

## Evaluation of Stress and Displacement in Maxillary Protraction in Facemask, Save (Biomedical Grade Peek) and Save (Stainless Steel) in Cleft Lip and Palate- An FEM Study

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### Abstract

**Introduction:** Maxillary deficiency is frequently observed in patients with operated unilateral complete cleft of the lip and palate. Orthopedic appliances such as facemask are commonly used in the correction of skeletal Class III in growing patients with maxillary deficiency. However, these appliances require patient compliance and social acceptance of wearing which affect the overall success rate. To overcome the limitations of Facemask therapy in skeletal Class III malocclusion, a novel device called "SAVE" has been developed. SAVE being a prototype, required a FEM study to understand the intricacies of the device. The present FEM study is conducted to assess the efficiency of SAVE in cleft lip and palate patients by comparing its device properties with the currently available gold standard, facemask appliance. **Methodology:** Three different forces were applied (600 grams, 800 grams and 900 grams) to the Finite Element Models (FEM) of three appliances (SAVE SS (Stainless Steel), SAVE (Biomedical Grade PEEK), and Facemask) used for maxillary protraction. The equivalent stress and Deformation on the appliance and the maxilla were measured and analyzed. **Results:** The result of the analysis revealed that the SAVE SS appliance generated lower stress at the anchorage head, moderate stress at the stents, and the highest stress at the main frame rod, although still less than the facemask. SAVE PEEK showed the least stress across all components, while the facemask recorded the highest stress, particularly at the crossbar and anchorage units. Regarding deformation, SAVE SS exhibited the least deformation, mainly near the anchorage unit, while SAVE PEEK displayed greater deformation, especially at the stents. The facemask experienced the highest deformation, primarily at the crossbar. Overall, SAVE SS demonstrated higher stress and lower deformation, making it a promising alternative to the facemask. **Conclusion:** The SAVE SS appliance could be used as an alternative to Facemask as it demonstrates higher stress and lower deformation with higher forces in both the maxilla and the appliance, suggestive of its use in maxillary protraction with less deformation in the appliance. Thus, SAVE SS shows strong potential to evolve as a dependable, patient-friendly alternative for early orthopedic correction in cleft patients

**Keywords:** Class III Skeletal malocclusion, Cleft lip and palate, SAVE, Facemask therapy, Stress and Deformation, Finite Element Method, FEM study

### Introduction

Despite the meticulous development of the medical technologies, management of skeletal class III malocclusions still remains one of the most challenging to Orthodontists.

Majority of subjects with a skeletal class III malocclusion present with maxillary retrusion and a normal or prognathic mandible or a combination of both.[1]

Maxillary deficiency is frequently observed in patients with operated unilateral complete cleft of the lip and palate.[2] Globally, it is estimated that prevalence of cleft lip with or without cleft palate ranges from 7.94 to 9.92 per 10,000 live births.[2] Overall, oral clefts in any form (i.e., cleft lip, cleft lip and palate, or isolated cleft palate) occur in about one in every 700 live births. [3]

Facemask therapy along with maxillary expansion is one of the conventional methods of treatment of class III in growing children with cleft lip and palate.[4] However, these appliances require patient compliance, skin irritation from the anchorage pads, and social acceptance of wearing which affect the overall success rate.[4-6]

Recently bone anchored maxillary protraction (BAMP) has been used. It attains absolute anchorage from miniscrews anchored in bone. BAMP have noticeably provided better results in the class III malocclusion treatment. [7] However, requirement of incision during placement, chances of infection, possible tooth germ injury, and irritation of the adjacent tissues by elastics or miniplates are the limitations of BAMP. The miniplates can also loosen due to insufficient bone density at early ages. [8]

With advancements in craniofacial orthopedics, multiple modifications of protraction techniques have been introduced to improve skeletal effects and reduce dependence on patient cooperation. Yet, despite these innovations, clinicians often confront challenges related to the biological limitations of the maxillary sutures, variability in healing responses, and the presence of postoperative scar tissue in cleft lip and palate patients. These factors not only reduce the predictability of orthopedic outcomes but also alter the vectors of force distribution, leading to inconsistent results across individuals. Furthermore, psychosocial factors such as discomfort, visibility of external appliances, and the impact on daily routines often decrease adherence, ultimately compromising treatment success. Thus, there remains a strong clinical demand for appliances that combine biomechanical efficiency with enhanced patient acceptability.

