



Original Article

PERCUTANEOUS INTERSPINOUS DEVICES TREATMENT IN PATIENTS AFFECTED BY LUMBAR SPINAL CANAL STENOSIS: A PRELIMINARY STUDY EVALUATING DURAL SAC USING WEIGHT BEARING MRI, BEFORE AND AFTER THE TREATMENT

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ABSTRACT

Lumbar Spinal Canal and Foraminal Stenosis is a widely diffuse pathological condition responsible for neurogenic claudication. Conventional MRI study may underestimate the disease. Percutaneous interspinous devices has been proposed when significant real stenosis occurs. To evaluate the real stenosis rate before and after the treatment in a population of 72/210 patients affected by symptomatic Lumbar Spinal Canal Stenosis and/or Lumbar Spinal Foraminal Stenosis treated with percutaneous Interspinous Process Device were evaluated by weight-bearing MRI using semi-automatic AI analysis. Seventy-two of a population of 210 patients eligible for Interspinous Process Device treatment underwent a Weight-Bearing MRI lumbar study the day before and one month after the surgical procedure. All the patients underwent percutaneous CT/Fluoro-guided Interspinous Process Devices implant. Minimum Clinically Important Difference, the Zurich Claudication Questionnaire and the Oswestry Disability Index score was rated. Fifty-two out of 210 patients (25% of the study population) became eligible for Interspinous Process Device surgery because Lumbar Spinal Canal Stenosis grading increased on weight-bearing MRI images only, as well as occult listhesis, detected in 21/210. Ratio improvement of the dural sac diameter was statistically significant in all the patients treated in the supine position (ratio 2.0, 95% CIs 1.58, 2.41) and standing position (ratio 3.13, 95% CIs 1.89, 4.37). Weight-Bearing -MRI is the best way to depict true dural sac size before and after Interspinous Process Device implants. Post- Interspinous Process Device studies demonstrated a significant increase in the actual dural sac area after the treatment when immediate postoperative follow-up was performed, reaffirming the

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effectiveness of Interspinous Process Device in treating Lumbar Spinal Canal Stenosis patients.

KEYWORDS: *Weight-bearing MRI, Spinal Canal Stenosis, Interspinous device, spacer, spine treatment*

INTRODUCTION

Lumbar spinal canal stenosis (LSCS) and lumbar spinal foraminal stenosis (LSFS) are considered one of the main causes of pain, disability, fall and depression in the elderly (1-3). Despite commonly referred as an age-related disease, the term “degenerative” could be considered a misnomer, as a genetic basis has been recently discovered (4); in fact, in LSCS patients, it has been demonstrated a decreased expression of the main anti-oxidant enzyme - named Catalase - in ligamentum flavum and a deficit of Elastine, responsible for abnormal degeneration of the ligaments associated with Amyloid deposits up to 50% of patients and increased Apolipoprotein AI (AApoAI) level in 12% of patients (5-7).

Clinical symptoms of patients with LSCS include low back pain, stiffness, leg paraesthesia/weakness, lower extremity radicular pain and “neurogenic intermittent claudication” (NIC), generally relieved by sitting and/or bending (1, 8).

Radiologic findings of spinal canal stenosis do not always correlate with symptoms; the diagnosis is typically based on accurate clinical history and physical examination. Imaging studies are useful to confirm the diagnosis and target the treatment (9); in this scenario, several radiological classification systems have been proposed for spinal canal stenosis grading, frequently evaluating the size of the dural sac or even the variation in spinal canal diffusivity, evaluating the variability of lumbar cauda equina nerves apparent diffusion coefficient (ADC) (10, 11).

Actually, the most accepted worldwide is the Schizas’s classification based on axial T2-weighted magnetic resonance images (MRI) visual evaluation grade of the spinal canal narrowing in 4 progressive degree (from “A” to “D”) (12).

Routinely, the grading of the lumbar stenosis is performed with conventional MRI study acquired in supine position, assuming the value of the stenosis remaining similar in orthostatic position; nevertheless, spinal curve and pelvic tilt differ significantly from supine to upright position, as for paravertebral muscle tones and the absence of physiological body weight. Consequently, there’s the realistic possibility in changing stenosis grade when the patient is evaluated in the upright position with a Weight-Bearing MRI system (WB-MRI), according to the changes in the spinal canal and related ligaments that have been demonstrated on dynamic MRI studies (2, 13, 14).

Generally, Schizas’s grade C and D only are considered suitable for surgery, while conservative treatment is preferred for grade A and B but the clinical evaluation still drove the treatment, probably also because the radiological conventional MRI evaluation is not so efficient. Actually, physical therapy, self-care and medication are the first step to manage the symptoms of spinal canal stenosis prior to any intervention; however, when conservative treatments fail to improve the patient’s pain, function and quality of life, interventional therapies can be considered (15).

Interspinous Process Devices (IPD), also known as “spacers”, are considered as an alternative, less invasive treatment versus conventional surgery in patients affected by LSCS or LSFS with similar functional results and less intra-operative complication than open surgery (16). The IPD are intended to be introduced (surgically or with a percutaneous approach) between the two adjacent spinous processes at the level of the symptomatic stenosis enlarging the interspinous space, stretching the yellow ligaments and widening - as a consequence- the dural sac area, mimicking the pain-relief position of kyphosis with a forced flexion of the stenotic level (17, 18). Several studies have been performed concerning the efficacy of spacers in enlarging the bony spinal canal area and the foramina on conventional computed tomography (19); however, the analysis of the real changes of the dural sac area immediately after IPD placement in up-right physiological position has never been evaluated.

In this scenario, our objective is to explore the potential for showcasing a potential shift in the grading and severity of LSCS in patients who exhibit symptoms. This change will be demonstrated by comparing conventional MR scans taken in a supine position with those obtained in an upright position using a specialized whole-body WB-MRI scanner. Furthermore, we assessed treatment outcomes by evaluating the actual enlargement of the dural sac area in an upright position for patients diagnosed with LSCS and/or LSFS immediately after a percutaneous spacer implant. To the best of our knowledge, no existing literature has described the evaluation of the genuine impact of IPD on the dural sac size in the upright position.

MATERIALS AND METHODS

Between September 2021 and June 2022, a total of 210 patients, who experienced mild to severe chronic neurogenic claudication, underwent lumbar spine scanning using a conventional 1.5T MRI. Subsequently, all patients diagnosed with LSCS were further assessed and classified according to the Schizas classification.

Patients classified as Schizas grade C and D were subjected to non-contrast CT scans of the lumbar spine, specifically at the level of stenosis. Those with narrowing caused by bony spurs, ossification of the ligamentum flavum, facet joint hypertrophy, extreme contact, or spondylolisthesis of adjacent spinous processes were excluded from the study. Additionally, individuals with a history of previous lumbar spine surgery, and those with spondylolysis and spondylolisthesis graded higher than 2 according to the Meyerding classification (18), were also excluded from the study.

For patients with LSCS deemed suitable for treatment, preoperative electromyography of the lower limbs was conducted to confirm the presence of moderate to severe nerve conduction impairment related to the disease.

All eligible patients for treatment underwent a state-of-the-art WB-MRI lumbar study using a 0.25 T scanner (G-scan Brio®, Esaote, Italy) both one day before and one month after the surgical procedure. The imaging protocol included a 2D Sagittal T2 FSE scan in supine and upright position, with an inclination angle of 81° sequences. The quantitative evaluation of LSCS was performed with a semi-automatic software (Q-Spine®, Esaote, Italy), able to automatically segment Vertebral bodies (L1 to S1) and the spinal canal, performing automatic measures (Vertebral Wedging, Listhesis index, Intervertebral Translation, Intervertebral Angles, Vertebral Collapse Index, Section of spinal canal, Canal thickness, Spine curvature and Foramen area) and, above all, providing a comparison environment giving evidence of the differences between supine and weight-bearing exams. Manual adjustment was performed in some cases when unsatisfactory segmentation was assumed by the operators and measurements were reviewed by two different neuroradiologists. Minimal value of cross-sectional area expressed in mm² at the treated level of stenosis, as well as at the level above and below were recorded both in conventional and orthostatic positions, corresponding to the narrowest slice of dural sac.

Those patients who met the criteria for LSCS treatment underwent clinical evaluation, where the intensity of pain was assessed using the Zurich Claudication Questionnaire (ZCQ), and their disability level was measured using the Oswestry Disability Index (ODI). These assessments were performed one day before and one month after the treatment.

The treatment's success was determined based on Minimum Clinically Important Difference (MCID), which were defined as follows: a minimum of 0.5-point improvement in ZCQ domains, an absolute ZCQ patient satisfaction score of 2.5 or lower, and at least a 10-point improvement in ODI (20-23). Technical success was defined as correct placement and deployment of IPD, demonstrated with computer tomography (CT), performed immediately after treatment.

Percutaneous IPD implant procedure

Standard informed consent was obtained. All the patients underwent percutaneous, hybrid procedures with CT and Fluoro-guided approach. The patients were positioned prone on the CT table and a combination of local anaesthesia (10ml Lidocaine 2%) in the deep paraspinal muscles and mild intravenous analgesia, and sedation was administered (*Fentanyl* 1–3 µg/kg/hour).

A low-dose preprocedural scan was performed to choose the correct entry-level point. Subsequently, a small (5–10mm) skin incision was made, and the former 6mm muscle dilator was inserted, via a posterolateral approach, into the interspinous space with appropriate positioning confirmed by further low-dose CT scans. The coaxial guidewire was then introduced through the former dilator and then coaxial dilators (incremental 2mm dilation) were placed. Using fluoroscopic guidance, several different-sized probes were then advanced through the dilator into the interspinous space to choose the proper IPD size. Once the adequate IPD size was selected, a PEEK-covered titanium device with wings for obtaining fixation (Q-Fusion®, Diametros Medical, Italy) was subsequently deployed into the interspinous space. In the end, dilators and holder were then removed and the skin was sutured. A quick postoperative CT scan was performed immediately at the end of the procedure, to confirm the device position and assess for immediate complications.

Statistical analysis

Statistical evaluation was performed with STATA 15. Descriptive statistics, including population data are presented

as means \pm standard deviation (SD) with range in brackets. Clinical results are presented as mean and 95% confidence intervals. For each patient, dural sac diameter was assessed both in supine and in stand-up position (tilt angle 81°), prior and after the interspinous spacer placement.

Ratio was calculated as follow:

$$Ratio = \frac{Dimension_{t1}^i}{Dimension_{t0}^i} (1)$$

Where is the dural sac diameter after surgery is (t1) for a patient i and the dural sac diameter before the surgery is (t0) for a patient i. We rely on a relative measure of dimensional change to assess the improvement after the procedure. Statistical significance was set at $p < 0.05$.

Post-op measurement obtained in the up-right position on weight bearing system always demonstrated statistically significant enlargement of the dural sac at the level of implanted ISD. We registered 100% of technical success rate with regular deployment and implant of the device in all the patients. No major complications have been reported in our series.

