicate that 12 hrs/day is an effective minimum threshold for achieving therapeutic benefits, consistent with the previous studies[13, 19, 20, 147, 189, 190]. Extending wear beyond 12 hrs/day may offer limited additional benefits in halting curve progression. For instance, Konieczny et al. reported no significant difference in curve progression rates (46.2% vs. 32.0%) or surgery indication rates (37.8% vs. 16.3%) between groups wearing orthoses for 12–16 hrs/day and > 16 hrs/day[19]. Similarly, Allington and Bowen found comparable progression rates (50.0% vs. 46.9%) between patients wearing orthoses part-time (12–16 hrs/day) and full–time (23 hrs/day)[190].

Significant differences in orthosis-wearing compliance were observed across clinical outcome groups, aligning with the findings of previous studies. Katz et al. reported daily compliance of 9.1 hours in the non-deterioration group versus 5.0 hours in the deterioration group, and 8.1 hours in the non-surgery group versus 4.3 hours in the surgery group[147]. Similarly, Karol et al. found compliance of 14.4 hrs/day in the non-deterioration group versus 11.2 hrs/day in the deterioration group, and 13.1 hrs/day in the non-surgery group versus 11.0 hrs/day in the surgery group[58]. Rahman et al. reported significant differences in the compliance rates between the groups of non-deterioration and deterioration (85% vs. 62%)[191].

This study's exclusive use of one type of spinal orthosis may limit the generalizability of the findings to other types or designs of orthoses. The quality of orthosis wearing, e.g., the tightness of straps, which could influence treatment effectiveness, was not assessed. Furthermore, participants' engagement in physical therapy during the treatment period was not monitored. Other potential risk factors for curve deterioration, including growth velocity, genetic predisposition, and lifestyle factors (e.g., physical activity levels or exercise habits), were not controlled due to the nature of the retrospective study design. Future research should consider these factors to provide a more comprehensive evaluation of orthotic treatment effectiveness.

7.6 Conclusion

The study demonstrated that consistently wearing spinal orthosis for at least twelve hours daily is essential to prevent curve deterioration and reduce the need for surgery in the patients with AIS. These findings could guide enhancements in treatment protocols and patient education, aiming to increase orthotic treatment compliance and improve outcomes. Moreover, this research provides clinicians and patients with a predictive framework for estimating the trajectory of curve progression based on orthosis-wearing compliance, offering a substantial benefit in effectively managing treatment expectations and outcomes.

CHAPTER VIII DISCUSSION AND CONCLUSION

8.1 Overview and Integrated Synthesis

This dissertation investigated how orthotic treatment effectiveness in adolescent idiopathic scoliosis (AIS) is shaped by the interaction of three major domains: brace biomechanics reflected by force application, patient-specific clinical features, and treatment compliance. Across five interrelated sub-studies, we examined (1) controlling force direction (CFD) estimated from CAD/CAM brace models, (2) the alignment between CFD and the curve's plane of maximum curvature (PMC), (3) intrinsic mechanical responsiveness measured by supine flexibility, (4) body habitus reflected by BMI, and (5) objective and subjective compliance, including dose–response patterns across the treatment period.

A central conclusion is that no single factor explains outcome variability in isolation. Instead, brace treatment behaves as an interdependent clinical system: how the brace targets the deformity (force orientation and structural alignment) determines the quality of in-brace correction; how the spine responds (flexibility and other intrinsic characteristics) governs how much correction is mechanically achievable; and how consistently the brace is worn determines whether initial correction translates into durable benefit. Accordingly, the following sections discuss each domain while emphasizing their interplay.

8.2 Force Application and Alignment with Structural Deformity

8.2.1 Key Findings and Discussion of Controlling Force Application

The analyses confirm that force orientation influences the immediate three-dimensional response to bracing. Posterolateral force directions tended to achieve coronal correction while better preserving thoracic kyphosis, whereas more anterolateral orientations were associated with greater kyphosis reduction, consistent with prior biomechanical and clinical observations [24, 46, 64, 88]. These findings reinforce that brace design should not be evaluated purely in the coronal plane; instead, corrective vectors should be considered relative to sagittal balance and curve geometry.