The evolution of skeletal anchorage systems has undeniably improved the orthopedic management of Class III malocclusions, yet the search for an ideal protraction device continues. An optimal appliance should deliver consistent orthopedic forces, minimize undesirable dental effects, avoid invasive surgical procedures, and remain comfortable enough to ensure uninterrupted wear. In cleft patients, the appliance must also accommodate altered anatomy, reduced bone availability, and increased susceptibility to soft tissue irritation. These stringent requirements highlight the need for a novel design

that reduces overall bulk, enhances stability, and eliminates the drawbacks associated with conventional facemask therapy and earlier bone-anchored systems. In this context, innovation in material science and digital biomechanical evaluation has opened new possibilities for designing next-generation appliances tailored to the unique needs of these patients.

To address these limitations of the treatment modalities like facemask, Facemask + RME, BAMP in maxillary protraction for Class III malocclusion, an innovative and novel device called "SAVE" was developed. This novel appliance is smaller in size with detachable components making it more patient compatible all while yielding optimal results in a shorter duration of time.

SAVE applies force through intraoral elastics to implants in both the upper and lower jaws. This appliance was designed to protract deficient maxilla in skeletal Class III malocclusion including patients with cleft lip and palate. As SAVE is a prototype, it required a FEM study to understand the intricacies of the device and to upgrade to a better version for its clinical use following the results of the study.

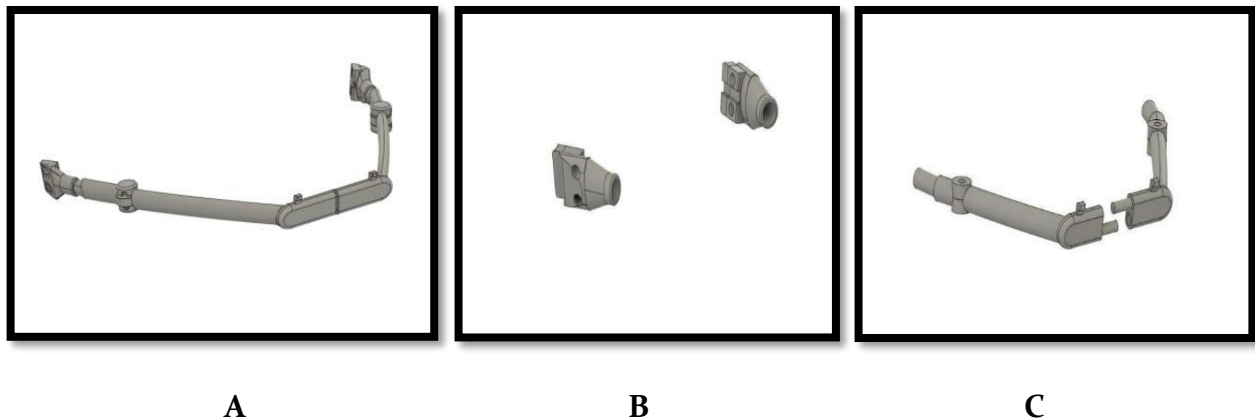
The Finite Element Method (FEM) is a valuable engineering tool that has been found in increasing use in the field of orthodontics due to its ability to deliver detailed yet precise information regarding stress on load application. It divides the object of study into a finite number of elements connected by a meshwork thereby making each element an individual object of study. [16] The FEM principle hinges on dividing complex structures into smaller elements, allowing for the application of physical properties like the modulus of elasticity to assess the object's response to external stimuli, such as orthodontic forces. [10]

Thereby, the present FEM study aims to analyze the stress distribution and deformation on the device and the maxilla with different protraction forces using SAVE (Biomedical Grade PEEK), SAVE (Stainless Steel) and to compare the same with Facemask appliances in Cleft Lip and Palate patients.

