ORIGINAL RESEARCH

Efficacy of SAVE: A Novel Maxillary Protraction Device—A Finite Element Analysis

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Abstract

Introduction: This study describes a novel device known as "SAVE" to effectively protract the deficient maxilla in class III malocclusion by quantifying and evaluating the changes in the maxilla through a finite element analysis (FEA).

Materials and methods: The patented novel SAVE device was three-dimensionally modeled using Autodesk Fusion 360. An existing computed tomography (CT) scan of a patient exhibiting class III malocclusion was used to generate a finite element (FE) model. The total number of nodes was 8,49,682 and 5,30,716 elements. The material of choice for the appliance was medical-grade polyetheretherketone (PEEK) polymer. The loading was performed to simulate maxillary protraction (after assigning material properties). The loading forces of 3.5, 5.5, and 9 N were simulated on each side with 30° angulations to the occlusal plane. The color changes in terms of areas of maximum (red) and minimum (blue) deformation.

Results: The FEA results with protraction forces of 3.5, 5.5, and 9 N showed deformation of the maxilla in the forward and downward directions. Equivalent von Mises stress on the SAVE appliance showed stress on the superior surface of the main frame and on the area below the struts where the force module was attached. In relation to the implant, the stress concentration was on the posterior and superior area around the implant.

Conclusion: The FEM analysis force vectors showed a forward and downward deformation of the maxilla with counterclockwise rotation, supporting the fact that the novel appliance could bring about effective maxillary protraction in a shorter duration.

Keywords: Class III corrector, Facemask, Finite element method, Maxillary protraction device.

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Introduction

Class III malocclusion is considered a complicated dentofacial deformity, which could be due to dental or skeletal decompensation or a combination of both, the majority of which are related to maxillomandibular bone discrepancies caused by maxillary deficiency.[1,2] The correction of this malocclusion with maxillary deficiency can be done orthopedically with facemask therapy, with or without maxillary expansion in growing patients.[3]

Dental inconsistencies may commonly be resolved by orthodontic treatment. However, class III malocclusion with skeletal discrepancies has three main categories of approaches: (1) at the end of primary dentition or beginning of mixed dentition: rapid maxillary expansion with face mask therapy,[4–6] (2) at late mixed dentition: skeletal anchorage by intermaxillary elastics for class III correction, and (3) after the growth has stopped: orthognathic surgery is performed.[7,8]

As a result of anteroposterior and transverse deficiency of the maxilla in class III malocclusion, face mask (FM) therapy provides a constant anterior force on the maxilla, which changes the orientation of facial growth.[9,10] Some demerits of face mask therapy are poor patient compliance, reduced duration of appliance wear, and social acceptance. Hence, a novel appliance was designed to overcome the demerits of the face mask.

The finite element method (FEM) serves as a powerful mathematical tool for constructing computer models that accurately depict the shapes and physical characteristics of complex geometric objects. Physical interactions of the various components of the model can then be calculated in terms of stress and strain. This method enables the computation of physical interactions among the diverse components within the model, providing insights into stress and strain. The significance of FEM becomes evident when dealing with complex anatomical structures and their interactions with surrounding tissues. Obtaining such detailed information through experimental or analytical means proves challenging, making FEM a valuable approach for unraveling the complexities of these intricate systems.

The displacement of the deficient maxillary complex depends on the magnitude, direction, and duration of the load applied to it.[11–14] Hence, the current study aimed to develop a novel device known as "SAVE" to effectively protract the deficient maxilla in class III malocclusion for the quantification and direction of force with finite element analysis (FEA).

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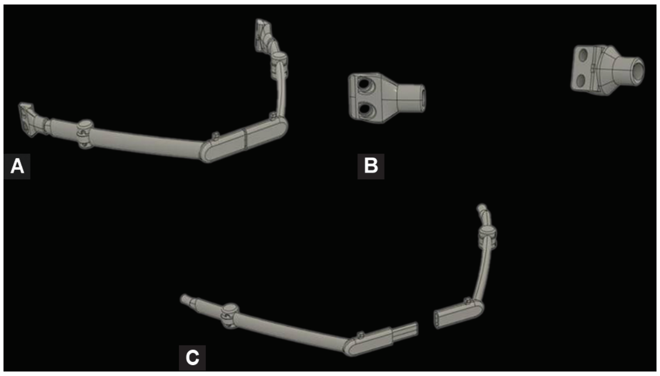
Materials and Methods