At the cohort level, CFD alone did not predict long-term outcomes, indicating that force direction in isolation is insufficient as a clinical predictor. This suggests that simply prescribing or targeting a single "preferred" force direction (e.g., a conventional angle) does not reliably translate into better stabilization across heterogeneous patients.

In contrast, interpreting force direction relative to structure, through CFD–PMC alignment, provided clinically meaningful information. Closer alignment was associated with additional 3D benefits in selected patients, supporting the concept that effective brace action depends on matching force orientation to the individual deformity plane. The added value of PMC-oriented targeting was more apparent when intrinsic correction capacity was limited (e.g., in less responsive spines), whereas in highly responsive cases the incremental advantage of precise targeting was smaller because adequate correction could be achieved under a wider range of reasonable pad orientations.

Overall, the message is clinically actionable: CFD on its own is insufficient; CFD interpreted relative to PMC provides a more informative framework for individualized brace optimization.

8.2.2 Clinical Interpretation and Indirect Validation of Estimated Controlling Force Direction

In this retrospective clinical cohort, CFD was not directly measured using in-brace force sensors. Instead, CFD was estimated from CAD/CAM brace models by quantifying the dominant orientation of pad-related shell deformation, reflecting routine practice in which braces are custom-fitted and iteratively adjusted but force-sensing systems are not part of standard care. Therefore, CFD should be interpreted as an estimate of force orientation derived from brace geometry rather than a direct measurement of in vivo force magnitude.

Although sensor-based validation was not available, the clinical meaningfulness of the estimated CFD was assessed indirectly using radiographic outcomes, which remain the accepted reference for evaluating brace effectiveness in AIS. The overall pattern of findings supports interpretability: CFD alone showed no association with outcomes, whereas CFD–PMC alignment demonstrated consistent and biomechanically coherent associations with 3D curve changes. This suggests that the estimated CFD captures relevant directional information, and that its clinical relevance emerges when interpreted relative to the individual deformity plane.

Nevertheless, this approach cannot quantify force magnitude, strap tightness, dynamic loading during daily activities, or modifications made after digital export. These limitations define the scope of inference and motivate future work integrating in-brace sensing or prospective measurement to strengthen the linkage between brace design parameters and delivered corrective loading.

8.3 Patient-specific Clinical Features

8.3.1 Intrinsic mechanical responsiveness: Supine flexibility

Supine flexibility emerged as a key indicator of mechanical responsiveness. Patients with higher flexibility achieved greater in-brace correction and were more likely to maintain favorable trajectories over follow-up. Importantly, flexibility also appeared to moderate the importance of other domains: less responsive spines were more sensitive to both mechanical targeting (e.g., PMC-guided alignment) and adherence, whereas more responsive spines could achieve acceptable correction despite modest deviations in brace mechanics, provided that adequate wear time was maintained. Clinically, these findings support the use of pre-brace flexibility assessment to guide expectation setting, follow-up intensity, and the level of design optimization required.

8.3.2 Body habitus: BMI

In this thesis, BMI did not show an independent association with outcomes when considered alongside brace mechanics and compliance. Although overweight patients may encounter practical challenges (comfort, pad transmission through soft tissue) and underweight patients may experience tolerance issues over bony prominences, these influences appear to operate primarily through correction quality and compliance, rather than BMI acting as a direct predictor. Therefore, BMI should not be viewed as a contraindication to bracing. Instead, it should prompt fitting and comfort adaptations (e.g., pad contouring, strap configuration, gradual force escalation), alongside close monitoring of wear behavior and skin tolerance.

8.4 Treatment Compliance and Effective Dose

Among all variables, compliance was the most decisive determinant of outcome. We observed a strong dose–response relationship: patients who wore their brace ≥12 hours/day achieved substantially better outcomes than those below this threshold, with maximal benefit approaching ≥16–18 hours/day. These findings replicate the BRAIST trial and other large studies, reinforcing 12 hours/day as a minimum "effective dose" for most patients [13, 20].