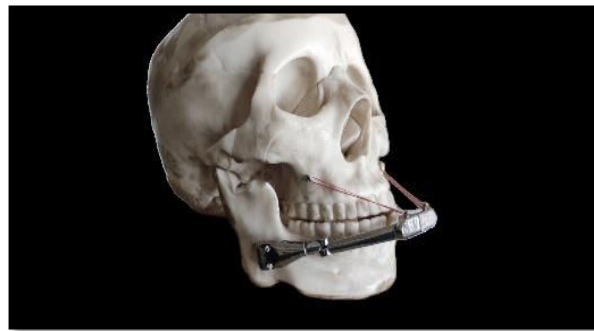
### **Methodology:**

SAVE is a novel maxillary protraction device which is semi fixed. It consists of an anchor head attached to the angle of mandible intra orally using bone screws. The right and left frame with struts for engaging elastics are detachable from the anchor heads. It was designed and printed with two different biomedical grade materials namely PEEK and Stainless Steel. (Fig 1 & 2) These were compared with the Petit type of face mask consisting of forehead cap, chin cap and a metal framework with a crossbar using Finite Element Method. Three-dimensional model of the skull was prepared with an existing CT

image of a cleft lip and palate patient with maxillary deficiency. Using the MIMICS software and CATIA V5 R19, a solid model was created. This geometric model was converted into a Finite Element Model.

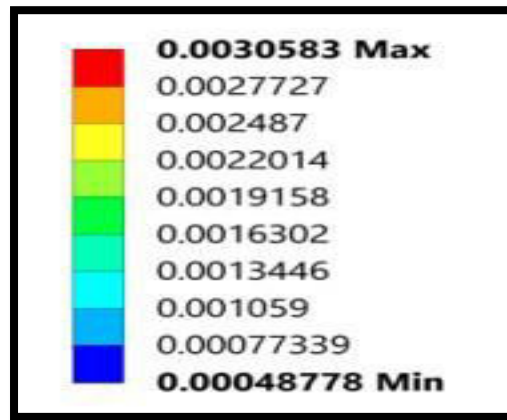


**Figure 1; a) Complete assembly of 3D modeled SAVE appliance, b) Anchorage head (Left and right), and c) Mainframe (Left and right)**



**Figure 2; Prototype of SAVE appliance**

Young's modulus and Poisson ratio were assigned to the modeled structure. (Table 1) The stress and deformation during maxillary protraction in Facemask, SAVE (Biomedical Grade PEEK) and SAVE (Stainless Steel) for three forces; 600g, 800g and 900g were obtained and compared. The results were obtained in the form of graphical design in which colors (varying from red to blue) represent the magnitude of Stress/Strain and deformation at that area. The palate of colors along with values is depicted on the side of the images. (Fig 3)



**Figure 3; The Color Representation of the magnitude of stress/strain and deformation**

**Table 1 - Material properties of different structures and orthodontic materials**

Material	Young's Modulus (E)	Poisson's ratio
Cancellous Bone	0.05-0.5 GPa	0.12
Compact Bone	7-30 GPa	0.40
Stainless Steel	160-180 GPa	0.30
Polyether Ether Ketone(PEEK)	3.5-3.9 GPa	0.39
Density of Cortical Bone		1600-2000 kg/m <sup>3</sup>
Density of Cancellous Bone		40-600 kg/m <sup>3</sup>

## Results

On application of 600 gms, 800 gms and 900 gms of force to the Finite Element Model of SAVE SS, the results obtained were such that the total stress on the appliance was 0.79689 MPa, 1.0639 MPa, and 1.1967 MPa respectively. (Table 2). Maximum stress corresponding to the color red was not seen anywhere along the appliance (Fig 4) The lowest stress was seen at the anchorage head (color blue). moderate levels of stress were seen near the struts (color yellow green), and the highest equivalent stress was seen on the main frame rod (color orange yellow).

In terms of total deformation of the appliance, the total deformation of the FEM model of SAVE SS was 2.57E-03 mm (Table 2). The highest deformation on the appliance was seen near the area corresponding to the struts and the least was seen towards the anchorage unit (Fig 5).