RESULTS

Out of the total of 210 patients, 82 individuals (39%) were classified as grade C (37/82) or D (45/82) based on the Schizas criteria. Despite undergoing conservative treatment for at least 6 months, this treatment approach was not successful for these patients. As a result, 72 out of the 210 patients were considered eligible for an IPD implant.

Among the eligible patients, there were 49 males and 23 females. The levels selected for the IPD implant were as follows: L2-L3 (N=1), L3-L4 (N=17), L4-L5 (N=47), and L5-S1 (N=7). The majority of patients (N=35) received a device size of 10, followed by size 8 (N=26) and size 12 (N=11).

Radiological evaluation

A total of 210 patients with LSCS or LSFS underwent WB-MRI. This resulted in a significant change in the diagnosis for some patients, with 47 out of 210 showing an increase in the grade of stenosis in the upright position (Fig. 1a-d).

Additionally, 5 out of 210 patients exhibited relevant foraminal stenosis at the L4/L5 (2 patients)



Fig. 1a-d. A 73yo male affected by positive clinical symptoms suggesting spinal canal stenosis, mild LSCS on conventional imaging and severe increase of stenosis when a weight-bearing MRI study was performed. On conventional supine MRI evaluation, only mild stenosis (grade A LSCS according to Schizas classification) was detected at the level of L4-L5 on sagittal (1a) and axial (1b) T2FSE scan, without any significant deformation of the dural sac nor cauda equina nerve root compression inside. On up-right WBMRI evaluation there is a dramatic increase of the stenosis at L4-L5 level, turning to grade D both on sagittal (1c) and axial (1d) T2FSE scans.

or L5/S1 (3 patients) level, which was only detected when in the upright position. Consequently, 52 out of 210 patients, representing 25% of the study population, became eligible for treatment solely due to the weight-bearing MRI images. These patients transitioned from grade A/B (no surgery advised) in the supine conventional position to grade C/D (surgery needed) when the weight-bearing MRI scan was performed. Moreover, occult listhesis associated with spinal canal stenosis was detected in 21 out of 210 patients, as a natural consequence of the disease, which was not appreciated on conventional MR imaging (Fig. 2a-d).

The WB-MRI evaluation showed an enlargement of the dural sac after the procedure (fig. 3a-d). Specifically, post-intervention, the dural sac diameter increased both when assessed in the supine position (ratio 2.0, 95% CIs 1.58, 2.41) and standing position (ratio 3.13, 95% CIs 1.89, 4.37), as depicted in Fig. 1.

The estimates at 0° and 81° are not statistically different at conventional $P < 0.05$ ($P = 0.06$). In the case of the standing position (orange box plot Table I), two patients displayed a very large relative increase in post-intervention dimensional improvement (Patient 1 ratio = 11.25; Patient 2 ratio 12). Patient 1 showed a dural sac size of 4 mm² prior to surgery and 45 mm² after the intervention. Patient 2 showed a dural sac diameter of 1 mm² before intervention and 12 mm² after. Ratio improvement assessed when the patient is standing (81°) without those two extreme cases is lower but still substantial (2.32, 95% CIs 1.83, 2.80).

The patients undergoing treatment showed improvement both in terms of MCID outcomes measured with ZCQ and functionality assessed with ODI; in particular, the average MCID had 1.2-points improvement in ZCQ domains and 2.1 score in absolute ZCQ patient satisfaction score, and the average ODI score improved from 54% mean value to 21%.

DISCUSSION

Anthropomorphic measurements of the anteroposterior (AP) size of the spinal canal are not significantly correlated with clinical symptoms in patients clinically diagnosed with LSCS. Therefore, when assessing and treating patients with LSCS, these measures should not be considered on their own (24).

In light of this, our study focused on evaluating the variation in spinal canal diameter expressed as a ratio, rather than relying solely on the absolute spinal canal diameter, to assess improvement after the procedure.

We observed a narrowing of the spinal canal in the standing position compared to the supine position before the IPD implants. This variation explains the development of neurogenic claudication and the worsening of symptoms typically experienced by patients with spinal canal stenosis when axial loads are applied.

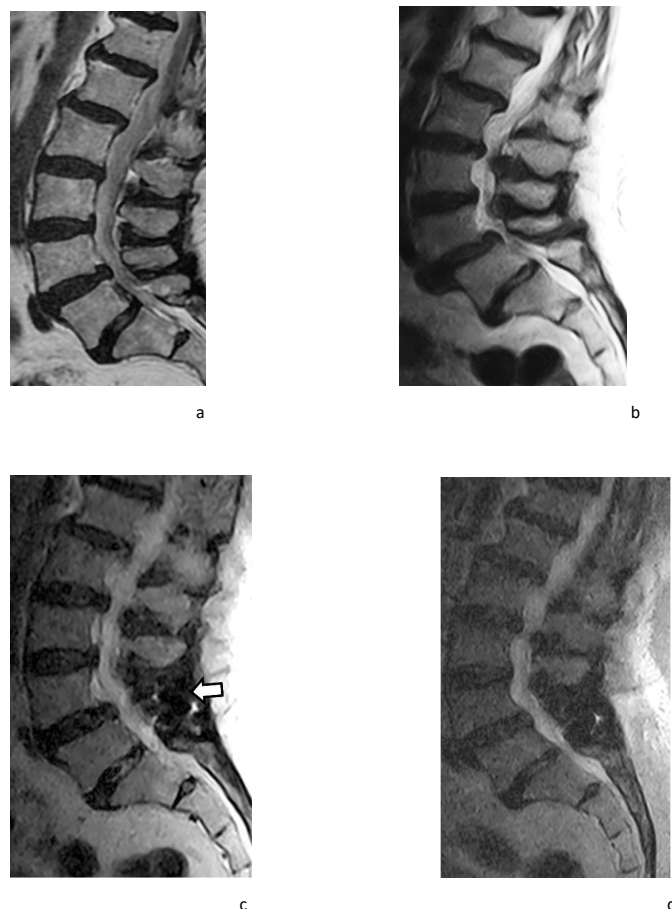


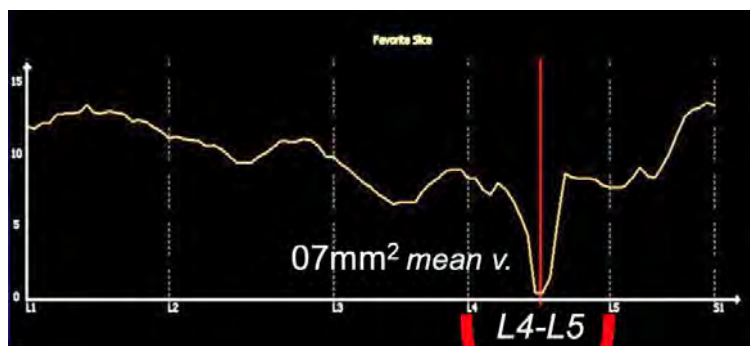
Fig. 2a-d. A 65yo female affected by LSCS, is evaluated of the dural sac area before and after the treatment with percutaneous Interspinous Device. Before the treatment, severe bulging of yellow ligaments at L4-L5 level (2a) is appreciated on T2FSE up-right weight bearing imaging, responsible for dural sac compression (grade D stenosis). The dural sac diameter size having mean value of 7mm² (2b) according to the automatic segmentation software (Q-spine®). The post-op T2FSE WBMRI imaging performed the very day after the treatment (2c) reveals evident stretching of posterior ligaments, increasing the size of the dural sac, as demonstrated by the dural sac diagram after the treatment (2d), now counting 78mm².

Furthermore, several studies have described the dilation of the spinal canal, spinal foramen area, and interspinous space on CT scan images after the introduction of IPD. However, evaluating the dural sac area on CT scans can be challenging due to poor density differentiation between ligament boundaries and the cerebrospinal fluid-filled dural sac, as well as the presence of bone and IPD metallic artifacts. Additionally, despite lumbar spinal canal stenosis being primarily affected by gravitational load stress, all the pre- and post-operative CT studies have been performed in the conventional supine position (19).

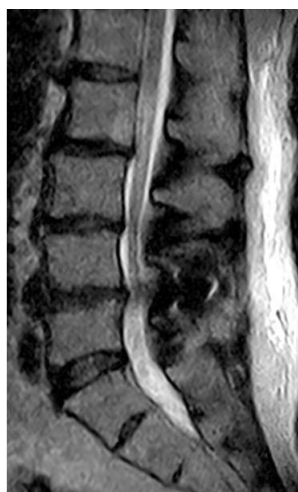
Moreover, various studies have reported the expansion of the spinal canal, spinal foramen area, and interspinous space on CT scan images following the introduction of IPD. However, assessing the dural sac area on CT scans can be challenging due to limited density differentiation between ligament boundaries and the cerebrospinal fluid-filled dural