Compliance also interacted with mechanical and anatomical factors. In rigid curves, high adherence sometimes compensated for suboptimal in-brace correction, whereas poor compliance could nullify the benefits of excellent correction in flexible curves. Importantly, brace design influenced wear behavior: uncomfortable or bulky braces eroded adherence, while lightweight, ventilated designs facilitated higher wear. Objective monitoring further improved compliance by providing accountability and feedback.

From a clinical perspective, the takeaway is that ensuring the patient actually wears the brace is as vital as the brace itself. Regular follow-up, patient education, and compassionate addressing of complaints are vital. Our study reinforces prior evidence that even the highest-quality brace will fail if left in the closet. Encouragingly, when patients and families understand the stakes. Many families used smartphone alarms, peer support groups, or reward systems to improve adherence. Thus, behavioral interventions form the third pillar of successful bracing.

In summary, compliance remains the primary modifiable driver of orthotic treatment success and must be managed with the same rigor as brace design.

8.5 Key Innovations and Significance

This thesis makes several original and clinically meaningful contributions to the understanding and optimisation of orthotic treatment for AIS. While brace treatment has been widely adopted for decades, its design and prescription remain largely empirical, and prior research has predominantly examined individual factors in isolation. By contrast, the present work advances the field through an integrated, structure-guided, and data-driven framework that bridges biomechanics, patient-specific characteristics, and real-world adherence.

First, this thesis introduces a novel quantitative approach for estimating controlling force direction from CAD/CAM orthotic models using computer vision techniques. Unlike conventional descriptions of brace mechanics that rely on qualitative assumptions or simplified two-dimensional representations, this approach enables systematic characterisation of force orientation across a large clinical cohort. Importantly, the findings demonstrate that CFD, when considered in isolation, is not a reliable predictor of treatment outcome. This negative result is itself an important contribution, as it challenges the long-standing implicit assumption that applying corrective forces along a single "preferred" direction is sufficient for effective correction.

Second, a central innovation of this thesis is the introduction and validation of the concept of force–structure alignment, operationalised as the angular relationship between CFD and the plane of maximum curvature. By explicitly linking force application to individual structural deformity orientation, this work moves beyond empirical brace design principles and provides a biomechanically grounded explanation for inter-individual variability in treatment response. The identification of clinically meaningful alignment thresholds further enhances the translational relevance of this concept and offers actionable guidance for future CAD/CAM orthosis optimisation.

Third, this thesis systematically integrates patient-related biomechanical modifiers, including spinal flexibility and body habitus, into the evaluation of orthotic effectiveness. Rather than treating these factors as independent predictors, the analyses demonstrate how flexibility interacts with force–structure alignment to shape mechanical responsiveness, while BMI contributes limited explanatory value when considered alongside alignment and compliance. This integrative perspective helps reconcile previously inconsistent findings in the literature and clarifies the relative importance of modifiable versus non-modifiable determinants.

Finally, by incorporating objectively measured orthosis-wearing compliance alongside biomechanical parameters, this work highlights the inseparable relationship between orthosis design and patient behaviour. The observation that alignment-related benefits persist even among patients with comparable wear time underscores that effective bracing requires both appropriate mechanical targeting and sufficient adherence. Collectively, these contributions advance AIS bracing from a predominantly experience-based practice toward a more personalised, evidence-informed paradigm, with direct implications for future CAD/CAM orthosis design and clinical decision-making.

Specifically, the originality of this thesis lies in: (i) the development of a quantitative, CAD/CAM-based method to estimate controlling force direction in scoliosis orthoses; (ii) the introduction of force–structure alignment, defined by the relationship between force direction and the plane of maximum curvature, as a clinically meaningful biomechanical construct; and (iii) the integration of biomechanical, anatomical, and behavioral factors within a unified analytical framework to explain variability in bracing outcomes.

8.6 Clinical Implications: Toward Personalized Bracing Strategies

The findings of this dissertation support a shift toward personalized bracing strategies in adolescent idiopathic scoliosis, in which treatment decisions are guided by individual biomechanics, anatomy, and lifestyle rather than uniform protocols. In particular, the relevance of controlling force direction and its alignment with the plane of maximum curvature highlights the need for three-dimensional customization in brace design. Advanced imaging and CAD/CAM technologies should therefore be leveraged not only for manufacturing efficiency but also for optimizing force orientation and pad configuration according to each patient's structural characteristics.