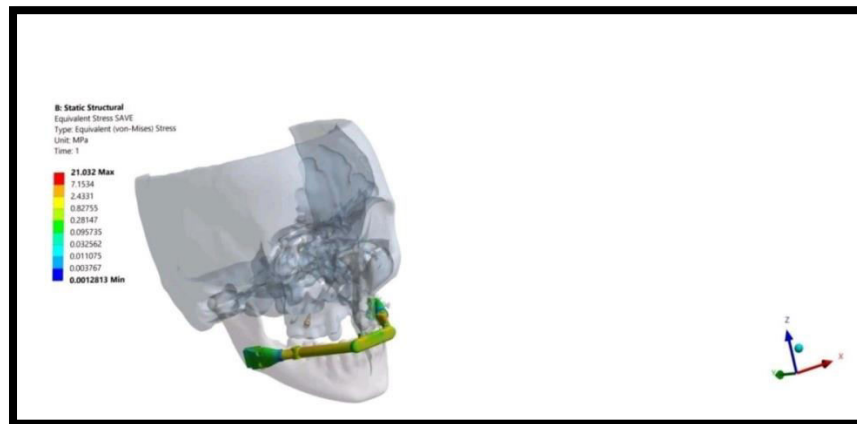


Figure 4; Equivalent Stress SAVE- SS

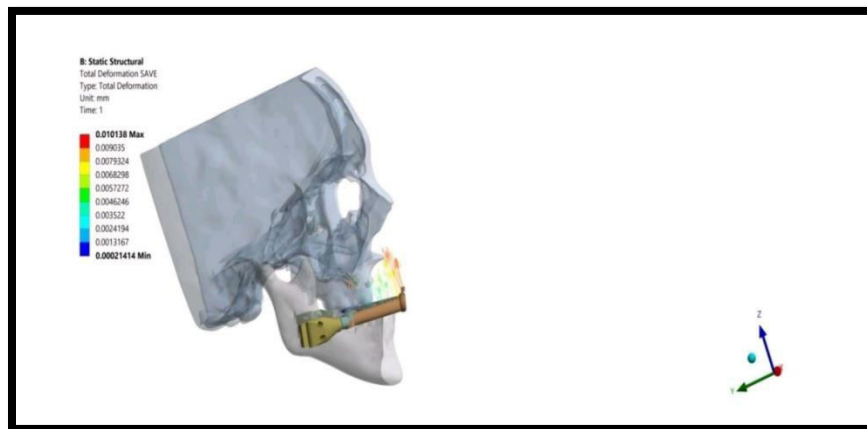


Figure 5; Total Deformation SAVE SS

Table 2; Equivalent Stress and total deformation of SAVE SS

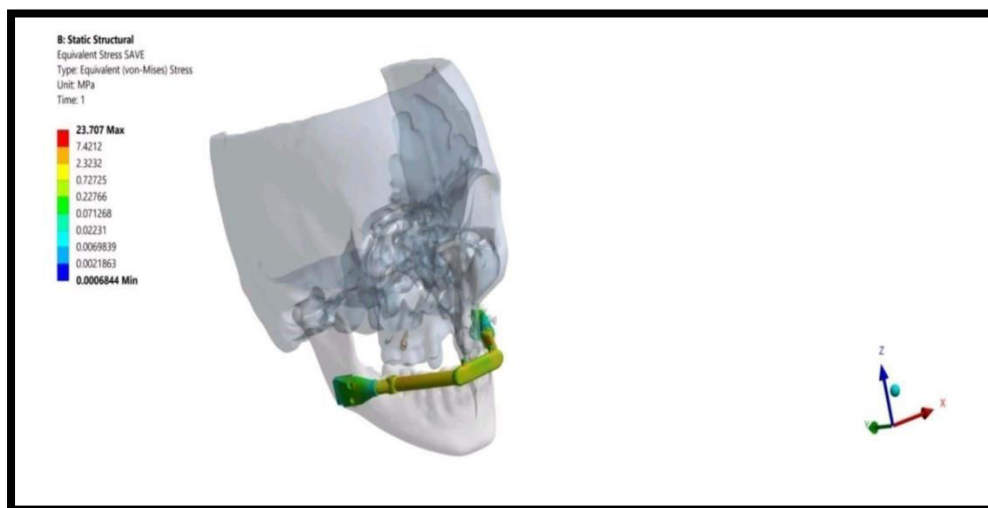
VARIABLES	FORCE 1 - 600 gms	FORCE 2 - 800 gms	FORCE 3 - 900 gms
Equivalent Stress ALL	5.07E-02	0.067653	0.0760990
Equivalent Stress SAVE(SS)	0.79689	1.0639	1.1967
Equivalent Stress Mandible	4.27E-02	0.057035	0.064156
Equivalent Stress Maxilla	1.65E-02	2.21E-02	2.49E-02
Equivalent Stress Implants	3.2728	4.3693	4.9148
Equivalent Stress peri-implant	1.50E+00	2.0068	2.2574
Equivalent Stress condyle	2.64E-01	3.52E-01	0.39636
Total Deformation ALL	2.63E-04	0.0003506	0.00039437
Total Deformation Maxilla	1.04E-04	0.00013893	0.00015627
Total Deformation Mandible	3.91E-04	0.00052183	0.00058697
Total Deformation SAVE(SS)	2.57E-03	0.0034352	0.003864