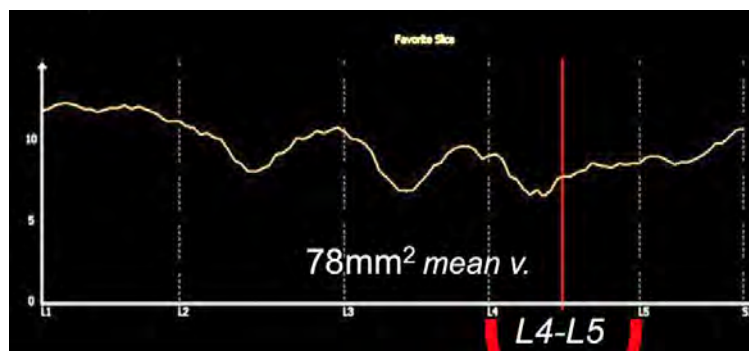
a



b



c



d

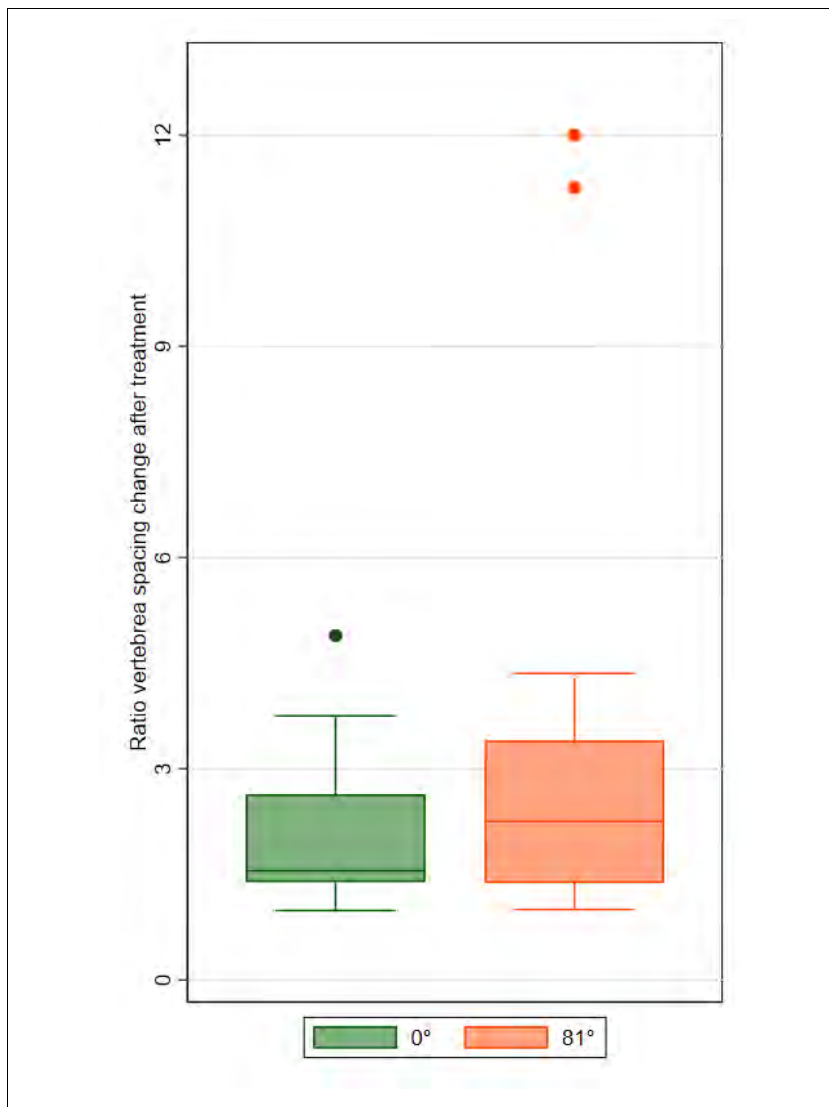
Fig. 3a-d. Treating occult LSCS + instability in severely symptomatic 77yo female suspected for LSCS and apparent normal spine on conventional supine T2FSE imaging. In supine position, no significant stenosis nor listhesis can be detected on T2FSE sagittal scan (3a). In orthostatic imaging (90degree), significant stenosis at the level of L4-L5 and grade I occult anterolisthesis of L4 is clearly demonstrated, according to the LSCS syndrome. After spacer-fixating device (white arrow in 3c), no spinal canal stenosis nor listhesis can be appreciated both on sagittal supine (3c) and up-right (3d) T2FSE scans.

sac, as well as the presence of bone and IPD metallic artifacts. Additionally, despite lumbar spinal canal stenosis being primarily affected by gravitational load stress, all the pre- and post-operative CT studies have been conducted in the conventional supine position (19).

A relatively new system called WB-MRI has emerged, offering the evaluation of the spine in a more physiological manner, specifically, in an orthostatic position under the trunk and head load stress of the patient. During WB-MRI, the patient stands in an upright position while a 3D evaluation of the spine is acquired using T2-scan technique. The results are then analyzed with a dedicated software called “Q-spine,” which compares all the data (such as dural sac area, foraminal area, grade of listhesis, and curvature of the spine) with the analogous scans acquired in the conventional supine position (25, 26).

Q-spine software is a semi-automatic quantitative analysis tool capable of rapidly calculating spine voxel variations between the supine and orthostatic positions. It provides measurements for the lumbar spine (from L1 to S1) including dural sac and foramina areas (in mm²), grade of listhesis (in mm), degree of local and global lordosis, and other measurements useful for analyzing the lumbar spine when comparing the conventional supine and upright positions. The 3D voxel

Table I. Ratio of intervertebral spacing assessed laying (0°) and standing (81°).



automatic measurement is particularly valuable in accurately evaluating spine changes, as a conventional single 2D measurement on axial or sagittal images may be significantly influenced by various biases, particularly related to different spinal positions during load-stress conditions.

As LSCS is significantly affected by load-stress, it is more logical to evaluate patients in the upright position (27, 28), as failure to do so may lead to the underestimation of lumbar stenosis risk (17-27). Hansen's research clearly demonstrated increased sensitivity and specificity in patients affected by LSCS and/or listhesis when evaluated using a WB-MRI system (28).

In our study, all patients underwent both WB-MRI scans in the upright and conventional supine positions before the IPD treatment. This was done to calculate the actual grade of LSCS and were re-evaluated immediately after the treatment to demonstrate the true extent of dural sac widening following IPD placement. Post-operative measurements, performed in the orthostatic position on WB-MRI, consistently showed a significant widening of the dural sac in comparison to the previous pre-operative scan, both in the supine and upright studies (as shown in Table I). This demonstrates the effectiveness of the IPD mechanism and the rationality in utilizing IPD implants for patients affected by LSCS.

Interestingly, our data indicates that the ratio increased in both supine and standing positions, but it is notably higher in the standing position (ratio of 3.13 vs 2 or 2.32 vs 2 if we remove the two cases with severe stenosis and very high improvement). Moreover, in patients with occult anterolisthesis detected solely on WB-MRI, the application of the IPD, with the included fixing system, resolved the hypermobility of the vertebrae in all unstable patients (as shown in Fig. 2c, d).

This is a key finding of our study, demonstrating the efficacy of IPD implants as devices capable of causing enlargement of the spinal canal that not only persists from the supine to standing position but also increases when axial loads are applied, explaining the clinical improvement in our population.

As a preliminary report, this study is limited by the relatively small number of patients evaluated. However, the statistical analysis was encouraging in adopting WB-MRI criteria to define the disease and evaluate the treatment results. Further case-control studies on a larger population are warranted to validate these findings. Moreover, the clinical follow-up was quite short. Probably a longer follow-up may be advocated to demonstrate clinical results in real-life.

CONCLUSIONS

IPD is a promising treatment option for patients suffering from symptomatic LSCS, offering favourable clinical and radiological outcomes, such as widening the dural sac, meanwhile and reducing the risks commonly associated with major surgical interventions (like decompressive laminectomy).

WB-MRI is currently the only diagnostic tool that allows a more physiological and cost-effective evaluation of the spine in an upright position, providing a true assessment of the dural sac's size before and after surgical treatment, as well as accurately grading LSCS. CT-based measurements typically underestimate the disease due to poor discrimination between ligaments and the dural sac, while conventional X-ray plain films during flexion-extension tend to overestimate the grade of listhesis. As a result, WB-MRI-based measurements should be considered the most accurate for LSCS patients treated with IPD. Furthermore, the Q-Spine software offers additional insights into biomechanical modifications related to posture and pathological conditions by employing 3D models and a comparison environment during weight-bearing evaluations.

Based on our results with WB-MRI, post-IPD studies demonstrated a significant increase in the actual dural sac area after treatment, when immediate post-operative follow-up was performed, reaffirming the effectiveness of IPD in treating LSCS patients.

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Original article

A CLINICAL INVESTIGATION OF HYALURONIC ACID FORTIFIED WITH AMINO ACIDS FOR ADDRESSING FACIAL AGING

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ABSTRACT

Within the field of aesthetic medicine, various methodologies have been employed to combat skin aging, particularly in the facial region. One such approach involves the utilization of hyaluronic acid to enhance water retention and support extracellular matrix integrity. This research aims to clinically and histologically assess the impact of combining low molecular weight hyaluronic acid fragments with amino acids (HAAM) on revitalizing facial skin through intradermal microinjections. A cohort of twenty female participants, with an average age of 45 falling within the range of 35 to 64, was included in this investigation. Among them, eight were in the postmenopausal stage, while twelve were in their childbearing years. Mesotherapy was employed to administer HAAM products to the patients for 4 sessions. The outcomes from the current investigation revealed that applying hyaluronic acid with fragments of 20 to 38 monomers, along with amino acids through the dermal injection technique, leads to an enhancement in the visual appearance of the treated

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patients' facial features. The clinical evaluation highlighted the significant influence of subcutaneous HAAM infiltration on both the dermis, improve pH levels, sebum production, skin hydration and enhance the overall clinical presentation of the facial region.

KEYWORDS: *Skin imperfections, Cutaneous biostimulation, Hyaluronic acid fragments, Aesthetic enhancement.*

INTRODUCTION

The human skin serves a dual role, acting as both a protective barrier and a mediator of metabolic and informational exchanges between the body and its external environment. Unfortunately, various external factors like ultraviolet radiation and internal stressors such as endocrine-metabolic conditions, coupled with the inevitable passage of time, can lead to a series of functional and structural changes in the skin. These alterations can compromise its integrity to varying degrees (1). This can manifest as issues like uneven pigmentation, lack of moisture, reduced elasticity, and microvascular transformations. These concerns can become particularly pronounced in critical areas like the face and décolleté, potentially becoming significant aesthetic concerns (2-4).

To counteract these skin imperfections, especially the emergence of wrinkles and related issues, the concept of "cutaneous biostimulation" has been proposed in the field of cosmetic procedures. This approach involves injective techniques aimed at revitalizing the skin's normal structure and functions. This is achieved through targeted interactions with the fibroblasts that form the skin and the surrounding extracellular matrix (5).

The current study investigates the potential of hyaluronic acid, alongside select organic and inorganic substances, in preventing and treating common skin imperfections. The primary objective is to clinically evaluate the impact of introducing low molecular weight hyaluronic acid fragments combined with amino acids (referred to as HAAM) through intradermal microinjections on the rejuvenation of facial skin.

MATERIALS AND METHODS

A total of twenty women, with an average age of 45 and ranging from 35 to 64, were enrolled in this study. Among them, eight were in the menopausal phase, while twelve were in the childbearing age range. The research took place within a private medical practice setting. The investigation was conducted in collaboration with a private, multi-specialty medical practice located in Montesilvano and Modena, Italy. The study adhered fully to ethical principles, including the guidelines set forth in the World Medical Association Declaration of Helsinki (6), as well as the additional requirements specified by Italian law.

Each participant provided informed consent prior to undergoing the prescribed procedure. Notably, none of the participants were aware of the specific condition being addressed through the treatment. All patients exhibited common characteristics, including generalized rhytidosis, inadequate skin hydration, and diminished sebum production. These conditions were observed under circumstances of dryness and low oxygen levels, and there were no modifications to their dietary habits during the course of treatment. Individuals who had made alterations to their diets, were pregnant, had a history of heavy smoking (20 cigarettes per day), had a history of allergic and/or irritant contact hand dermatitis, were afflicted with systemic diseases, or had psychiatric disorders were excluded from participation. After anamnestic information collection and physical evaluation, the patients were submitted to pH measurement, assessment of sebometry and hydrometry; photography in the glabella, and malar-cheek regions. All patients received the HAAM products (SKIN-B® Italfarmacia, Rome, Italy) by mesotherapy technique, for 8 weeks providing a treatment on a weekly basis with the use of 2.5 cc syringes and 13 mm 30G needles. The solution was inoculated into the deep layer of the dermis with a suitable amount of at least 0.2 / 0.3 mL in the cutaneous points every 15 days, for 4 times.