Brace prescription and treatment intensity should likewise be individualized based on risk profiles. Pre-brace flexibility, in-brace correction, skeletal maturity, and curve magnitude provide practical guidance for tailoring wear schedules, follow-up intervals, and escalation thresholds. Body habitus, while not an independent predictor of outcome, may modify how corrective forces are transmitted and tolerated, underscoring the importance of anatomical adaptation in brace construction.

Equally critical is the integration of compliance-enhancing strategies into routine care. Objective wear-time monitoring, patient education, comfort optimization, and psychosocial support should be regarded as integral components of effective treatment rather than adjuncts. Multidisciplinary collaboration among orthopedists, orthotists, physiotherapists, and psychosocial professionals is therefore essential. Collectively, these findings advocate a patient-centered, adaptive approach to bracing that aligns biomechanical optimization with real-world adherence to maximize long-term outcomes while preserving quality of life.

8.7 Limitations and Future Work

This thesis has several limitations. First, the retrospective single-center design limits causal inference and may reduce generalizability, although it enabled analysis under consistent clinical protocols. Second, the focus on a single brace system (Hong Kong CAD/CAM brace) may limit applicability to other orthoses with different mechanical principles.

Third, controlling force direction was estimated rather than directly measured, and the approach does not capture force magnitude, strap tension, dynamic loading, or post-fitting modifications. Fourth, some subgroup analyses (e.g., BMI extremes) were limited by sample size and may be underpowered. Fifth, BMI was used as a simplified proxy for body habitus and does not reflect detailed body composition or tissue mechanical properties. Sixth, compliance was primarily quantified as wear time, without simultaneous measurement of strap tightness or interface pressure distribution. Finally, patient-reported outcomes (PROs), such as pain, comfort, daily function, and quality of life, were not systematically collected, which limits the ability to directly evaluate patient-centered treatment impact alongside radiographic correction.

Future work should prioritize prospective, multi-center validation; integrate in-brace sensing technologies (e.g., pressure and force mapping) to quantify both the direction and magnitude of delivered loading; and extend outcome assessment beyond radiographic measures to include patient-reported outcomes, comfort, function, and quality of life. Data-driven prediction tools that integrate structural, clinical, biomechanical, and adherence data may further support precision bracing by enabling individualized risk stratification, optimization, and longitudinal monitoring.

8.8 Conclusion

This dissertation examined how mechanical aspects of force application, patient-specific clinical features, and treatment compliance collectively shape the effectiveness of orthotic treatment in AIS. Across five interrelated sub-studies, the findings demonstrate that controlling force direction and its alignment with the spine's three-dimensional deformity are critical for achieving in-brace correction; that spinal flexibility and BMI further influence how effectively these forces translate into structural change; and that complaince to prescribed orthosis-wearing time is essential, with higher compliance strongly associated with reduced risk of curve progression and surgery. Importantly, these domains interact: deficiencies in one can negate the benefits of others, whereas coordinated optimization yields the best outcomes. Together, these results highlight the limitations of a "one-size-fits-all" approach and reinforce the need for personalization in orthotic treatment.

Clinically, the work highlights the importance of combining advanced orthosis design with individualized patient management and systematic compliance monitoring. By aligning controlling forces with structural deformity, accounting for patient-specific features, and enhancing compliance, orthotic treatment can become more effective, tolerable, and sustainable. Ultimately, the effectiveness of orthotic treatment in AIS is maximized when orthosis biomechanics, patient characteristics, and adherence are integrated into a personalized approach supported by clinicians, patients, and families together. Ultimately, the effectiveness of orthotic treatment in AIS is maximized when biomechanics, patient characteristics, and treatment compliance are integrated into a personalized approach supported by clinicians, patients, and families together. These insights contribute to an evolving paradigm of scoliosis care that is increasingly evidence-based, technology-assisted, and patient-centered. Continued research and innovation will further refine these strategies, with the ultimate goal of making orthotic treatment a more reliable, effective, and patient-friendly intervention that improves outcomes and enhances the quality of life for patients.

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