Class II Skeletal Growth Modification Treatment: Has Hope Triumphed Over Evidence?

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The hierarchy of evidence in the health sciences is primarily determined by study methodology and avoidance of systematic bias. As such, the systematic review and meta-analysis of randomized controlled trials sits at the top of the evidence pyramid while case studies, anecdotes, and personal opinions are located at its base. Ideally, clinical practice guidelines and reference manuals should be developed with this hierarchy in mind and clearly state what level of evidence supports any given clinical recommendation. When there is inadequate evidence to guide a clinical recommendation, we need to clearly state that. Unfortunately, many clinicians do not differentiate between the levels of evidence and consequently elevate highly biased studies to the level of the randomized controlled trial. Nowhere is this more evident than in the American Academy of Pediatric Dentistry Councils on Clinical Affairs' and Scientific Affairs' Reference Manual of Pediatric Dentistry best practice statement on the management of the Class II malocclusion.

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Boston Children's Hospital 300 Longwood Avenue, Hunnewell 416 Mailstop BCH3071, Boston, MA 02115 Phone:+ 857-218-4896 he Reference Manual presents the following information on the management of Class II skeletal malocclusions¹: Growth-modifying effects in some studies did not show an influence on the Class II skeletal pattern,¹⁷⁷⁻¹⁷⁹ while other studies dispute these findings.^{180,181} There is substantial varia-tion in treatment response to growth modification treatments (headgear or functional appliance) and no reliable predictors for favorable growth response have been found.^{168,174}

The fundamental question here is *not* can we correct Class II skeletal malocclusions orthodontically but can we correct them via growth modification? A neophyte reader will interpret the first sentence as indicating that the literature on this question is equivocal. However, if a critical reader examines the evidence cited in references 177-179 and 180,181, it is clear that the Class II skeletal pattern cannot be modified by orthodontic or orthopedic appliances. How can I say this? The 3 studies that found no growth modifying effects were 1 systematic review and 2 randomized controlled trials.²⁻⁴ The 2 studies that "dispute" these studies were both retrospective case control studies.^{5.6} Retrospective case controlled studies are low on the evidence pyramid and suffer from problems of bias related to the validation of information obtained and the selection of an appropriate control group.

As an orthodontist who has taught management of the developing dentition and occlusion to pediatric dental residents for over two decades, each year I experience the same moral distress when it comes to discussing Class II skeletal growth modification treatment with my students. In theory, we should all agree that teaching any subject in 2022 requires utilization of the best available evidence from the peer-reviewed literature.⁷ In practice, however, not all of the stakeholders involved in the administration and oversight of pediatric dental and orthodontic residency programs seem to agree on what constitutes the best evidence and unfortunately some spurious information finds it's way into the curriculum. My late friend Bill Proffit used to say, "You're entitled to your own opinion but not your own facts". At the end of the residency program, our student's ability to synthesize a cogent, evidence-based opinion on any topic is frequently confounded by their exposure to diverse sources of information such as politically driven policy statements, clinical practice guidelines, reference manuals, clinical experience with individual faculty and board examinations just to name a few. What is incumbent on us, their teachers, is to educate them that all evidence in the peer-reviewed literature is not equal, that some sources of information are not a substitute for the rigors of scientific investigation and not all purported scientific investigation is actually science at all.

The topic of Class II skeletal growth modification remains fraught with tension. While pediatric dentistry and orthodontics have shared the aspirational goal of modifying skeletal growth, the accrued evidence has proved this strong theory very weak in practice. A more practical goal for our specialties should be to graduate a generation of evidence-based critical thinkers who are primarily driven by achieving reliable, repeatable clinical outcomes for their patients.

Acknowledgement

The opinions expressed in this paper are solely Dr. Ackerman's and do not represent those of Boston Children's Hospital and Harvard School of Dental Medicine.