Statistical analysis

The study data were analyzed by the statistical software package Graphpad 8 (Prism, San Diego- CA USA) through a special designed form. The D'Agostino & Pearson test was conducted for the normal distribution assessment and visually

represented by the QQ-distribution plot. The paired t-Student test was conducted to measure the significance of the study variables differences before and after the treatment. The level of significance was considered for $p < 0.05$.

RESULTS

All participants successfully completed the follow-up period. Treatment involving the use of injectable HAAM medical devices yielded favorable outcomes, visually captured through photographs. This was manifested by a noticeable reduction in periorbital and frontal wrinkles, an enhancement in skin texture, an increase in skin radiance and firmness, along with volumetric improvements. These immediate enhancements contributed to a visibly healthier and more aesthetically pleasing skin appearance (Fig. 1).

Physical examinations indicated a noteworthy enhancement in dermal appearance of various facial regions including the glabella and malar-cheek regions. This improvement was noted in the metrics of pH levels, sebum production, and skin hydration when compared to the baseline measurements (Table I).

Ultimately, the study successfully achieved its intended objective, specifically showcasing that the application of medical devices containing hyaluronic acid fragments spanning 20 to 38 monomers via injection techniques led to a noticeable aesthetic enhancement in the facial features of the treated patients. The improvement primarily observed within the first month. Importantly, this enhancement was statistically significant (Fig. 2, Table I).

DISCUSSION

The findings of the present study underscore that employing medical devices containing hyaluronic acid fragments spanning 20 to 38 monomers, coupled with amino acids through dermal injections, leads to a discernible enhancement in the aesthetic quality of treated patients' facial features. The utilization of HAAM treatment appears to have a tangible impact on

Table I. Summary of the effectiveness before and after the biomodulation treatment (mean, standard deviation).

	pH-metry		Sebometry [$\mu\text{g}/\text{cm}^2/\text{min}$]		Hydration [$\text{g}/\text{m}^2/\text{h}$]	
	Before	After	Before	After	Before	After
Mean	4.81	5.81	39.8	59.1	57.5	67.9
SD	± 0.95	± 1.40	± 2.5	± 3.3	± 4.8	± 3.7
Lower 95% CI	4.36	5.15	38.66	57.6	55.3	66.3
Upper 95% CI	5.26	6.46	41.00	60.6	59.8	69.6
p- value	p=0.03		p<0.01		p<0.01	

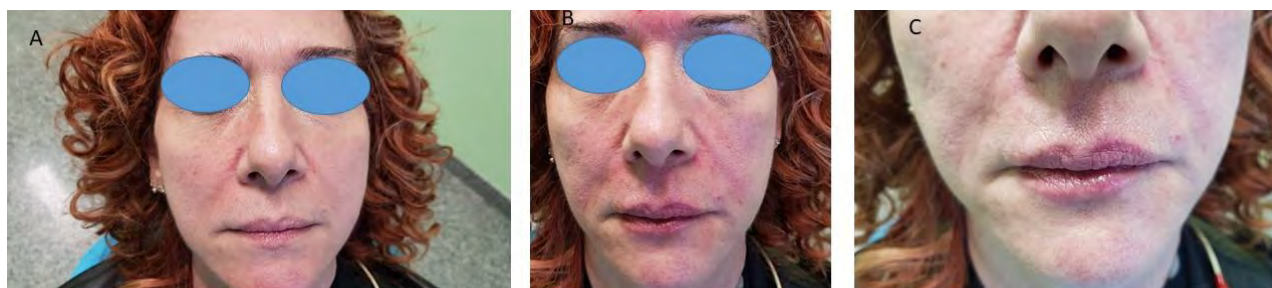


Fig. 1. A. Before treatment. B. Immediately after treatment with the injectable medical devices of the HAAM was associated with a mild and transient erythema. C. After 2 months favourable results are visible at a photographic level.

epidermal hydration, potentially indicating an increased availability of water for regular physiological processes (7).

Hyaluronic acid stands out as the predominant glycosaminoglycan within the extracellular matrix, attaining its peak concentration in highly hydrated tissues like the vitreous fluid and the umbilical cord (8). Enzymatic activity by hyaluronidases fragments this acid, subsequently triggering processes like angiogenesis, tissue remodeling, and cellular turnover (9, 10). The length of these hyaluronate fragments (HF) directly influences their biological effects. A greater number of receptor sites exposed to longer HF reduces the likelihood of ligand detachment from the cell surface. A gradual increase in HF length, transitioning to 20-22 monomers, correlates with a substantial surge in receptor avidity, which then triples (11, 12). An HF containing 20 monomers, composed of two hexamers separated by an octamer with a probable favorable conformation (e.g., helicoidal), each binding to a CD44 receptor, achieves an optimal state (13).

The integration of hyaluronic acid fragments with amino acids (HAAM) aptly meets the requirements of contemporary physiological biomodulation. These HAAM complexes effectively achieve their objective of redirecting metabolic and informational flows to restore the morpho-functional balance in imperfect skin. This concept draws a parallel to the role of musical instruments within an orchestra, altering sound or tone to achieve a harmonious effect (14).

Multiple studies conducted both *in vivo* and *in vitro* have reported that amino acids serve as stimulants for protein synthesis (15, 16).

The incorporation of amino acids helps in maintaining a stable pH within the extracellular matrix.

Furthermore, these amino acids could potentially be harnessed for the synthesis of bioactive peptides (17). During this process, primary amino acids like glycine, L-proline, and L-alanine play a crucial role in synthesizing collagen polypeptide chains. Meanwhile, glycine, L-valine, L-alanine, and L-proline are vital for elastin synthesis (18). Subsequently, branched-chain amino acids like L-valine, L-leucine, and L-isoleucine are indispensable for promoting the synthesis of actin, a contractile protein present in myofibroblasts derived from fibroblasts (19). Serine, a targeted amino acid in post-translational kinase/phosphatase modulation processes, serves as a precursor for arachidonyl-serine, an endocannabinoid recently discovered for its capacity to stimulate endothelium repair and angiogenesis (20). Lastly, cysteine serves as a

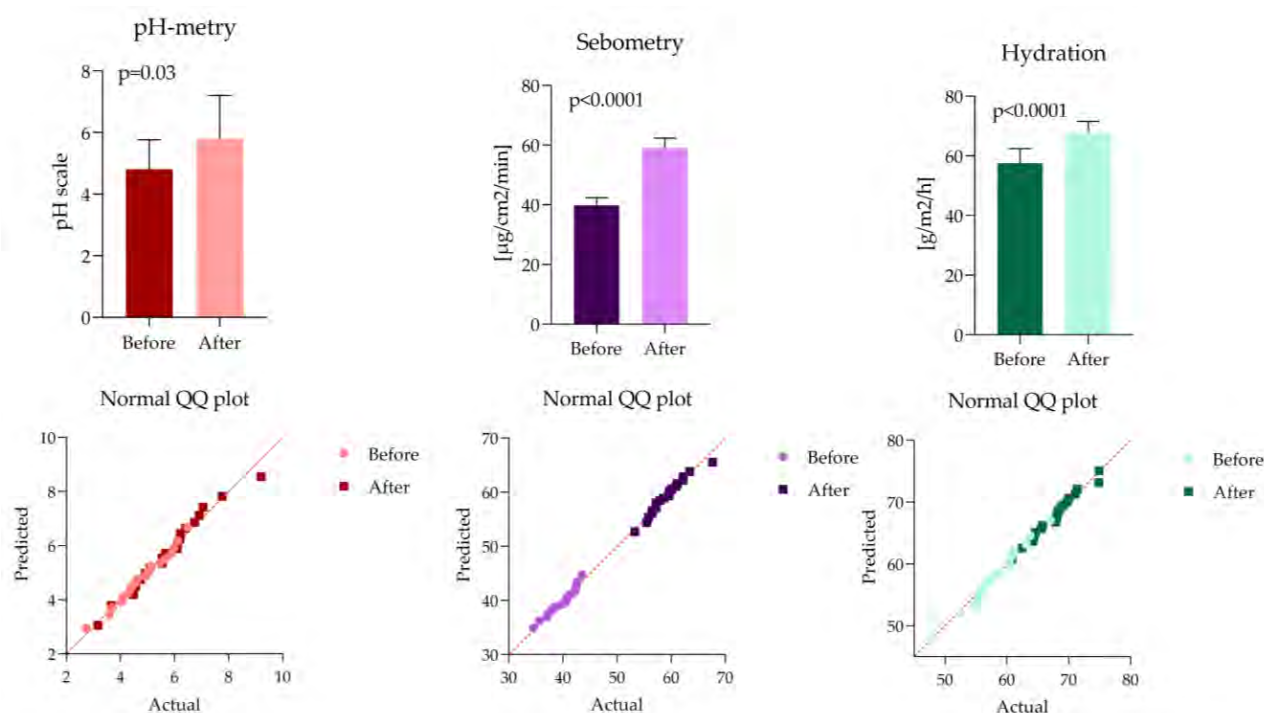


Fig. 2 The bar graphs show the number of pH-metry, sebumetry and tissue hydration, before and after the treatment (paired *t*-Student test).

precursor for glutathione, the most potent intracellular antioxidant (21, 22). Its role is pivotal in modulating the impact of reactive oxygen species (ROS), as an excess of ROS could be detrimental to cellular repair processes (23).

In summary, the utilization of HAAM through injection technique improve pH levels, sebum production, skin hydration and enhances the aesthetic appearance of the treated patients' facial features.

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Original Article

A NOVEL CLASSIFICATION AND A CHART-MAKING DECISION FLOW PROPOSAL FOR FIXED FULL-ARCH IMPLANT-SUPPORTED PROSTHESIS

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ABSTRACT

Full-arch screw-retained implant-supported rehabilitations represent a dependable solution for thoroughly treating edentulous patients or those with terminal dentition. Despite extensive literature discussing and reporting data to refine the outcomes of these treatments, there is a notable gap in guidance focusing on post-surgical phases, especially in a schematic and detailed manner addressing prosthetic concerns. This paper seeks to bridge this gap by delineating a standardized workflow in the daily approach to managing patients seeking full-arch screw-retained implant-supported prostheses. It builds upon existing research while introducing a novel, structured guide to assist practitioners after the surgical phase up to the final prosthesis delivery. Moreover, we introduce a comprehensive classification system for viable full-arch screw-retained implant-supported prostheses, supplementing it with a decision-making flowchart. This tool, forged from both daily workflow experiences and thorough existing literature, aims to aid in selecting the most appropriate prosthetic design tailored for each patient. To validate the applicability and effectiveness of the proposed classification and workflow, we conclude with a series of case studies showcasing successful full-arch rehabilitations where this decision-making flowchart has been practically applied.

KEYWORDS: *full arch implants supported rehabilitations, classifications, decision flowcharts, frameworks, digital and analogical flow in dentistry*

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INTRODUCTION

Full-arch screw-retained implant-supported prostheses are increasingly acknowledged as a reliable treatment modality for patients presenting a failing dentition or complete edentulism. These prostheses offer the opportunity to provide patients with a customized, enduring, and functionally effective solution, addressing both functional and aesthetic considerations in their rehabilitation.