Description of the Device

The patented novel SAVE device was three-dimensionally modeled using Autodesk Fusion 360 software (Fig. 1A) (patient application number: 201941006367). The anchorage head is the part of the device that will be secured/fixed to the angle of the mandible with the help of bone screws. The anchorage head consists of two slots for the placement of bone screws, which help with its stabilization. It also consists of a channel for the insertion and removal of the main frame (Fig. 1B). The main frame consists of two units: the left and right frame, which is the removable part of the device. The medial end of the anterior part of the right frame consists of one small rod and a channel on the left frame. The rod will slide into the channel of the opposite frame, making it one unit once assembled. The upper surface of the horizontal part of the right and left frame consists of struts, which will help in engaging elastics to apply force.

A small hinge joint was added to the posterior end of the main frame before the insertion rod; this facilitated minor movement in the transverse plane for accommodation of varying mandibular size (Fig. 1C). The material of choice for the appliance is medical-grade polyetheretherketone (PEEK) polymer, due to its biocompatibility and structural stability. An existing computed tomography (CT) scan exhibiting class III malocclusion was used to generate a finite element (FE) model (Fig. 2). The DICOM files of the same were imported into Materialise Interactive Medical Image Control System (MIMICS) software, Materialise NV, Belgium.



Figs 1A to C: (A) Complete assembly of the "SAVE" device; (B) Anchorage heads; (C) Removable main frames with struts for engaging force module


Fig. 2: DICOM images from CT

The scanned model from MIMICS was in STL format and was converted to an FE model for further simulation. The 3D model of the SAVE device was assembled with the FE model of the skull for simulation. Infrazygomatic crest (IZC) screws of 12 mm length and 2 mm diameter were 3D modeled and incorporated at the infrazygomatic crest, and the maxillary arch did not contain any orthodontic appliance. Material properties were meticulously assigned to various structures, including the device, bone, and teeth. These material properties were derived from experimental data obtained in prior studies (Table 1). The base of the skull was restrained to prevent undesirable motion that might occur in response to the protraction load on the dentoalveolar structures. The calculation was performed using steady-state analysis, and the properties of the skull model were isotropic without incorporating sutures due to computational constraints, thereby enhancing the precision of the study findings.

Note: Deformation and stresses were determined at the SAVE appliance, maxilla, and infrazygomatic crest (IZC) screw implant placement site.

Application of Forces

Maxillary Device

The loading was performed to simulate maxillary protraction from IZC screws to the struts of the SAVE appliance. The protraction loads were simulated at 300 angulations to the occlusal plane, representing orthodontic and orthopedic forces. Load 1 was 3.5 N, load 2 was 5.5 N, and load 3 was 9 N (Figs 3A to C), respectively.

Results

The results showed changes in terms of total deformation and von Mises stresses. The total number of nodes was 8,49,682 and 5,30,716 elements. The color changes in terms of areas of maximum and minimum deformation and stresses were seen after the material properties were assigned. The red color shows the maximum, and the blue shows the minimum deformation and stress regions.

The finite element model of the SAVE appliance and IZC screws was assembled on the finite element model of the skull. A protraction force of 3.5, 5.5, and 9 N was applied from the SAVE appliance to the IZC on either side of the maxilla with a 300 angulation to the occlusal plane.

The results were calculated in terms of total deformation in the following regions of the maxilla: zygomaticomaxillary, nasomaxillary, and mastoid regions, and in terms of von Mises stress on the SAVE appliance and the area where the IZC screw was placed.

The analysis of total deformation revealed that the protraction force brought about a forward and downward movement of the maxilla, depicted by colored arrows. The highest deformation was

Table 1: Young's modulus and Poisson's ratio for the materials

Material	*Elastic modulus (MPa)*	*Poisson's ratio*
Compact bone	13400	0.3
Cancellous bone	1370	0.3
PEEK polymer	4100	0.4

Data from Tanne and Sakuda.[18] The values are in Megapascal (MPa) seen in the zygomatic arch, posterior two-thirds of the maxilla, and the area corresponding to the pterygomaxillary region in all protraction forces. It was represented by green-colored arrows showing downward and forward directions. The magnitude of deformation was 0.00024044 mm at a force of 3.5 N. The nasomaxillary complex, incisors, and anterior nasal spine showed deformation in the upward direction, represented by blue arrows, indicating the least amount of deformation. The deformation around the mastoid region was in the downward direction, represented by blue arrows (Fig. 3A). The magnitude of deformation on application of 3.5, 5.5, and 9 N is given in detail (Table 2 and Figs 3A to C).

