

Rampa

- Down Syndrome
- Antley-Bixler Syndrome
- Arnold Chiari Malformation

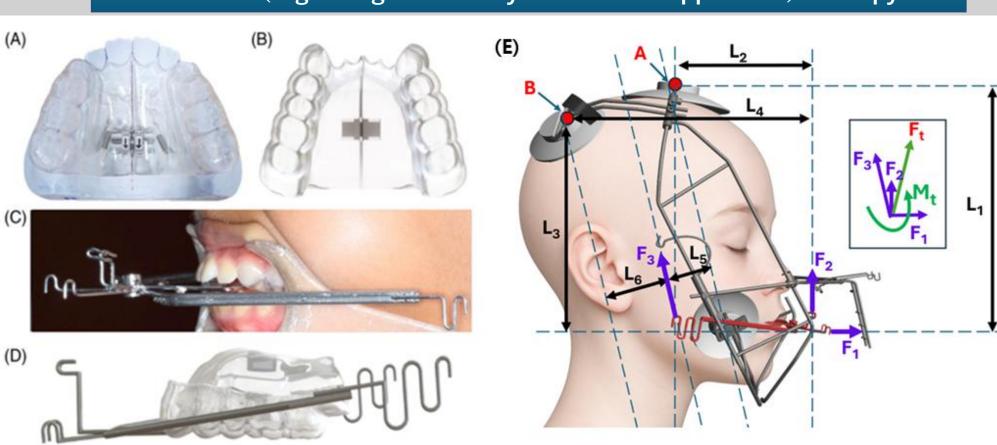
Nonsurgical Treatment of Down syndrome patients using RAMPA therapy: Craniomaxillofacial growth guidance method

Yuko Okai-Kojima¹, Yasushi Mitani², Bumkyoo Choi³, Morio Tonogi⁴, Shouhei Ogisawa^{4,5}, Takehiko Shimizu⁶, Seiko Nemoto-Yamamoto⁶, Nakada Hiroto⁷, Yamaguchi Rie⁸, Dakemura Ryo⁹

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Introduction: RAMPA Therapy (RT) is a nonsurgical treatment method that uses an extraoral device and an intraoral device simultaneously to induce anterosuperior protraction of the skull and expansion of the palatine bone (maxilla). Patients with Down syndrome frequently present with craniofacial abnormalities, such as midfacial hypoplasia, which contribute to a cascade of clinical issues including chronic sinusitis and Obstructive Sleep Apnea (OSA). This case report details the comprehensive, multi-systemic improvements observed in a Down syndrome patient following a craniomaxillofacial growth guidance protocol (RT).

RAMPA (Right Angle Maxillary Protraction Appliance) therapy



RAMPA System

Subject

The patient was a 14-year-old girl who was diagnosed with mosaic Down syndrome after birth and was initially diagnosed with sinusitis and malocclusion of the teeth.

Methods

<u>CBCT Image</u>: KaVo 3D eXam+ (KaVo Dental Systems)

Photographs were taken at the first visit (before treatment) and 137 days after the start of treatment (after treatment).

Method of Treatment: RT is used to expand the dentition and three-dimensionally expand the maxillary complex to secure space for tooth

eruption^[1-3] for 1 cycle of RT. RT was performed for 137 days. Image Analysis: Threshold Range $-1000 \sim -625$

Image analysis was performed with the nasal cavity ranging from the anterior edge of the adenoid to the external nostril

Analysis Item: * Presence of opacity of sinuses and morphometry of the nasal cavities