On application of 600 gms, 800 gms and 900 gms, the results obtained were such that the total stress on the appliance was 0.6096 MPa, 0.81384 MPa, and 0.38565 MPa respectively was noted with the FEM model of SAVE PEEK appliance (Table 3). Similar to SAVE SS, maximum stress levels were not seen anywhere along the appliance (Fig 6). The lowest stress levels were seen with respect to the anchorage heads (color blue). Moderate levels of stress seen near the struts (color yellow green) and the highest equivalent stress seen at the main frame rod (color yellow).

The total deformation on SAVE PEEK was a little higher than SAVE SS. The model had a deformation value of 6.53E-03 mm (Table 3). Similar to SAVE SS highest deformation seen near the struts area, and the least deformation seen at the anchorage head and the main frame rod (Fig 7).

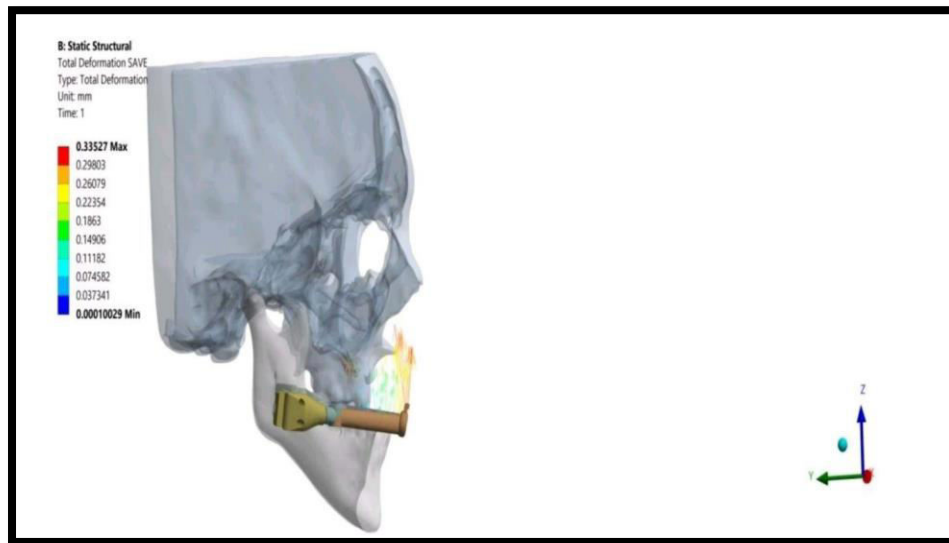
**Table 3; Equivalent Stress And Total Deformation Of Save-Peek**

VARIABLES	FORCE 1- 600 G	FORCE 2- 800 G	FORCE 3- 900G
Equivalent Stress ALL	0.25681	0.34285	0.38565
Equivalent Stress SAVE(P)	0.6096	0.81384	0.91544
Equivalent Stress Mandible	6.93E-02	9.25E-02	1.04E-01
Equivalent Stress Maxilla	1.67E-02	2.23E-02	2.51E-02
Equivalent Stress Implants	3.2719	4.3681	4.9134
Equivalent Stress peri-implant	1.50E+00	2.0071	2.2576
Equivalent Stress condyle	3.74E-01	4.99E-01	5.62E-01
Total Deformation ALL	1.67E-03	2.23E-03	2.50E-03
Total Deformation Maxilla	8.41E-05	1.12E-04	1.26E-04
Total Deformation Mandible	4.52E-04	6.03E-04	6.79E-04
Total Deformation SAVE(P)	6.53E-03	8.72E-03	9.81E-03