Equivalent von Mises stress on different parts of the SAVE appliance was measured on the application of the loads mentioned. It showed that the maximum stress was seen on the superior surface of the main frame near the hinge, represented by red color. On application of a force of 3.5 N, the maximum stress was 13.116 MPa; with 5.5 N, it was 20.611 MPa; and with 9 N, it was 33.727 MPa (Table 3). The area below the struts, where the force module was attached, experienced the second-highest stress distribution, indicated by orange color (Fig. 4).

Equivalent stress in the infrazygomatic crestal bone around the IZC screw was measured after the application of the loads. The stress concentration was around the posterior superior region of the bone surrounding the IZC screws at the bone-implant interface. The maximum stress for 3.5 N was 2.882 MPa, for 5.5 N was 4.5302 MPa, and for 9 N was 7.4131 MPa (Figs 5A to C and Table 4).

Discussion

The SAVE appliance is designed to overcome the limitations of existing maxillary protraction devices. Class III malocclusion may arise from skeletal or dental etiology. In cases involving skeletal class III malocclusion, approximately 40–60% of patients exhibit maxillary deficiency, making maxillary protraction a viable treatment strategy.[15] Facemask therapy has been documented in the literature as an approach for addressing class III malocclusion.[16,17] The optimal timing for intervention is during the eruption of the maxillary incisors, typically occurring between 7 and 9 years of age.[18] While protraction facemask therapy is a commonly employed early treatment method, it presents challenges, including issues with

Table 2: Deformation of maxilla with the force of 3.5, 5.5, and 9 N and angulation of 30°

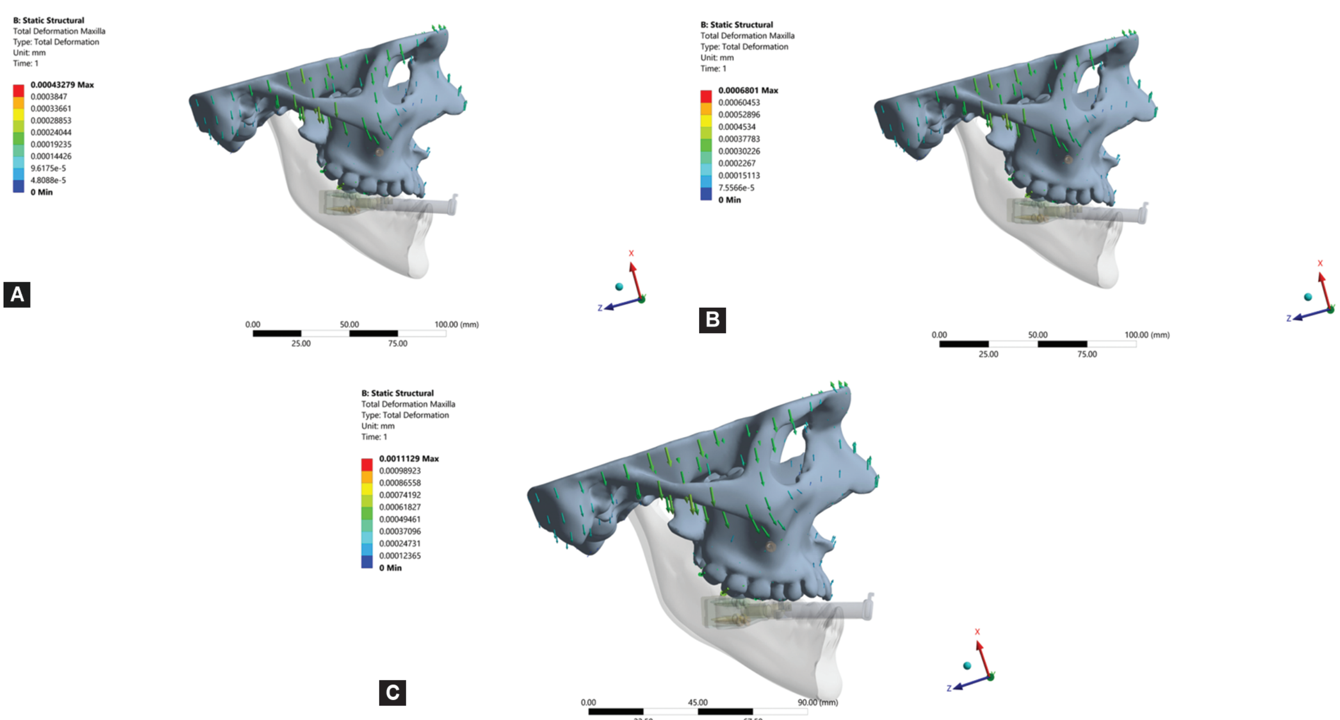
Force	*Zygomatico-maxillary (mm)*	*Nasomaxillary (mm)*	*Mastoid region (mm)*
3.5 N	0.00024044	0.0000480888	0.000096175
5.5 N	0.00037783	0.000075566	0.00015113
9 N	0.00061827	0.00012365	0.00024731