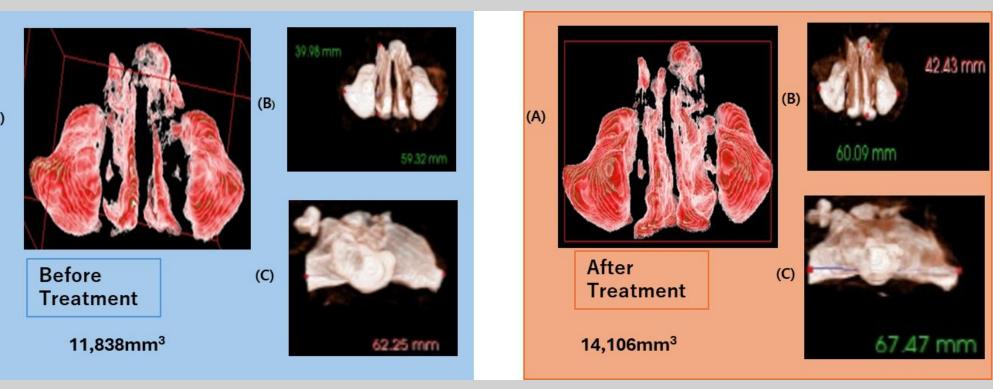
> * The Sino-Nasal Outcome Test (SNOT-22) is a QOL questionnaire used to evaluate the effectiveness of treatment for rhinosinusitis. The test was conducted when no obvious cold symptoms were observed.



❖ The left photo is before treatment, and the right photo is after RT. Improvement in the three-dimensional effect of the eyeball and the asymmetry of the corners of the mouth can be seen before and after RT.

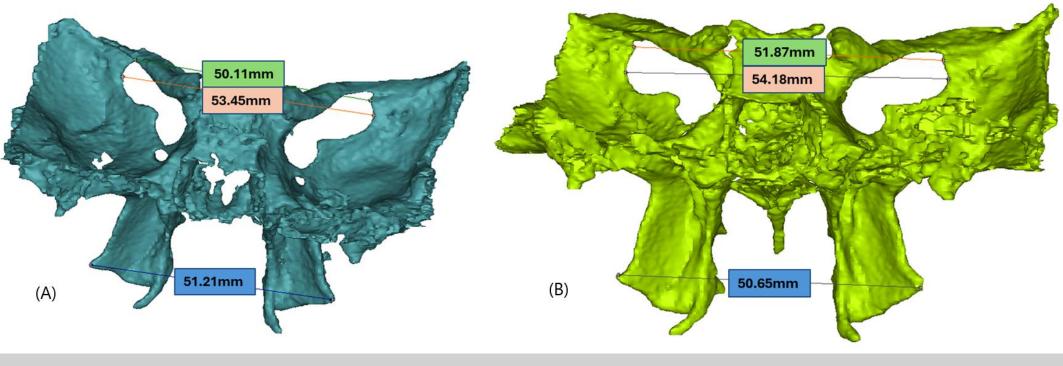


❖ The narrowed palate and distortion have improved, the



CT measurements of the nasal cavity; (A) Volume, (B) Vertical & Horizontal lengths, (C) Anterior & Posterior lengths

❖ The volume increased by 19%.



❖ Before treatment, mucosal thickening was observed in the maxillary and sphenoid sinuses, but CT images taken 137 days after treatment showed that the opaque appearance of the maxillary sinus had changed to a transparent appearance, and the opening of the right maxillary sinus ostium was confirmed.

Change of sphenoid bones; (A) at first visit, (B) after RT

❖ The transformation of the sphenoid bone from RAMPA therapy is profoundly significant. It's not just a change in shape—it's a foundational improvement that enhances overall health. This single change expands the airway to improve breathing, which in turn corrects posture and guides healthy facial growth. It also stabilizes the pituitary gland, allowing for balanced hormonal function, and secures critical neuro-vascular pathways, optimizing the body's core physiological systems.

Results: Following the treatment period, a comprehensive and multi-systemic improvement was observed:

- 1. Sinus and Nasal Improvement: Post-treatment CT scans showed the disappearance of sinus opacity and the complete opening of the previously blocked right sinus ostium. The nasal cavity volume increased by 19%, correlating with a dramatic improvement in subjective symptoms, as evidenced by the SNOT-22 score dropping from **62 to 1**.
- 2. Airway and Sleep Apnea Resolution: The cross-sectional area of the narrowest part of the airway increased by nearly 70% (from 35.3 mm² to 59.7 mm²). Consequently, the AHI was reduced from **8.9 to 2.3**, falling within the range considered optimal for children, and habitual snoring was resolved.
- 3. Craniofacial and Skeletal Remodeling: Significant structural improvements were noted, including the correction of the narrowed palate, alignment of the upper and lower jaw midlines, and a visible reduction in facial asymmetry.
- 4. Sphenoid Bone Transformation: Critically, CT analysis confirmed an anterosuperior movement and morphological change of the sphenoid bone. This change in the keystone bone of the skull base signifies a deep, foundational remodeling of the entire cranial structure, not merely a localized maxillary or dental shift.
- 5. Auditory Function Improvement: An interesting secondary finding was the natural release of impacted earwax, suggesting improved Eustachian tube function secondary to the expansion of the upper airway.

Discussion and Conclusion: The results of this case are significant as they demonstrate that a single, non-invasive therapeutic intervention can address a wide array of interconnected symptoms. The treatment did not merely manage symptoms but corrected the underlying structural etiology of midfacial hypoplasia. The profound change in the sphenoid bone, in particular, validates the treatment's ability to induce true craniofacial remodeling. This growth guidance approach presents a powerful and holistic treatment paradigm for improving not only airway and respiratory health but also overall craniofacial structure and quality of life in patients with Down syndrome.

- 1. Mitani Y, et al., Craniofacial changes in patients with Class III malocclusion treated with the RAMPA system., Int. j. Orthod. 21(2): 2-8, 2010.
- 2. Mitani Y, et al., Anterosuperior protraction of maxillae using the extraoral device, RAMPA; finite element method, CMBBE, 21(13): 722-729, 2018.
- 3. Mitani Y, et al., Finite element and clinical analyses of effects of a new intraoral device (VomPress) combined with extraoral RAMPA on improving the overjet of craniofacial complex, CMBBE, 25(10): 1099-1110, 2022
- 4. L. K.-Gozal, What Is "Abnormal" in Pediatric Sleep?, RESPIRATORY CARE, 55(10): 1366-1376, 2010





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(A) RAMPA intraoral appliance, (B) Appearance wearing RAMPA