Furthermore, the increasing adoption of digital technologies in dentistry (1) has enabled clinicians to perform such rehabilitation and do it rapidly. In the context of implant dentistry and its prosthetic timing, three loading protocols can be identified. Conventional or delayed loading is when the first provisional is delivered at least two months after the implant placement surgery. Early loading is referred to as the delivery of the provisional between one week and two months after the surgery, while immediate loading is defined as the provisional delivery within 1 week from the implant placement, with most protocols aiming to stay within the 48-hour mark. In recent years, immediate loading timing protocols have garnered increasing attention, with numerous studies focusing on surgical factors and preliminary evaluation to determine their success rate (2). The recently introduced “Same Day Delivery” approach, which has further reduced the technical time, effectively transforms compromised dentitions into aesthetically pleasing ones within hours (3). These solutions restore masticatory, phonetic, and aesthetic functions more swiftly than previous methods and offer tailored options to meet individual patients’ best needs. Importantly, they do not exhibit significant disadvantages compared to other treatment alternatives (4).

Clinicians must consider many factors when formulating a comprehensive treatment plan for full-arch screw-retained prostheses (5). These considerations encompass both mechanical and biological aspects, as well as individual patient preferences (6). The mechanical and biological considerations associated with such cases have been extensively discussed. With the aid of digital technologies and CAD/CAM, it has become increasingly feasible to provide immediate-load full-arch provisionals that offer pleasing aesthetics and enhanced durability (7). However, it is noteworthy that a substantial portion of the existing literature predominantly focuses on the surgical aspects when addressing full-arch rehabilitations (8 - 10), with relatively few resources offering a clear pathway for the actual design of the provisional prosthesis (11). Addressing this limitation, the Columbus Bridge Protocol (CBP), which finds its roots in the Novum Protocol (12), was introduced by Tealdo et al. (13). This protocol aims to create a fine-tuned load on the post-surgical provisional through the optimization of prosthetic factors, primarily focusing on the fit of the metal framework, as well as the stability and the even load distribution of the provisional.

Acknowledging that the term ‘provisional’ implies that the device is not intended to endure throughout the rehabilitation lifespan is essential. While a high-quality provisional is indispensable for soft tissue maturation and aesthetics during immediate loading protocols, the final restoration is designed to be long-lasting. Therefore, clinicians must clearly understand the design options for the final restoration to achieve a high success rate and ensure patient satisfaction.

This paper addresses the lack of prosthetic standardization within the domain of full-arch screw-retained implant-supported prostheses, regardless of whether they are subject to immediate loading. Readers will receive a comprehensive overview of the procedural steps typically employed in clinical practice, as practised by the authors, encompassing the entire spectrum from initial treatment planning to the ultimate delivery of the final restoration. The primary objective of this paper is to introduce a classification system designed to provide a lucid and systematic decision-making framework for the final restoration’s design. Drawing insights from clinical reports, the intention is to offer guidance to clinicians involved in rehabilitating edentulous jaws. Additionally, this paper will demonstrate the effective integration of recent advancements in digital dentistry into conventional workflows.

Surgical and prosthetic protocol for full-arch screw-retained implant-supported rehabilitations.

Many experts emphasize the fundamental role of precise diagnostic information as the cornerstone of effective treatment planning (14, 15). Properly charting the treatment trajectory from the initial consultation is vital for success.

In this paper, the Authors delineate their daily protocol for creating full-arch screw-retained implant-supported prostheses, applied in both immediate and non-immediate loading situations (Fig. 1). The procedure starts with systematic data collection, followed by a strategic implant-prosthetic planning based on the acquired information. The subsequent

surgical stage includes implant placement and temporary prosthesis delivery, scheduled based on the loading protocol; this leads to the preparatory stage for the final restoration, entailing provisional reevaluation and the necessary recordings for an accurate fit and pleasing aesthetics. Before concluding with the delivery of the final restoration, an aesthetic try-on is conducted.

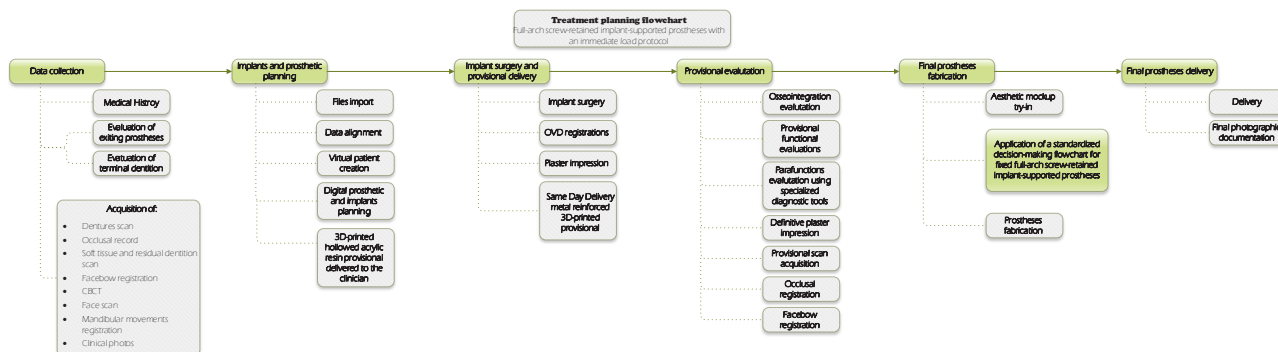


Fig. 1. Treatment flowchart for fixed full-arch screw-retained implant-supported prostheses. *Data collection*

The data collection step (Fig. 2) holds fundamental importance as it not only allows for determining whether the patient seeks a full-arch fixed restoration but also provides valuable insights into the type of restoration best suited for the specific scenario. The process begins with a meticulous anamnesis, gathering information about the patient’s general health, medical history, medications, and psychosocial elements.

The subsequent objective examination and radiological assessment vary depending on the patient’s current oral status. For denture wearers, an evaluation of the existing device is necessary. If it is deemed functional and aesthetically suitable, it can be used as a starting point for a full-arch prosthesis after proper relining. Alternatively, a new denture should be fabricated from scratch, with special attention to determining the occlusal vertical dimension (OVD), phonetics, aesthetics, and soft tissue support, as it serves as a reference for provisional fabrication. The introduction of digital technologies has made the use of Digital Smile Design (DSD) in planning software (Exocad version 3.1 Rijeka) a viable option, potentially obviating the need for a new denture under specific conditions.

The subsequent step has been significantly influenced by the integration of intraoral scanners (IOSs) and other registration tools into daily clinical practice. In the past, acquiring prosthetic information from a denture required the creation of a radiological guide or adherence to the Double Scan Protocol (14). Nowadays, clinicians can directly acquire this information in a digital STL format using an intraoral scanner (Aoralscan 3, Shining 3D). Dentures can be scanned outside the mouth one by one, with the option of using additional markers for smoother acquisition (DentalMark, SureMark®), and then manually aligning them in occlusion to capture an occlusal registration using scannable silicones (Occlufast CAD, Zhermack). The approach may vary depending on the condition of the opposing arch, but even a removable denture on a single arch can be scanned extraorally and later aligned intraorally. Regardless, the generated files should be carefully checked for continuity in both the inner and outer surfaces.

For edentulous patients, acquiring oral soft tissue data becomes a separate step. This can be particularly challenging

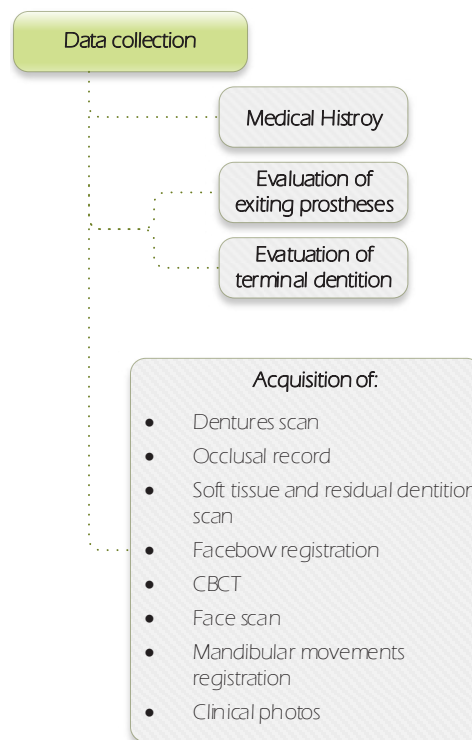


Fig. 2. Illustrates the various steps involved in the data collection phase.

when the crest is significantly resorbed, and usual landmarks are lost. In such scenarios, it is beneficial to place sticky markers in reproducible positions before both IOS scanning and CBCT acquisition to facilitate both the scanning process and subsequent data alignment.

In cases where the patient still retains natural teeth, the initial examination should focus on the diagnosis and therapeutic indications for each tooth, considering endodontic, prosthetic, and periodontal aspects (16). When the dentition is judged as a failing one further elements are to be considered before extraction: the clinician should inspect the aesthetic of the current situation, considering asymmetries or patients concerns. When the dentition is deemed failing, additional elements are considered before extraction. Clinicians should evaluate the current aesthetic situation, considering any asymmetries or patient concerns. The authors of the CBP protocol also recommend performing periodontal probing, which will later influence the choice of restoration (11). A digital impression of the failing dentition and soft tissues is taken.

In any of the mentioned scenarios, we acquire a facebow registration using digital technologies (Artex facebow, Artex). As an additional recommendation, we propose proceeding with the model plastering on the semi-individual articulator (Snow white plaster, Kerr) in an outpatient setting. It's essential to ensure that the dental laboratory possesses an exact replica of such an articulator set with the same parameters. This approach not only facilitates the shipment of smaller packages to the dental lab, eliminating the need to ship a facebow, but also fosters smoother communication between technicians and prosthodontists.

For both failing dentitions and edentulism, further anatomical information is required. A CBCT scan is acquired and exported in DICOM format, while a face scanner (MetiSmile, Shining 3D) captures extraoral soft tissue and smile line data. In this phase, the use of a mandibular movement registration tool (Cyclops, Itaka) is advised. Through specific hardware components, this tool registers dynamic occlusion.

Further information is obtained, useful also for later comparison, shooting a standardized set of photos. The protocol starts by providing reproducible setting, not only by consistently setting the camera and the framing, but also guiding the patient in natural head position (NHP), which is proved to have greater standardization over other possible references (17). At this stage the authors usually take two front-facing shots. First, with the patient sat down in NHP and the dental assistant at his back holding a set of Y-shaped cheek retractors, an open mouth photo is acquired. Subsequently the dental assistant gently removes the cheek retractors, trying to not move the patient's head, and the same shot is acquired but with the patient slightly smiling.

Implants and prosthetic planning

Once all the essential anatomical, prosthetic, and aesthetic data have been adequately collected, these are consolidated into a unified platform, effectively creating a virtual patient (Fig. 3). To accomplish this, we adopt specialized software (Exocad version 3.1 Rijeka) due to its integrated capabilities. This software not only facilitates comprehensive diagnosis and planning for full-arch screw-retained implant-supported rehabilitation but also streamlines prosthetic design within the same environment.