Table 3: Equivalent von Mises stress on SAVE appliance with the force of 3.5, 5.5, and 9 N and angulation of 30°

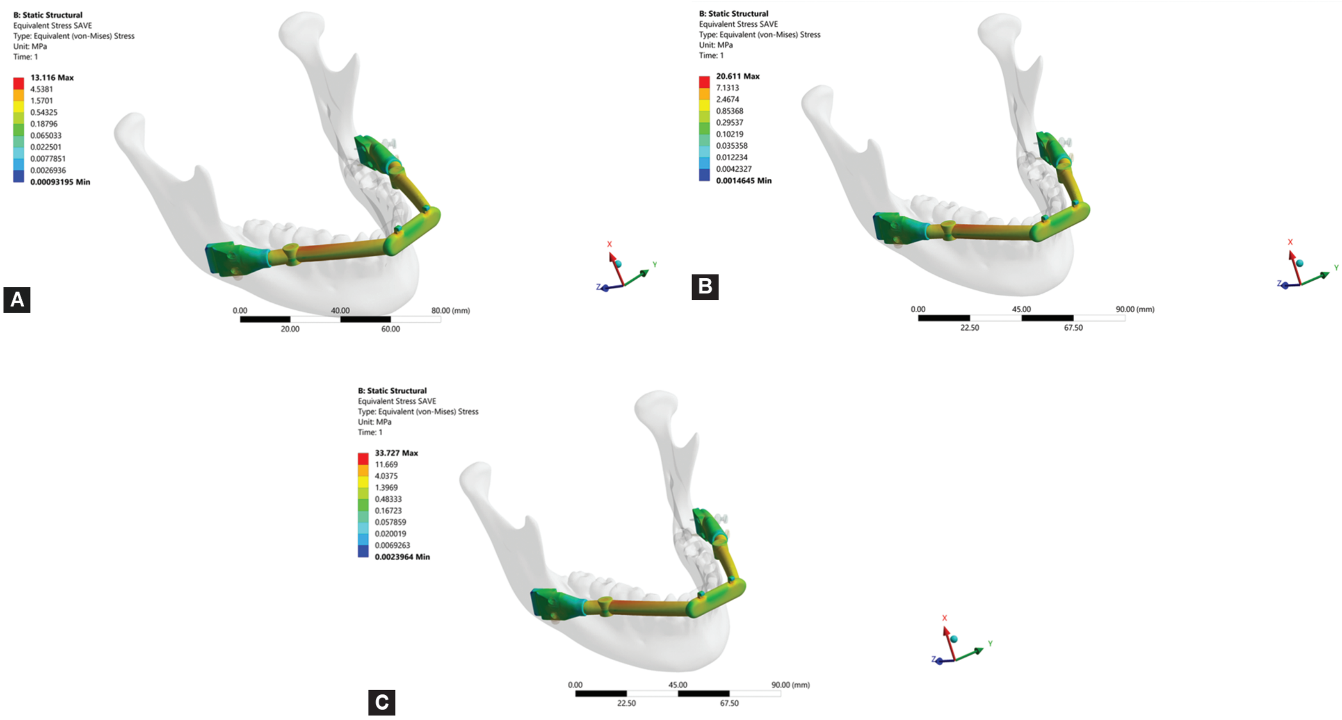
Force	*Equivalent von Mises stress*
3.5 N	13.116 Mpa
5.5 N	20.611 Mpa
9 N	33.727 Mpa