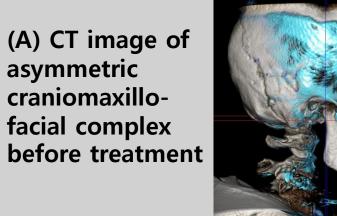
➤ Please answer all questions about the severity and frequency of symptoms. For each item below, please circle the number that best describes your (or your child's) symptoms. □	No Problem⊷ ू	Very mild problem-	Mild or slight problem: 1	Moderate Problem ⁻¹ 3	Severe Problem -	Problem as bad as it can be □	Maximum S items= 1	➤ Please answer all questions about the severity and frequency of symptoms. For each item below, please circle the number that best describes your (or your child's) symptoms. □	No Problem⇔ ູ	Very mild problem-	Mild or slight problem-	Moderate Problem	Severe Problem- 2	Problem as bad as it can be □	Maximum 5 items⇔‡
1. Need to blow more	0+2	14	2⊕	347	\odot	542	ته ته	1. Need to blow more	040	Θ	2⊕	3⊕	40	50	0 0
2. Stuffy nose	0↔	1€	2≓	342	4≓	(5)	0	2. Stuffy nose≓	(9)	144	2≓	342	4≓	5+3	43
3. Sneezing	0⊹□	142	(2-)	342	4≓	542	43	3. Sneezing₁□	(3)	1≓	2₽	3⊕	4≓	5+2	43
4. Runny nose≓	0+□	144	2≓	34□	4≓	(<u>5</u>)	0	4. Runny nose⊨	(b)	142	2≓	34₽	4=	543	43
5. Coughing	0⊷	①	2≓	342	4≓	5⊕	Ę,	5. Coughing	(9)	144	2⊕	342	4≓	543	43
6. Runny nose running down your throat	0⊷	1≓	2≓	34□	4	542	Ę	6. Runny nose running down your throat□	(3)	1≓	2⊬	3⊕	4=	542	43
7. Sticky runny nose₽	0↔	100	2≓	342	4≓	(<u>5</u>)	0	7. Sticky runny nose⊬	(3)	142	2⊬	3⊕	4+3	5.0	43
8. Clogged ears⊧	0⊷	①	2⊕	343	4≓	547	ą.	8. Clogged ears	3	142	2⊕	3⊕	4+2	5+2	43
9. Feeling dizzy	0	142	2≓	343	4≓	542	43	9. Feeling dizzy⊎	(6)	1∉	2≓	342	4≓	5+2	43
10. Ear pain⊷	0	142	2≓	34□	4≓	5.0	43	10. Ear pain⊌	(3)	1⊕	2≓	3⊕	4≓	542	43
11. Pain or Pressure in the face	0+□	142	2⊕	3⊕	4	543	43	11. Pain or Pressure in the face	(3)	142	2⊕	34₽	4=	542	42
12. Difficulty in smelling or tasting	0	1≓	2≓	342	4≓	5==	Ę	12. Difficulty in smelling or tasting⊌	(6)	1∈	2≓	3⊕	4=	542	43
13. Having trouble falling asleep₽	0⊹□	142	2≓	342	4≓	(5)	0	13. Having trouble falling asleep₽	(3)	1⊕	2⊕	34□	4≓	542	43
14. Waking up in the middle of the night	0↔	147	2+3	342	442	\/	0	14. Waking up in the middle of the night	(6)	142	2⇔	342	44	5+2	43
15. Lack of a good night's sleep₽	0+□	147	2⊕	343	4≓	(3)	ą3	15. Lack of a good night's sleep⊨	(6)	1∈	2₽	3⊕	4≓	542	43
16. Waking up tired₽	0⊷	1≓	2≓	342	4≓	(5)	Ę	16. Waking up tired⇔	(6)	1⊕	2⊕	3⊕	4=	542	43
17. Feeling tired on a daily basis₽	0⊷	1€	2≓	(A)	4≓	542	Ę	17. Feeling tired on a daily basis₽	(6)	142	2≓	3⊕	4≓	5+2	43
18. Feeling unmotivated ₽	0↔□	1€	2	342	4≓	547	42	18. Feeling unmotivated	(0)	142	2≓	342	4=	543	63
19. Reduced concentration□	0⊷	1€	2≓	(A)	4≓	547	43	19. Reduced concentration□	(6)	1⊕	2≓	342	4≓	542	43
20. Frustrated/restlessness₽	0↔	142	2	343	4≓	547	43	20. Frustrated/restlessness₽	(b)	142	2⊕	342	4=	542	43
21. Feeling depressed⊌	0₁□	7	(4)	342	4≓	542	÷	21. Feeling depressed₽	0	142	2⇔	3+2	4+	542	43
22. Feeling embarrassed blowing or sniffing	0⊷	10	2≓	3≓	(542	Ę	22. Feeling embarrassed blowing or sniffing	(6)	144	2⇔	3⊕	4≓	542	42
your nose□								your nose⊨)						

Changes in SNOT-22 before and after RAMPA

❖ SNOT-22 was 「62」at the first visit, but changed to 「1」 after RT treatment.







asymmetric

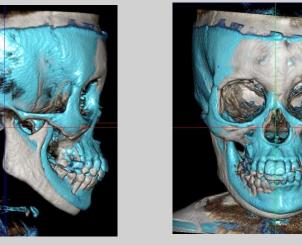
(B)Improvement

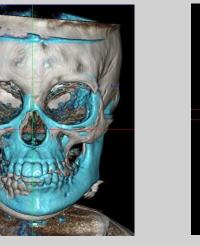
of asymmetric

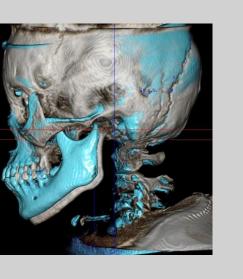
after treatment

skeletal

morphology







(C) Differences in skeletal morphology before and after treatment. Blue indicates areas of the skeleton that were changed by RT.