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Reply

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Dear Dr. Ackerman,

Your viewpoint hits on the most complex problems to diagnose, discuss, treat and publish and I thank you, for bringing up a most challenging text.

The fundamental question with this discussion relies on how we measure success or failure.

Cephalometrics and cephalometric measurements have been the chore of orthodontic diagnosis, treatment planning, and result assessment.

All the published material in the area of early management of class II malocclusion, and systematic studies rely on cephalometric measurements to diagnose skeletal class II and come to conclusions.

- Objectively, cephalometrics is the gold standard for orthodontic diagnosis. We rely on metrics (measurements, measurable data) because they are easy to understand and compare before and after results.
- Metrics can be easily explained to parents.
- Metrics can quantify changes produced in a patient, generating numerical data that can be converted into usable statistics from a larger sample population.
- Metrics can be used to explain treatment outcomes using a specific technique or comparing techniques.

Cephalometrics, however, do generate significant problems. We need to recognize that flattening a face and bones of growing child, a four actively growing dimensional entity into a two-dimensional picture cannot be quantified. Numbers cannot be applied to a biological model because each structure, spaces, physiological needs, growth, genetics, environment act, react and interact with each other at different moments during the whole growth process, which bring us to this phrase coined by Cameron that:

"Not everything that can be counted, counts and not everything that counts can be counted" ¹

We know that finding and pointing accurately anthropometric or derived points do present some challenges which derive into debatable analyses.

Guessing where the reference point is located can alter an angle, thus a potential treatment plan, because a rotational 1millimeter error from a landmark placed of 10 centimeters produces a displacement of the observed portion of 1.74mm². Moyers and Bookstein ³ showed how several shapes could be drawn through 3 points without altering the angular measurement. Unfortunately, many clinicians have adopted adolescent cephalometric measurements in growing children, misleading the clinician into poor diagnoses, treatment planning and expected poor results.

This is the result to the poor knowledge of craniofacial growth and development. Treating when no treatment is needed, or clinicians choosing to wait for the last breath of symptoms and treat late rather than look for the etiological factors and intercept them.

You pointed out.

As such, the systematic review and meta-analysis of randomized controlled trials sits at the top of the evidence pyramid while case studies, anecdotes, and personal opinions are located at its base.

Unfortunately, all the systematic studies in this area present several flaws. The main one, Cephalometrics and the diagnosis of class II malocclusions of an ANB> 4° ,⁴ without mentioning other significant variations that exist in many aspects of the patients who have skeletal discrepancies^{5,6}, including, but not limited to, growth potential (or maturation level), the severity of skeletal discrepancies, growth direction, differential skeletal patterns, compliance with the growth modification appliances, active treatment and retention protocols and length, psychosocial status.

Can we forget that Class II malocclusions and corrections should also be gauged, measured, and evaluated by their overjet discrepancy, its anterior tooth angulations, molar and cuspid relationships, as well as by facial characteristics, mainly the patient's profile?

The combination of two or more of these above variables and the interactions of genetic and environmental factors account for the variability and unique expression of class II malocclusions. Summing them up, we can end up with more than 200 inconsistent possibilities. With the myriad and problems how come cephalometric measurements with all its flaws can have the final word and verdict:(Growth modification- NO growth modification) forgetting to look at the most significant clinical changes such as facial and occlusal, the structure(s) involved in the class II, but most importantly using adolescent measurement and applying them to numbers that do not match an actively growing human being.

This wide spectrum of dentofacial combinations makes systematic studies on early class II corrections groundless, starting in these cases with their flawed hypothesis that class II ANB > to 4° in growing children, unfounded, thus, conclusions baseless.

Angles, lines and numbers to come out with a conclusion that early management of class II malocclusions do or do not bear significant cephalometric changes to grant early treatment?

Why this happens?

Our academic preparation and thinking process continues to be a reductionist and separatist, and tries to disaggregate complexity into small parts to make this problem more manageable and understandable.