Table 4: Highest equivalent stress around the implant site in the maxilla with the force of 3.5, 5.5, and 9 N and angulation of 30°

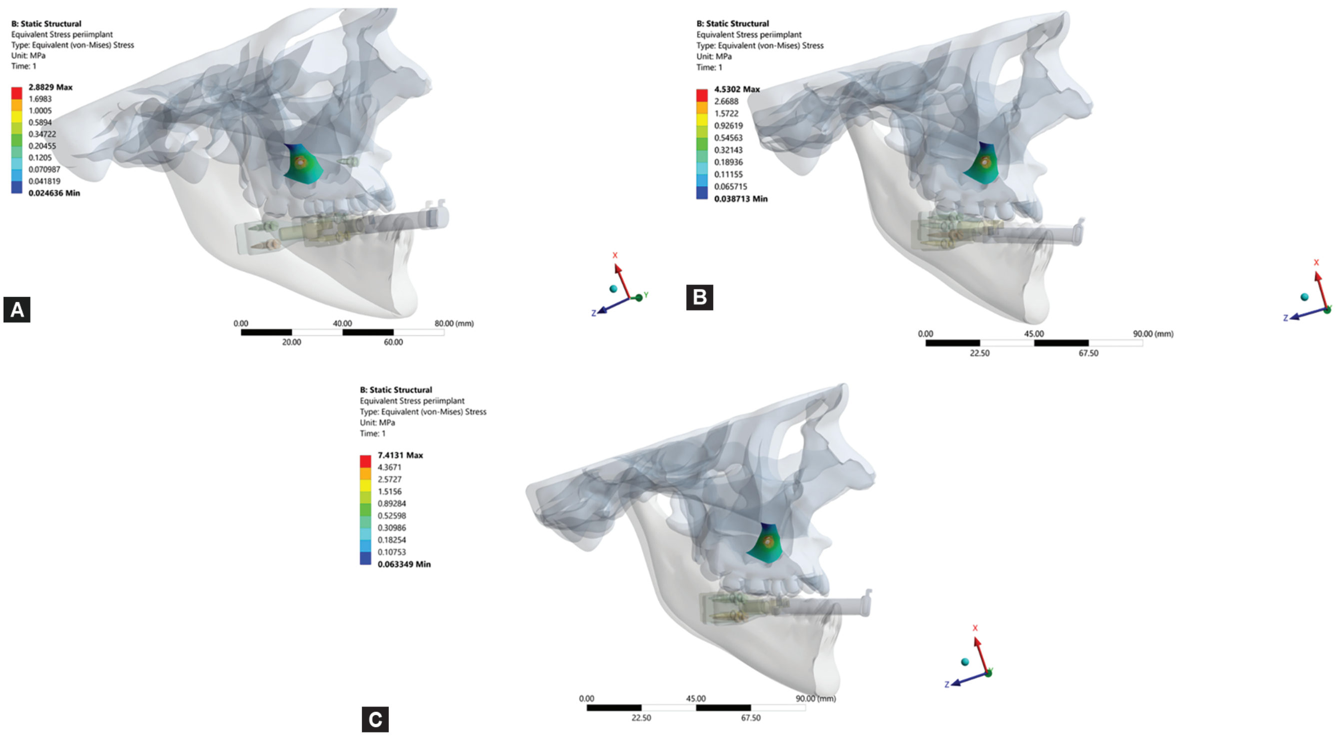
Force	*Equivalent von Mises stress*
3.5 N	2.882 Mpa
5.5 N	4.5302 Mpa
9 N	7.4131 Mpa



Figs 3A to C: (A) Total deformation, load of 3.5 N, 30° angulation; (B) Load of 5.5 N, 30° angulation; (C) Load of 9 N, 30° angulation



Figs 4A to C: (A) Equivalent von Mises stress, load of 3.5 N, 30° angulation; (B) Load of 5.5 N, 30° angulation; (C) Load of 9 N, 30° angulation



Figs 5A to C: (A) Equivalent stress around the implant site, load of 3.5 N, 30° angulation; (B) Equivalent stress around the implant site, 5.5 N; (C) Equivalent stress around the implant site, 9 N

patient compliance and undesired dentoalveolar effects.[19] The SAVE appliance has a minimalistic design, which is semifixed and will ensure increased patient compliance.