CT Image

Item	Measurement	Interpretation					
Measurement Time	October 19, 2024, 10:34:11 PM - October 20, 2024, 05:50:02 AM (7 hours, 15 minutes, 51 seconds)	Total sleep time and test duration					
Apnea-Hypopnea Index (AHI)	8.9 events/hour (65 total events)	Mild sleep apnea					
Apnea Index (REI(A))	7.1 events/hour (52 total events)	Frequency of apnea events					
Hypopnea Index (REI(H))	1.7 events/hour (13 total events)	Frequency of hypopnea events					
Event Duration	Minimum 3 seconds, Average 16 seconds, Maximum 84 seconds	Range of respiratory event durations					
Oxygen Desaturation Index (ODI)	2.4 events/hour (18 total events)	Low frequency of oxygen desaturation					
Desaturation Duration	Minimum 15 seconds, Average 42 seconds, Maximum 137 seconds	Range of oxygen desaturation durations					
Pulse Rate	Minimum 47 bpm, Average 67 bpm, Maximum 139 bpm	Range of pulse rates					
Oxygen Saturation (%SpO2)	Minimum 91%, Average 97%, Maximum 99%	Range of oxygen saturation levels					
Item	Measurement						
Measurement Time	February 21, 2025, 10:57:30 PM - February 22, 2025, 6:24:28 AM (7 hours, 26 minutes, 58 seconds)						
Apnea-Hypopnea Index (AHI)	2.3 events/hour (13 total events)						
Apnea Index (REI(A))	2.3 events/hour (13 total events)						
Hypopnea Index (REI(H))	0.0 events/hour (0 total events)						
Event Duration	Minimum 6 seconds, Average 10 seco	Minimum 6 seconds, Average 10 seconds, Maximum 26 seconds					
Oxygen Desaturation Index (OD	2.5 events/hour (14 total events)						
Desaturation Duration	Minimum 8 seconds, Average 29 seco	Minimum 8 seconds, Average 29 seconds, Maximum 70 seconds					
Pulse Rate	Minimum 44 bpm, Average 59 bpm, Maximum 95 bpm						

Polysomnography (PSG) before and after treatment

Minimum 90%, Average 97%, Maximum 99%

❖ AHI decreased from 8.9 to AHI 2.3

Oxygen Saturation (%SpO2)

❖ The treatment goal for children is to reduce AHI to less than 1, but realistically it is considered desirable to reduce AHI to 1-5 levels and improve symptoms.

Explanation for dislodged earwax



- (A) Middle ear and ear canal at first visit,
- (B) Middle ear and ear canal 137 days after RT

The reasons why the Down syndrome patient's earwax was dislodged during RT:

Discharge by Mechanical Force: The improved jaw movement from RAMPA therapy, in accordance with the laws of 'force and motion,' applies direct **pressure and stress** to the ear canal. This force overcomes the 'static friction' holding the earwax in place, serving to physically push out the impacted material.

Restoration of Gas Pressure Equalization: The health of the ear relies on the principle of 'pressure equilibrium,' where the air pressure inside the middle ear must equal the atmospheric pressure outside. RAMPA therapy improves the function of the Eustachian tube, which connects the nose and ear, restoring airflow that was previously blocked. As a result, the 'negative pressure' state inside the middle ear is resolved and equilibrium with atmospheric pressure is achieved. This normalizes the functional environment of the entire ear, allowing for proper discharge of secretions.

In short, this phenomenon demonstrates that physical force pushed out the stalled earwax and that the air pressure imbalance was resolved, normalizing the ear's function. This is an objective sign that RAMPA therapy improves the fundamental physical and physiological **environment** by changing the body's structure.

Patients and their families' feelings and impressions about the **RAMPA** treatment process:

"I look like my younger self again", "It's easier to breathe through my nose now", "My eczema has cleared up. I don't get pimples anymore", "I've gotten so much taller", "My head feels clear now. I can focus better on my studies", "My scoliosis has improved", "I don't need to wear glasses anymore. My strabismus has improved a lot", "I used to catch colds all the time, but not anymore", "I've never felt this good in my entire life", "My shoulders feel much lighter", "I feel more confident interacting with people now", etc.