Following the data import, including the CBCT scan (if required), intraoral soft-tissue scan, prostheses scan, opposing arch/prosthesis scan, occlusion bite and dynamic occlusion, facebow registration, and face scan, our next step involves aligning these models utilizing the dedicated wizard feature. An important point to note before moving forward is the orientation of the triangles in the digital scan of a prosthetic device. Like all STL files, this scan is represented by a mesh of small triangles, which typically face outward. This can be likened to having an impression of the denture that's awaiting casting into a physical model.

To fully understand the need for inversion, we must delve into how digital scans operate. When an intraoral scan is executed, the outcome is an STL file that depicts the object's surface through a mesh of triangles. In most scans, these triangles are oriented so that their normals point outward, representing the external surface of the scanned object. However, in certain contexts, such as when aiming to

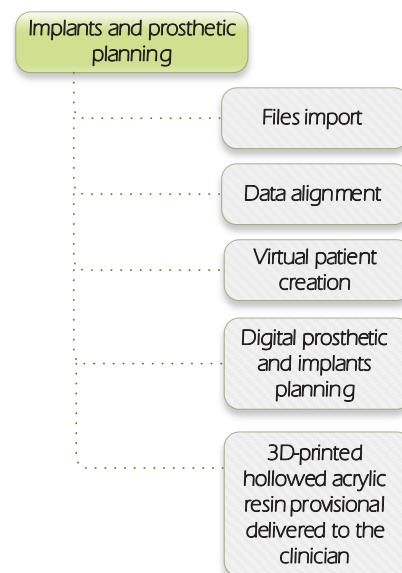


Fig. 3. Illustrates the various steps involved in the implant and prosthetic planning phase.

create a negative model of the denture for designing and fabricating devices that must perfectly replicate the original denture, it becomes necessary to invert the orientation of these triangles.

This digital step simulates the process of creating a negative mold, that compared to an analogic impression would be a plaster cast, eliminating the manual need to duplicate dentures in plaster. Fortunately, most dental CAD software solutions, including Exocad, provide a function to digitally invert the model's vertices.

This virtual patient serves as a virtual workspace, allowing the dental technician to operate as if the patient were physically present. Collaborating closely with the prosthodontist, the technician designs a temporary prosthetic device intended for immediate delivery on the day of implant placement surgery. For edentulous patients, we consider compensating for soft tissue deficiencies based on an evaluation of the distance between the cervical portion of the prosthetic teeth and the alveolar ridge. Compensation is deemed necessary when this distance exceeds 25% of the length of the prosthetic teeth. In cases of failing dentition, these considerations are guided by the mean probing depth, serving as an indirect measure of bone and soft tissue resorption. A value of 5 mm or more typically indicates the need for soft tissue replacement. In any scenario, the false gingiva is incorporated into the manufacturing process after the surgery is completed.

If the existing occlusal vertical dimension (OVD) is deemed suitable in terms of function and aesthetics, we proceed to create and verify proper contacts using the virtual patient established earlier. It is imperative to note that the OVD encompasses both the freeway space, essential for aesthetics and function, and the prosthetic space, establishing a bidirectional relationship with prosthetic design. For more complex cases, an intermediate restoration is designed and fabricated to assess aesthetics and function rigorously. Alternatively, Digital Smile Design (DSD) can be employed.

The concluding phase involves providing the clinician with the temporary restoration. The authors typically employ A2 colored acrylic resin, 3D-printed from a CAD project, and later manually customized to achieve tooth characterization and refine the restoration. The adoption of acrylic resin for provisionals aligns with substantial support in the literature, owing to its capacity to absorb stresses that might otherwise be transmitted at the implant-bone interface (18). Notably, the provisional is initially delivered in a hollowed-out state, ready for subsequent assembly to the metal framework. This framework is fabricated through welding a metal bar to the provisional cannula, previously screwed onto the angled abutments.

Implant surgery and screw-retained immediately loaded provisional delivery.

The subsequent surgical phase (Fig. 4) is case-specific, but the authors adhere to certain general principles. As a general guideline, the utilization of long and wide tilted implants (measuring 13 mm or more) with a rough surface, an external hex connection, and angled abutments is favored, avoiding reliance on regenerative procedures and reducing cantilever length. In cases where immediate loading is planned an insertion torque exceeding 40Ncm is targeted, also considering surgical site underpreparation.

These principles, as outlined in the Columbus Bridge Protocol (11), are derived from research comparing stress distribution in the bone surrounding immediately-loaded tilted implants versus traditional straight implants and their associated outcomes (19, 20). Research has shown that using longer tilted implants, particularly when splinted with a framework, results in a more even stress distribution in the surrounding bone compared to straight implants. Furthermore, tilted implants often obviate the need for additional bone regeneration procedures. They also enable the placement of longer implants, thus achieving the primary stability crucial for immediate loading (21-25), and they assist in reducing cantilevers.

The surgical procedure begins with the extraction of any remaining failing teeth. Following an immediate placement protocol, implants are inserted along with low-profile angled abutments. Before suturing, abutments are placed, and a plaster impression is obtained using an open-tray technique. Subsequently, an interocclusal registration wax is created and later relined with aluminium wax, considering both the presurgical and planned occlusal vertical dimension (OVD) as measured on fixed landmarks. On the same day, within the framework of

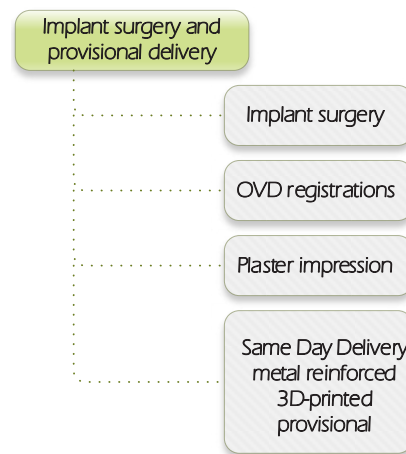


Fig. 4. Illustrates the sequential steps in the implant surgery and provisional delivery phase.

the “Same Day Delivery” concept, an in-house dental laboratory produces a passive metal framework. Verification of its passive fit through a single screw test precedes its secure attachment to the provisional superstructure.

Evaluation of provisional restoration after 4 months

Following a four-month interval, the transition to the phase of prosthetic reassessment (Fig. 5) is made. At this stage, careful attention is given to ensuring the provisional restoration aligns seamlessly with both the patient’s aesthetic expectations and the biomechanical functional requisites. Adjustments are made as necessary, considering the extent of functional wear, if present. If significant modifications are deemed essential, the option of crafting an additional provisional restoration is considered. It’s important to note that, in cases following a delayed loading protocol, this phase represents the fabrication of the initial provisional restoration, with evaluations deferred to later stages.

To enhance the probability of success in fixed full-arch screw-retained implant-supported rehabilitations, a pivotal factor that merits precise consideration when evaluating the appropriateness of a temporary restoration is parafunctions and bruxism. A recent study by Thymi (26), through interviews with oral implantologists practicing in non-academic clinical environments in the Netherlands, has highlighted that the majority of clinicians do not perceive bruxism as a contraindication to implant therapy, provided that pain is absent. Furthermore, it has been noted that certain clinicians do not factor bruxism into their material selection for rehabilitation. In this context, a recent systematic review and meta-analysis by Häggman-Henrikson (27) indicate that individuals classified as probable bruxers may exhibit an elevated risk of implant failure in comparison to non-bruxers. In the case of immediately loaded implants, this heightened risk may be attributed to diminished proprioception around the implants and the detrimental consequences of micromovements during the orthopedic healing process of peri-implant bone.

Given the current lack of unequivocal evidence concerning the impact of bruxism and parafunctions on full-arch rehabilitation, and drawing insights from our collective experience, the adoption of advanced diagnostic and monitoring tools proves advantageous for addressing patients presenting such conditions. These diagnostic tools come to the forefront primarily when both the patient and the clinician express contentment with the aesthetic and functional aspects of the provisional restoration, yet the patient reports discomfort despite the absence of clear evidence indicating imbalanced occlusal contacts and muscular stresses.

One such tool the authors employ is an electromyography system specifically designed for dental applications, complemented by its dedicated software (Teethan®). This system aids in the precise identification of a patient’s parafunctional activities, including the specific muscles involved and their distribution within the occlusal scheme. To further enhance diagnostic accuracy, the incorporation of a portable Holter (BruxOff®) gives insight in the diagnosis and continuous monitoring of sleep bruxism (SB) when worn uninterruptedly for a minimum duration of 6 hours. These diagnostic tools offer more than mere identification; when seamlessly integrated into the clinician’s workflow and coupled with physiotherapy, they facilitate the fine-tuning of provisional function based on significant findings and patient complaints, ensuring adaptation before proceeding to the fabrication of the final restoration.

At this juncture, additional data acquisition becomes imperative. Thanks to the previously mentioned systems a comprehensive dataset is compiled, including STL models of the provisionals (Aoralscan 3, Shining 3D), an occlusal record (Occlufast, Zhermack), soft tissue scan, a facebow registration (Artex facebow, Artex), and plaster impressions using an open-tray technique (Snow white plaster, Kerr). The principles governing data variation to accommodate specific scenarios, as delineated in the data acquisition section, are diligently applied.

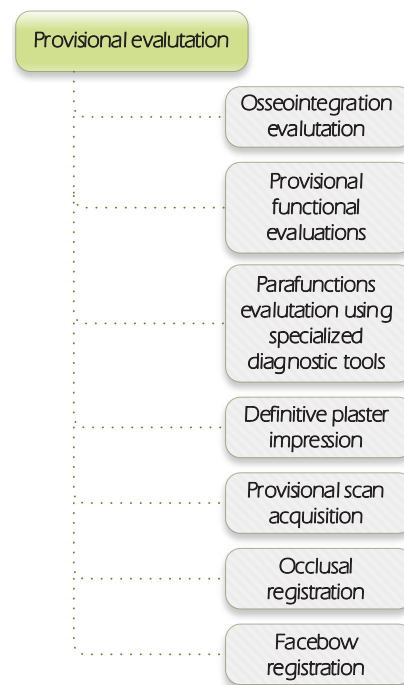


Fig. 5. Illustrates the sequential steps in the provisional evaluation phase.

Fabrication of a fixed screw-retained full-arch implant-supported prosthesis

In this phase, clinicians encounter critical decision-making challenges regarding prosthetic design (Fig. 6). These considerations will be addressed in a subsequent paragraph. For now, the workflow will be described, assuming that these decisions have been made for continuity.

The dental laboratory receives both analog and digital patient information and proceeds to create a wax denture for the final aesthetic try-in. It is important to emphasize the concept of integration between digital and analog procedures. According to our perspective, supported by literature (28, 29), digital impressions' precision is not comparable to conventional plaster impressions when considering full-arch rehabilitations. For this reason, digital technologies are utilized in many steps of author's daily practice, but plaster impressions are preferred for such cases.