**Figure 6; Equivalent Stress SAVE-PEEK**





**Figure 7; Total Deformation SAVE PEEK**

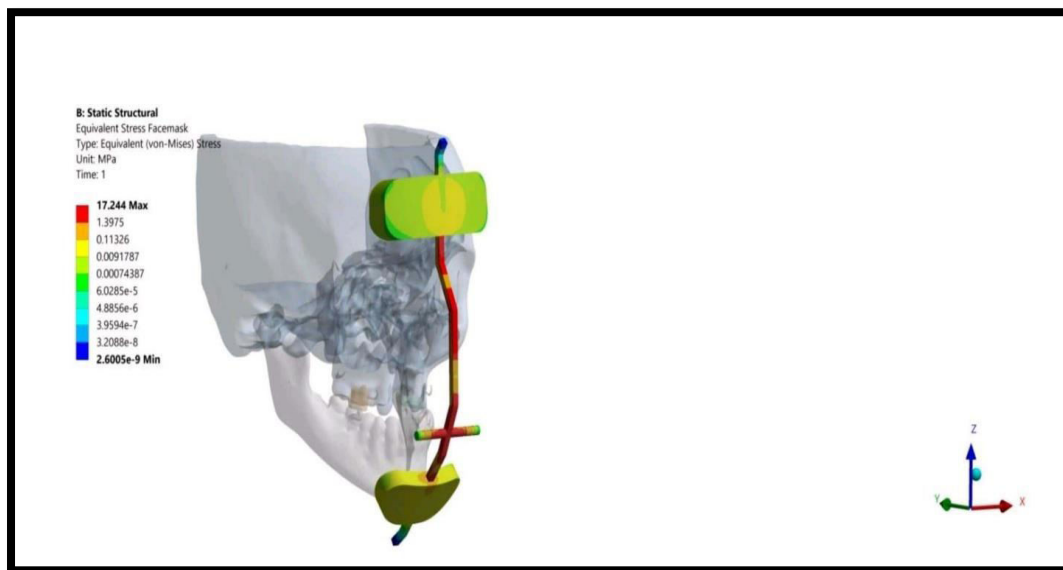
The equivalent stress on the FEM model of facemask on application of 600 gms, 800 gms and 900 gms were 0.34161 MPa, 0.45606 MPa, and 0.513 MPa respectively (Table 4 and Fig 8). The highest stress levels were seen at the crossbar (color red). Moderate levels of stress are seen at the forehead cap and chin cap (color yellow green)

The total deformation on the FEM model of Facemask was higher than both SAVE SS and SAVE PEEK. The total deformation value for the facemask was 3.74E-03 mm. The highest deformation is seen at the crossbar of the mainframe (Fig 9).

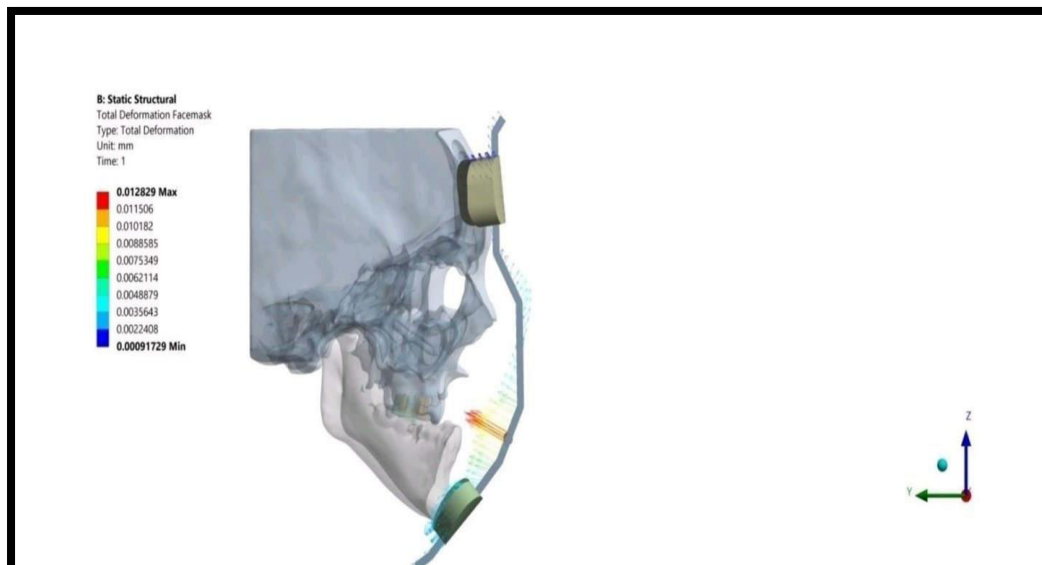
**Table.4. Equivalent Stress and total deformation of Facemask**