The SAVE appliance is also partially fixed, reinforcing patient compliance. The anchor heads of the appliance are fixed to the angle of the mandible with miniscrews. The introduction of skeletal anchorage systems has revolutionized maxillary protraction by using surgical mini plates for anchorage, ensuring skeletal support and maximizing orthopedic effects. The bone-anchored maxillary protraction method, or the BAMP protocol, introduced by De Clerck et al., is one where modified surgical mini plates are placed in both the maxilla and mandible, connected by class III intermaxillary elastics.[20] This technique applies pure bone-borne orthopedic forces for a longer time, minimizing dentoalveolar compensations and enhancing patient compliance. Despite the effectiveness of BAMP, it necessitates surgical intervention for both the insertion and removal of the appliance.[21] The complications of BAMP include increased failure rates when used in young patients due to poor bone quality.[22]

FEM analysis of the SAVE appliance with medical-grade PEEK polymer as a material shows that the maximum stress was seen on the superior surface of the main frame and on the area below the struts where the force module was attached. This stress was significantly low to cause permanent deformation or failure of the appliance because of the excellent strength, stiffness, and durability of PEEK polymer. The other advantages of PEEK are its biocompatibility and elastic modulus, which is comparable to that of cortical bone. The flexibility in designing and production with additive manufacturing (3D printing) paved the way for choosing a suitable material for this study.

A protraction force of 3.5, 5.5, and 9 N was applied with an angulation of 30° to the occlusal plane in the FEM model. The selected force levels ranged from orthodontic force to orthopedic force based on the literature.[17] The force vector showed deformation of the maxillary bone in a forward and downward direction. The deformation and distribution of the stress with respect to the zygomaticomaxillary, nasomaxillary, and mastoid regions showed a counterclockwise rotation and forward displacement of the maxilla in a desired manner.[18] Similar skeletal changes were observed in other maxillary protraction devices, such as the facemask.[19]

Maxillary protraction using the SAVE appliance is performed at a force level of 9 N, which is equivalent to 900 gm of orthopedic force on either side of the arch of the maxilla. This is an increase of 100 gm compared to the most-used force level.[23] However, it is still within the maximum allowable orthopedic force.[24] Consequently, the high force levels will result in a faster and shorter duration of maxillary protraction.

Conclusion

With this FEM study, it can be concluded that this novel device helps in the correction of class III malocclusion effectively in a forward and downward direction. The name "SAVE" stands for saving the retrognathic maxilla, thus avoiding surgical interventions. Further clinical evaluation is required to assess the efficacy and reliability of the SAVE appliance. The advantages of the SAVE appliance design are that it is more aesthetic, patient-friendly, offers better compliance, is hygienic, durable, and can withstand the application of heavy orthopedic forces to bring about faster skeletal changes.

Limitations

This study shows a positive change in response to the protraction force with the SAVE appliance on the maxilla. However, clinical outcomes may vary depending on individual variation in biological structures, as the model is considered isotropic since the incorporation of sutures was not possible due to technical constraints.