Moving forward, dental technicians incorporate additional data into the existing information, including updated face scans, occlusal registrations and a functionally adapted, aesthetically pleasing provisional. The framework is designed in a CAD environment using a virtual patient (Exocad version 3.1 Rijeka). It is initially tested for passivity through a virtual one-screw test before being sent to an external facility for manufacturing. Simultaneously, the superstructure is integrated into the project. Upon receiving the metal structure, a further passivity test is conducted, both on the plaster model and in the patient's mouth.

The final steps, which vary based on the chosen prosthetic design, encompass creating the superstructure, adding characterizations to it, assembling the framework with the aesthetic superstructure, and finalizing the rehabilitation in vivo (Fig. 7). An optional but highly recommended step is capturing photographs of the final conditions, following the same pattern described during the data acquisition phase.

Factors influencing the prosthetic design.

In their clinical practice authors employ five primary types of full-arch screw-retained implant-supported prosthetic designs. While this range doesn't cover the ever-expanding array of options, it is worth noting that some, namely full monolithic Zirconia restorations and PEEK (polyether-ether-ketone) frameworks, are intentionally excluded.

The exclusion of full monolithic Zirconia restorations is motivated by their increased susceptibility to chipping, despite their potential for superior soft-tissue response and aesthetic appeal compared to Titanium frameworks (30-32). Similarly, PEEK, which has gained popularity in the dental community, is not part of the repertoire. PEEK is found to be unsuitable for permanent restorations due to its tendency to undergo plastic deformation, abrasion, and fracturing, especially under stress. This is largely attributed to its low elastic modulus and relative softness (33).

The first solution suggested is the Toronto bridge, which involves a CAD/CAM designed and manufactured framework made of either Titanium or Chromium-Cobalt (Cr-Co) alloy combined with denture teeth and resin compensation for soft tissue loss. The second design, called Natural bridge, is similar in framework but incorporates fully customized Composite resin teeth, polymerized in a transparent mold, for aesthetic veneering. The Thimble technique is the third option, featuring a Titanium or Chromium-Cobalt alloy framework containing stumps, or thimbles, that replicate the function of natural teeth abutments and support individually luted monolithic Zirconia crowns. The fourth solution, namely the Titanium-Zirconia bridge, uses a CAD/CAM titanium framework luted on a milled monolithic Zirconia superstructure or a cut-back customized Zirconia veneering. Finally, there is a design that employs a CAD/CAM Titanium

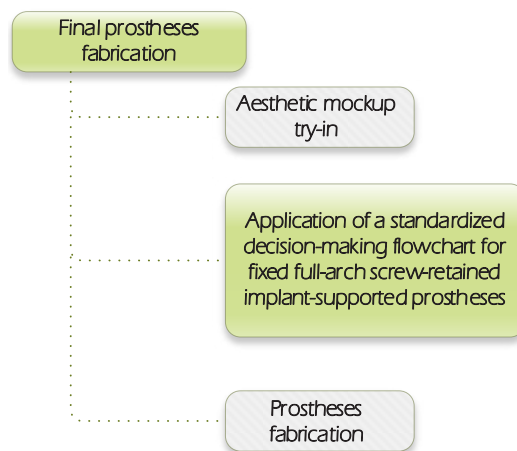


Fig. 6. Illustrates the sequential steps in the final prosthesis fabrication phase.

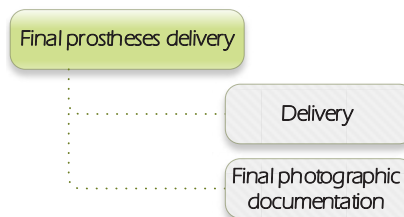


Fig. 7. Illustrates the sequential steps in the final prosthesis delivery phase.

framework with ball attachments to support a removable metal-reinforced overdenture. One last design worth citing is the full Zirconia framework one, presenting a monolithic Zirconia framework combined with either monolithic zirconia or ceramic veneering stratified over a carved monolithic Zirconia structure for teeth. As stated, we don't embrace this last design due issues related to its fit and passivity. The following figure offers an overview on presented options (Fig. 8).

Classification of full-arch screw-retained implant-supported prostheses

<i>Classification</i>	<i>Framework</i>	<i>Aesthetic Covering (teeth)</i>
1) Toronto bridge	Titanium/Chromium-Cobalt (CAD/CAM)	Denture teeth
2) Natural bridge	Titanium/Chromium-Cobalt (CAD/CAM)	Composite resin
3) Thimble technique	Titanium/Chromium-Cobalt (CAD/CAM)	Single Zirconia crowns
4) Titanium-Zirconia bridge	Titanium	Milled monolithic zirconia or customized zirconia using Cut-Back
5) Bar overdenture	Titanium	Counter-bar embedded in a removable overdenture
6) Full Zirconia	Zirconia CAD/CAM	Monolithic zirconia or Stratified ceramic on monolithic zirconia

Fig. 8. Options for full-arch screw-retained implant-supported prostheses.

Chromium-Cobalt alloy vs titanium as framework materials.

Chromium-Cobalt is renowned for its strength, longevity, biocompatibility, and resistance to corrosion (34). It can also be effectively bonded with ceramics. However, the traditional casting techniques for Cr-Co come with their set of challenges. The cumulative effects of distortion and porosity, coupled with high labor expenses, make the finishing process intricate.

In contrast, Titanium frameworks are recognized for their corrosion resistance and biocompatibility, largely attributed to a slender protective oxide layer (35). To achieve these characteristics, titanium requires specific casting and finishing techniques, especially considering its high melting point of approximately 1668°C and a swift oxidation rate surpassing 900°C. This calls for advanced equipment. Notably, at 883°C, titanium transitions from an alpha-hexagonal configuration to a beta-cubic form. This alteration alters the framework and forces ceramics to be fired at temperatures under 800°C.

Distortions and porosity, common challenges in this domain, are effectively tackled using CAD/CAM methodologies. This is particularly beneficial for extensive rehabilitations, like full-arch structures, when utilizing titanium and Chromium-Cobalt. The accuracy offered by CAD/CAM facilitates the manufacturing processes and minimizes distortions and porosity, ensuring an enhanced fit and reduced bacterial attachment (36). When the two are compared (Fig. 9) Titanium seems to be the material of choice for the framework of full-arch screw-retained implant-supported prosthesis due to its enhanced biocompatibility, aside from the scenarios in which either prosthetic space is lacking or long cantilevers are planned (37).

Aesthetics

Rehabilitation procedures should be tailored to meet the individual aesthetic requirements of patients. In scenarios where a high degree of customization is sought to achieve superior aesthetic outcomes, Zirconia outpaces other alternatives owing to its natural appearance. Composite resin dentitions, however, may sufficiently meet the demands of less demanding patients. Additionally, the extent of smile exposure necessitates careful evaluation of design choices to avoid potential disadvantages; for instance, the transition line to soft tissues in a Toronto bridge might be less bothersome for individuals with a low smile line, compared to those with a high smile line.



Fig. 9. CAD/CAM metal framework comparison. Chromium-cobalt alloy and titanium.

Available prosthetic space and minimum material thickness requirements

Determining the available prosthetic space, calculated by subtracting the Freeway space from the OVD, is pivotal in steering the prosthetic design choice, thereby averting complications such as veneer chippings or framework fractures. In the Toronto bridge solution involving a Cr/Co framework, it is advised to maintain as minimum thickness parameters 0.5 mm for tube and 2.5 mm for section. A similar approach applies to the Titanium framework but with differing values, 0.8 mm and 4 mm for tube and section, respectively.

Employing the Natural bridge solution generally involves larger volumes while adhering to the same framework thickness parameters. The Thimble technique showcases a more anatomical structure, enhancing volumes significantly while imposing a minimum Zirconia thickness of 0.6 mm. Conversely, the luted Titanium-Zirconia bridge solution, characterized by its vertical extension, prescribes a minimum thickness of 0.8 mm for Zirconia, aligning with the minimum thickness values dictated for the frameworks. Full Zirconia solutions recommend a minimum thickness of 0.6 mm, with a special emphasis on increased palatal thickness to reduce the risk of fractures at common stress points caused by forces acting on the implant.

The authors consider the bar overdenture and the luted Titanium-Zirconia bridge the ones requiring the most vertical prosthetic space, followed by the thimble technique and other solutions (38-41).

Ease of repairability

With patients undergoing full-arch rehabilitation averaging 61 years of age (42), and taking into account the 2020 reported life expectancy in Europe of 80 years (43), the age factor becomes pivotal in the context of long-term planning. Considering the age at which a specific patient is receiving the rehabilitation is crucial in the long term.

In this regard, the Thimble technique emerges as a prudent choice for young adults with enough financial means. Despite its higher fabrication costs, it facilitates relatively economical and straightforward repairs, since luting single crowns on the mesostructure allows their individual replacement without necessitating extensive procedures. Composite resin and denture teeth share this benefit, also offering chairside reparability for minor fractures.

Hygienic potential

Given the documented decline in self-care and oral hygiene abilities in elderly patients, the selection of an appropriate solution becomes central to sustaining oral health (44-47). Reports denote a superior hygienic potential in overdentures, advocating for their preference among elderly individuals with diminished manual dexterity (44).

Nature of the opposing dentition and patient's parafunctions

It is well established that implant-supported prostheses have a reduced proprioception if compared to the natural

dentition (48). The material chosen for the occlusal surfaces should be balanced with its effects on the opposing dentition, for instance privileging Composite resin if the opposing arch presents natural teeth partially compromised by periodontal disease. This can be of lesser impact in elderly with a reduced masticatory force and no parafunction, but it is of primary importance in young people. Moreover, zirconia is not advised in parafunctional patients for its high hardness, that more likely leads to chippings rather than abrasions.

Conservation of the OVD

Owing to its robust mechanical properties, Zirconia emerges as the most suitable material for maintaining a consistent occlusal vertical dimension (OVD) among the options considered. In contrast, materials such as acrylic resin or Composite resin are prone to abrasion in response to masticatory forces. This abrasion is influenced by the nature of the opposing arch’s dentition and can lead to significant alterations in a patient’s occlusal vertical dimension over time.

Zirconia is a durable and wear-resistant material, making it a great choice for long-lasting full-arch rehabilitations. This is especially true for younger patients who need a solution that will maintain a stable OVD for many years. This material pairs with the Thimble technique, offering a reliable choice for young adults. However, if this option isn’t suitable due to its high cost or other factors such as age-related considerations, a Titanium-Zirconia bridge is a viable alternative.

The decision-making

Taking into account the previously presented data, the provided flowchart serves as a helpful guide for clinicians when selecting the most suitable prosthetic option for a particular patient (Fig. 10). It’s essential to acknowledge that while this flowchart offers valuable guidance, strict adherence may not always be appropriate, as adjustments may be needed to accommodate variations in both practitioner preferences and patient needs. Additionally, when considering options that may involve either a Chromium-Cobalt alloy framework or a Titanium framework, it’s advisable to refer to the relevant sections for further details and considerations.