VARIABLES	FORCE 1 - 600 G	FORCE 2 - 800 G	FORCE 3 - 900 G
Equivalent Stress ALL	5.07E-02	0.067653	0.076099
Equivalent Stress Facemask	0.34161	0.45606	0.513
Equivalent Stress Mandible	0.058648	0.078297	0.088071
Equivalent Stress Maxilla	0.025381	0.033885	0.038115
Equivalent Stress Condyle	6.86E-02	0.091599	0.10303
Total Deformation ALL	7.31E-04	0.0009755	0.0010973
Total Deformation Maxilla	4.56E-04	0.00060888	0.00068489
Total Deformation Mandible	8.91E-04	0.0011896	0.0013381
Total Deformation Facemask	3.74E-03	0.0049897	0.0056126





**Figure 8; Equivalent Stress FACEMASK**



**Figure 9; Deformation of the appliance Facemask**

On increasing the force levels, there was an increasing trend seen with respect to the values of the equivalent stress and total deformation of all the three FEM models of the appliances. The SAVE PEEK experiences maximum amount of deformation and SAVE SS experiences the least amount of deformation in the appliances with increasing loads of force.

## Discussion

Cleft lip and palate is a condition in which there is incomplete union of the skeletal and soft tissue processes during development. It can be limited to the soft tissue i.e. lips or it

can extend to the alveolar process to palate. Due to this hypoplasia of the maxilla is usually seen which gives those patients a skeletal class III.[11]

The treatment of Class III malocclusion with maxillary deficiency aims to protraction of maxillary complex which can be achieved by surgery in non-growing adults and by non-surgical techniques in growing patients.[12] The facemask is the most common maxillary protraction appliance used in correcting a Class III malocclusion caused due to deficient maxilla in a growing individual. Discomfort, compliance issues and aesthetic concerns associated with extra oral appliances like the face mask play a significant role in treatment acceptance and adherence.[13-16]

The limitations of traditional treatment modalities led to the introduction of a novel appliance designed for maxillary protraction, known as the SAVE appliance. This appliance offers several advantages over traditional modalities, including a smaller size, detachable components, and improved patient compatibility. By reducing the physical appearance of extra oral appliances and minimizing discomfort associated with intraoral devices, the SAVE appliance aims to enhance patient acceptance and compliance while achieving optimal treatment outcomes in a shorter duration.

Yan et al. (2013)[1] revealed that bone anchorage resulted in more translatory movement of the craniomaxillary complex compared to dental anchorage, with differential stress patterns along the sutures and bone surfaces. Similarly in our study the FEM analysis showed higher stress and deformation in maxilla when forces were applied in the SAVE SS group than in the Facemask group which can be attributed to the anchorage point for force application. However the SAVE PEEK group showed the least amount of stress and deformation in the maxilla when forces were applied.

Our study showed that there is significant stress formation in the facemask group along with a significant amount of deformation in the appliance which is similar to the study by Gazzani et al.(2018) [17]. According to the authors, higher protraction forces and downward force inclinations resulted in increased stresses and deformations on the facemask structure. However, the facemask demonstrated elastic deformation within the limit of its material properties, indicating its ability to withstand protraction forces without compromising performance.

Gaetano Ierardo et al (2017) [18] utilized digital workflows to fabricate orthodontic space maintainers using PEEK polymer, highlighting the advantages of PEEK, such as biocompatibility and customization, in fabricating effective orthodontic appliances. Bathala et al. [19] revealed that PEEK has shown better properties, expanding its

applications beyond implant materials to various clinical situations in dental practice because of its superior mechanical properties as well as biocompatibility.

PEEK is a high-performance, thermoplastic and heat resistant material. It has good mechanical properties, resistant to chemical attack, resistant to abrasion and resistant to hydrolysis. It is lightweight, self-lubricating and has very good flow during processing. It can be filled with carbon fibre, graphite, molybdenum disulphide to further improve the mechanical strength.[20,21]

In the present study while comparing the stress and displacement using facemask, SAVE (SS) and SAVE (PEEK) it was observed that the amount of stress and displacement produced by SAVE PEEK in maxilla is the least which makes PEEK polymer an ineffective material.

FEM analysis gives an insight to the working of these appliances in digital workflow which can be used to analyse the changes it brings about in a model. In the current study the amount of stress and displacement is analysed for a novel appliance SAVE and a conventional treatment modality using facemask on a patients finite elemental model with cleft.