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References

1. Lacour M. Contraindications to the use of extraoral forces in dentofacial orthopedics. Rev Stomatol Chir Maxillofac 1976;77(3):563–567.
2. Küçükkeleş N, Nevzatoğlu S, Koldaş T. Rapid maxillary expansion compared to surgery for assistance in maxillary face mask protraction. Angle Orthod 2011;81(1):42–49. DOI: 10.2319/042210-220.1
3. Aileni KR, Rachala MR. Early treatment of class III malocclusion with Petit facemask therapy. Int J Orthod Milwaukee 2011;22(4):41–45.
4. Tanaka OM, Araújo EA, Oliver DR, et al. A finite element analysis of the maxillary first molar PDL with maxillary protraction in a mixed dentition class III malocclusion. Orthod Craniofac Res 2015;18(4):242–250. DOI: 10.1111/ocr.12102
5. Ngan PW, Hagg U, Yiu C, et al. Treatment response and long-term dentofacial adaptations to maxillary expansion and protraction. Semin Orthod 1997;3(4):255–264. DOI: 10.1016/s1073-8746(97)80058-8
6. Baik HS. Clinical results of the maxillary protraction in Korean children. Am J Orthod Dentofacial Orthop 1995;108(6):583–592. DOI: 10.1016/s0889-5406(95)70003-x
7. Parton AL, Tong DC, De Silva HL, et al. A 9 years review of orthognathic surgery at the University of Otago. N Z Dent J 2011;107(4):117–120.
8. Proffit WR, Turvey TA, Phillips C. Orthognathic surgery: a hierarchy of stability. Int J Adult Orthodon Orthognath Surg 1996;11(3):191–204.
9. Macdonald KE, Kapust AJ, Turley PK. Cephalometric changes after the correction of class III malocclusion with maxillary expansion/facemask therapy. Am J Orthod Dentofacial Orthop 1999;116(1):13–24. DOI: 10.1016/S0889-5406(99)70298-2
10. Kim JH, Viana MA, Graber TM, et al. The effectiveness of protraction face mask therapy: a meta-analysis. Am J Orthod Dentofacial Orthop 1999;115(6):675–685. DOI: 10.1016/s0889-5406(99)70294-5
11. Billiet T, de Pauw G, Dermaut L. Location of the centre of resistance of the upper dentition and the nasomaxillary complex. An experimental study. Eur J Orthod 2001;23(3):263–273. DOI: 10.1093/ejo/23.3.263
12. Jain S. Clinical tip for adjusting reverse pull Facemask/headgear assembly. J Clin Diagn Res 2016;10(1):ZH01–ZH02. DOI: 10.7860/JCDR/2016/16492.7125
13. Keles A, Tokmak EC, Erverdi N, et al. Effect of varying the force direction on maxillary orthopedic protraction. Angle Orthod 2002;72(5):387–396. DOI: 10.1043/0003-3219(2002)072<0387:EOVTFD>2.0.CO;2
14. Roberts WE, Viecilli RF, Chang C, et al. Biology of biomechanics: finite element analysis of a statically determinate system to rotate the occlusal plane for correction of a skeletal class III open-bite malocclusion. Am J Orthod Dentofacial Orthop 2015;148(6):943–955. DOI: 10.1016/j.ajodo.2015.10.002
15. Toth JM, Wang M, Estes BT, et al. Polyetheretherketone as a biomaterial for spinal applications. Biomaterials 2006;27(3):324–334. DOI: 10.1016/j.biomaterials.2005.07.011
16. Jones DP, Leach DC, Moore DR. Mechanical properties of poly(ether-ether-ketone) for engineering applications. Polymer 1985;26(9):1385–1393. DOI: 10.1016/0032-3861(85)90316-7
17. Gazzani F, Pavoni C, Giancotti A, et al. Facemask performance during maxillary protraction: a finite element analysis (FEA) evaluation of load and stress distribution on Delaire facemask. Prog Orthod 2018;19:1–5. DOI: 10.1186/s40510-018-0217-1
18. Tanne K, Sakuda M. Biomechanical and clinical changes of the craniofacial complex from orthopedic maxillary protraction. Angle Orthod 1991;61:145–152. DOI: 10.1043/0003-3219(1991)061<0145:BACCOT>2.0.CO;2

19. Westwood PV, McNamara JA, Baccetti T, et al. Long-term effects of class III treatment with rapid maxillary expansion and facemask therapy followed by fixed appliances. Am J Orthod Dentofacial Orthop 2003;123(3):306–320. DOI: 10.1067/mod.2003.44
20. De Clerck HJ, Cornelis MA, Cevidanes LH, et al. Orthopedic traction of the maxilla with miniplates: a new perspective for treatment of midface deficiency. J Oral Maxillofac Surg 2009;67:2123–2129.
21. Cevidanes L, Baccetti T, Franchi L, et al. Comparison of two protocols for maxillary protraction: bone anchors versus face mask with rapid maxillary expansion. Angle Orthod 2010;80:799–806.
22. Van Hevele J, Nout E, Claeys T, et al. Bone-anchored maxillary protraction to correct a class III skeletal relationship: A multicenter retrospective analysis of 218 patients. J Craniomaxillofac Surg 2018;46(10):1800–1806.
23. Baccetti T, Franchi L, McNamara JA. Treatment and posttreatment craniofacial changes after rapid maxillary expansion and facemask therapy. Am J Orthod Dentofacial Orthop 2000;118(4):404–413. DOI: 10.1067/mod.2000.109840
24. Gazzani F, Pavoni C, Cozza P, et al. Stress on facial skin of class III subjects during maxillary protraction: a finite element analysis. BMC Oral Health 2019;19(1):31. DOI: 10.1186/s12903-019-0724-6