The reductive/analytic disjunctive thinking approach of using a cephalogram to draw conclusions, might be too simplistic. Using one or two angle measurements, in a growing child where all craniofacial structures contribute directly or indirectly to the patient's global changes, cannot give an adequate understanding of complex, interconnected growth phenomena. We cannot isolate these occurrences from their genetic and environment, and operate with the disjunctive logic of **either/or**.

You also suggested:

At the end of the residency program, our student's ability to synthesize a cogent, evidence-based opinion on any topic is frequently confounded by their exposure to diverse sources of information such as politically driven policy statements, clinical practice guidelines, reference manuals, clinical experience with individual faculty and board examinations just to name a few. What is incumbent on us, their teachers, is to educate them that all evidence in the peer-reviewed literature is **not** equal, that some sources of information are **not** a substitute for the rigors of scientific investigation and **not** all purported scientific investigation is actually science at all.

I completely agree with you with this statement, unfortunately, the rigors of scientific investigation cannot be applied, especially in the case of class II malocclusions in growing children due to the significant intrinsic and extrinsic variations such as taking into account all the inconsistencies discussed earlier and new ones such as compliance. Communication and bonding with a child are key for the success or treatment failure, because we are dealing with a person and not numbers and unfortunately, connection and bonding cannot be quantified.

From my personal viewpoint, I believe it is always better in this case to educate by doing, not by just following rules. No formal education, will be the best teacher than trying and burning your finger when we play with matches, or just as no book will teach us how to play piano (*in vitro*). We learn a language by speaking it, or a game by playing.

We need to recognize that quantitative evaluation should support but not supplant qualitative, expert assessment.

As an orthodontist who has taught management of the developing dentition and occlusion to pediatric dental residents for over two decades, each year I experience the same moral distress when it comes to discussing Class II skeletal growth modification treatment with my students. In theory, we should all agree that teaching any subject in 2022 requires utilization of the best available evidence from the peer-reviewed literature.

Moral distress, and questioning are good. It is always better to shape in our students "a well-made head, than a full one" *Montaigne M*.

Considering the amount of early class II interceptions performed worldwide, as clinicians and academicians we should make every effort to contribute to the current literature, developing new diagnostic protocols and guidelines in growing children at different ages considering facial, dental structures with the help of more advanced technology, to develop comprehensive and universal treatment protocols to generate well-designed long-term randomized controlled clinical trials. This will eventually help the future systematic reviews and meta-analyses that are considered the highest level of evidence.

The fact is that 6 out of 10 children do have malocclusions *(more than caries in many countries)*. Longitudinal studies in Class II patients indicate that *"environmental"* Class II dento-skeletal characteristics can appear as early as the primary dentition⁷. Most of them do not self-correct and remain *"aggravate"* into adulthood ^{8,9}.

The main responsible program to diagnose and intercept all these problems are the Pediatric Dentistry programs, because most of the malocclusions appear in the primary dentition or early mixed dentition and these can be diagnosed and intercepted early. No treatment, will aggravate with time, and late treatment will narrow the full treatment potentials.

Unfortunately, we do not teach our students, because many of us were never trained to see them.

"What the eye doesn't see and the mind doesn't know, doesn't exist." *Lawrence DH, Lady Chatterley's Lover*.

Making the decision to intercept a malocclusion entails a great responsibility. Expertise is key.

I have no doubt that Pediatric and Orthodontic educators should continue to teach craniofacial growth and growth modification to their residents. The application of growth and development in the early management of malocclusions should also be part of these programs.

For some reason, the American Journal of Orthodontics, changed its name to American Journal of Orthodontics **and Dento-***facial Orthopedics*.

Early interception of malocclusions, works. I have been involved with children with all different malocclusions for 40 years and I have co-authored 3 books in this area. This last one is an 850-page book which will be published by Wiley by the end of 2022.

> Dr Marc Saadia, DDS,MS. Editor-in-Chief The Journal of Clinical Pediatric Dentistry.

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