Also, the facemask group showed anticlockwise deformation of maxilla which is dependent on the point of force application. While this is the case, the deformation of maxilla by SAVE appliance was clockwise. The study was conducted by giving forces of 600gms, 800gms and 900gms to the maxilla. The increasing force showed development of more stress and displacement across all models. Similarly the stress and deformation among the appliances showed that the deformation is least in the SAVE SS group and highest in SAVE PEEK group. Equivalent stress showed highest value by SAVE SS and least by Facemask.

With the ability to adjust the location and angulation of mini-implants, clinicians can customize treatment plan and the SAVE to suit the specific needs and anatomy of each patient. This level of control can lead to more predictable outcomes, comfort and potentially shorter treatment durations compared to Facemask therapy, where adjustments are limited to appliance fit and elastic force levels.

Furthermore, the SAVE appliance minimizes the risk of soft tissue irritation or discomfort commonly associated with extraoral appliances like the Facemask. Unlike Facemask, SAVE minimizes the reliance on patient compliance for treatment success. This can lead to improved patient comfort and satisfaction throughout the course of treatment. Though Facemask therapy remains a valuable treatment modality in treatment of skeletal Class

III, SAVE could be particularly advantageous in cases where patient cooperation may be challenging to maintain, such as with younger children or individuals with behavioral or compliance issues.

Another important aspect worth considering is the clinical practicality of incorporating the SAVE appliance into routine orthodontic practice, particularly in centers managing a high volume of cleft lip and palate cases. The simplified design and intraoral anchorage may reduce chairside time, streamline follow-up visits, and make the overall workflow more efficient for clinicians. In addition, the ability to digitally simulate stress distribution through FEM before clinical application supports a more individualized approach to treatment planning, allowing orthodontists to anticipate outcomes and plan modifications in advance. This integration of digital biomechanics with appliance innovation aligns with the current movement toward precision orthodontics, where customized, patient-specific interventions are preferred. Although the results of this FEM study are promising, future research incorporating long-term clinical data, patient-reported outcomes, and comparative studies in larger populations will be valuable in establishing the SAVE appliance as a reliable alternative to existing protraction methods.

In addition to biomechanical advantages, the SAVE appliance also presents potential benefits from a psychosocial perspective, especially in young cleft patients who often struggle with self-esteem and social acceptance. Traditional extraoral appliances like the facemask can draw unwanted attention, sometimes discouraging consistent use and affecting emotional well-being. In contrast, SAVE's entirely intraoral design minimizes visibility and may positively influence a patient's willingness to undergo and continue treatment. This increased acceptance can translate into more consistent force application and better cooperation, ultimately enhancing the overall effectiveness of the protraction therapy. As patient-centered care becomes more prioritized, such considerations are increasingly significant in appliance selection.

It should be noted that the investigated appliance "SAVE" is a prototype which offers several advantages with few setbacks. We plan to overcome these setbacks with further studies with application of other appropriate material for SAVE which could possibly produce equally effective results as the gold standard treatment "Facemask". Further clinical studies are essential for assessing the changes and efficiency of the SAVE appliance to better evaluate it and compare it to the established treatment modalities.

## Conclusion

The finite element method (FEM) analysis yielded observations across three scenarios: SAVE SS, SAVE PEEK, and FACEMASK. In SAVE SS, equivalent stress implants exhibited the highest value, while total deformation SAVE PEEK had the highest value for total

deformation. FEM analysis highlighted equivalent stress of SAVE SS as the most influential. Our study shows promising results for the use of SAVE SS for the correction of maxillary deficiency in patients with cleft lip and palate. These findings offer a new horizon of clinical intervention considering patient compliance in high regard. Its favorable stress distribution profile further supports its suitability for future clinical validation and wider orthodontic application

In addition, the comparison with traditional facemask therapy further emphasized the mechanical advantages of the SAVE system. While facemask appliances rely heavily on extraoral anchorage and patient cooperation, the FEM results demonstrated that SAVE devices—particularly SAVE SS—delivered more concentrated and efficient stress distribution directly to the maxillary complex. This targeted load transfer minimizes unwanted dental displacement and enhances orthopedic response, which is especially crucial in cleft lip and palate patients where surgical scarring and altered bony anatomy often limit the effectiveness of conventional appliances. Thus, the FEM outcomes validate the biomechanical potential of SAVE SS as a stable, internally anchored protraction method that may significantly improve predictability and treatment efficiency in clinical practice.

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