Application of the proposed classification

Application of the proposed classification is exemplified through a series of five clinical cases, illustrating how the classification system was effectively utilized. All patients received treatment in an outpatient setting, following the

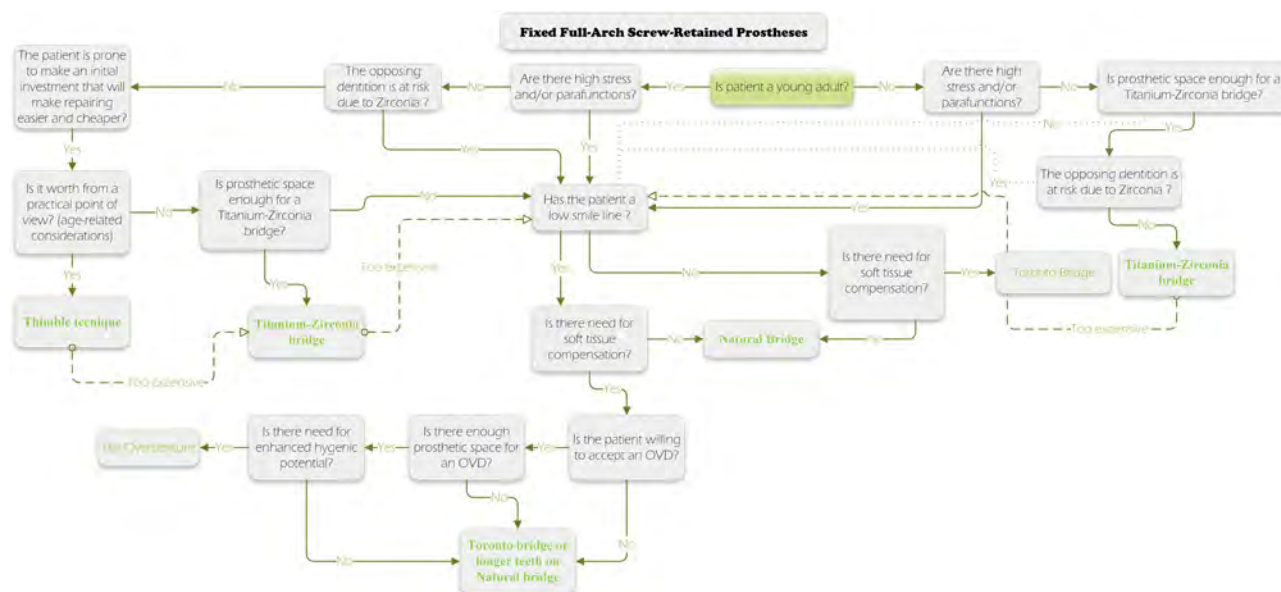


Fig. 10. The proposed decision-making flowchart. Straight lines and dotted lines are the main path, the latter indicating a major redirect. Dashed lines redirect the clinician when a given solution doesn’t fit the specific patient (mainly due to costs). OVD stands for overdenture.

outlined workflow. These case studies not only validate the classification but also provide practical insights into its application, aiding practitioners in adapting it to their unique clinical scenarios.

CASE I: TORONTO BRIDGE

A 76-year-old male, wearing complete removable dentures in both jaws, presented at our attention requiring a fixed solution to replace the removable rehabilitation. As reported in the previous sections we acquired all the relevant medical information about the patient’s health and no contraindication to implant therapy was found. The existing denture was then analyzed and deemed unsatisfactory in terms of OVD, aesthetics and functions. Upon relining of the dentures all the necessary scans and photos were acquired (Fig. 11, 12).



Fig. 11. Data acquisition step. Initial photos. *A*): photos without dentures in situ, showing the class III relationship between the jaws; *B*): Photos with dentures in situ, showing inadequate soft-tissue support.

A new OVD was determined to meet both aesthetic and functional criteria. Initially assessed digitally, it was subsequently transformed into a PMMA try-in (Fig 13). Surgery followed, involving the placement of four tilted implants (two pterygoid and two straight) in the maxilla, and four implants (two tilted) in the lower jaw. An open-tray technique was used to obtain a plaster impression for delivering an immediately loaded provisional, which was 3D printed based on an aesthetic project and later equipped with a metallic mesostructure (Fig. 14). Note that the pterygoid implants were not loaded during this initial phase.

Upon completion of the osseointegration period, the pterygoid implants were incorporated as supporting pillars in the provisional restoration. The proposed classification was consistently applied



Fig. 12. Data acquisition step. Existing denture. *A*): Existing dentures being relined; *B*): Occlusal registration inside the mouth.



Fig. 13. New dentures try-in. Notice the newly determined OVD and the enhanced soft tissue support.

at this stage, although an initial assessment could have been made in previous steps (Fig. 15). Considering all relevant factors, a Toronto bridge was determined as the most suitable prosthetic design for this patient.

A plaster impression using an open-tray technique and an occlusal registration in centric relation were acquired to fabricate an aesthetic try-in. Once the try-in was deemed optimal, a metallic framework (Fig. 16) was manufactured.

This framework was then sent to a local milling center to obtain a Chromium-Cobalt mesostructure. Upon its delivery to the dental laboratory, a one-screw test was conducted on the plaster casts, followed by an in vivo test. Standard procedures for the fabrication of the final prostheses were followed (Fig. 17). In the final step, the completed restoration was delivered to the patient, and photos of the result were taken for comparative and future reference (Fig. 18).

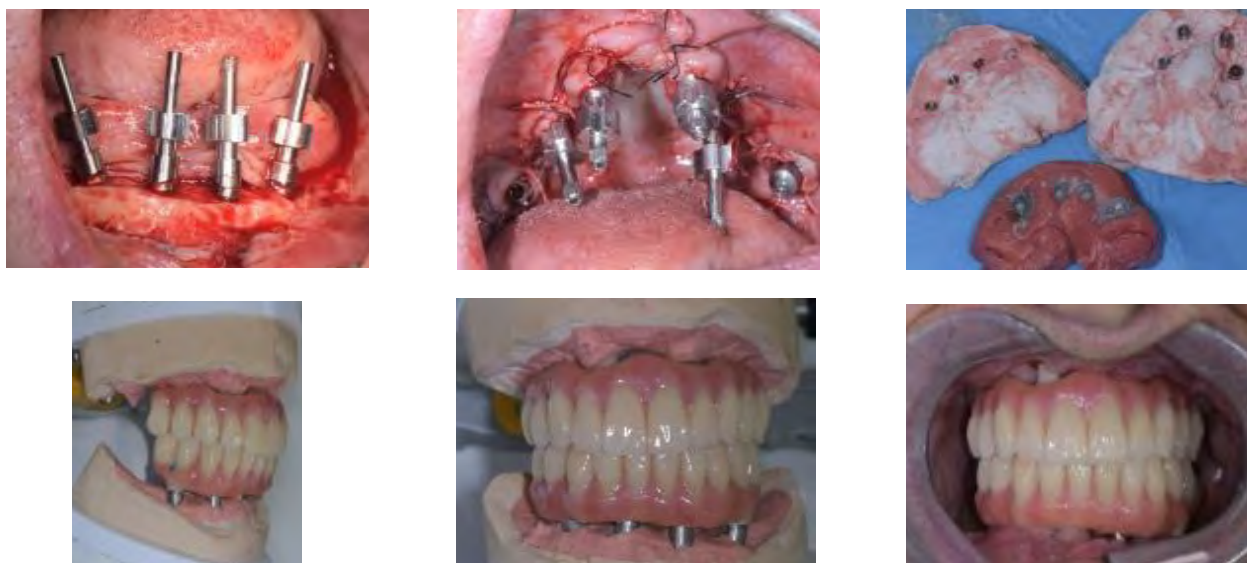


Fig. 14. Provisional registrations and delivery. Note the absence of open-tray transfers on the pterygoid implants.

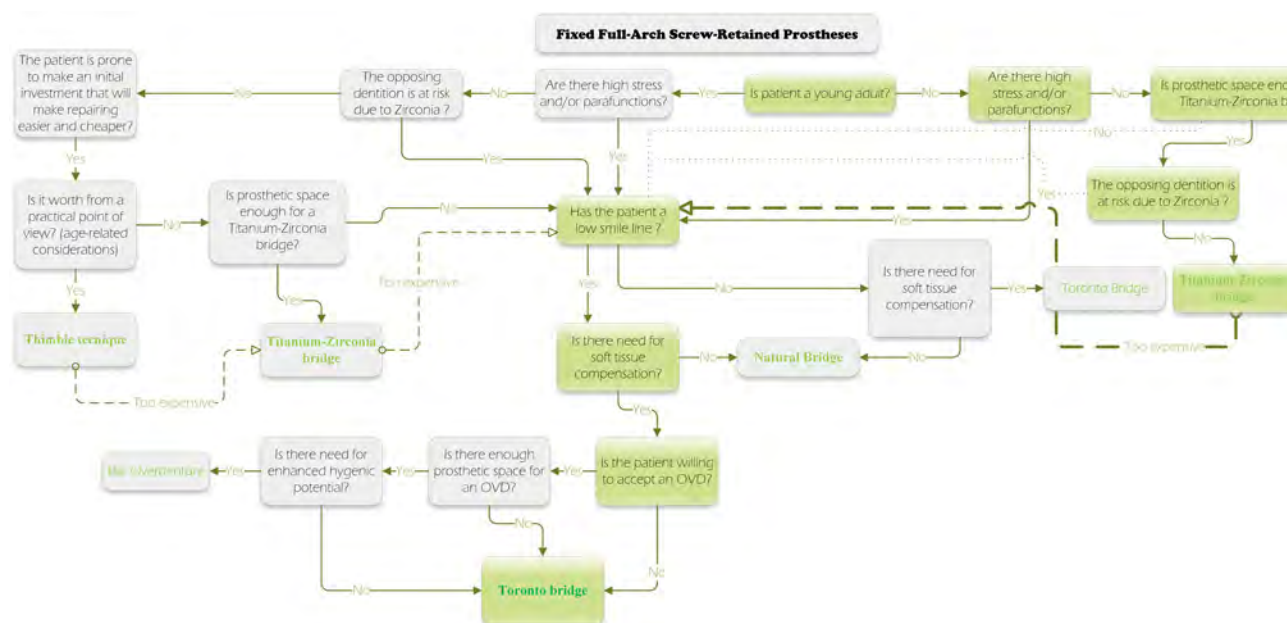


Fig. 15. Decision-making flowchart applied for a Toronto bridge.

CASE II: NATURAL BRIDGE

In the case of a 63-year-old edentulous patient seeking fixed upper jaw rehabilitation. The authors found it better to be more concise in the discussion of this patient, given the extensive coverage of clinical and laboratory procedures in previous sections.



Fig. 16. Clinical and laboratory procedures to design the metallic framework.

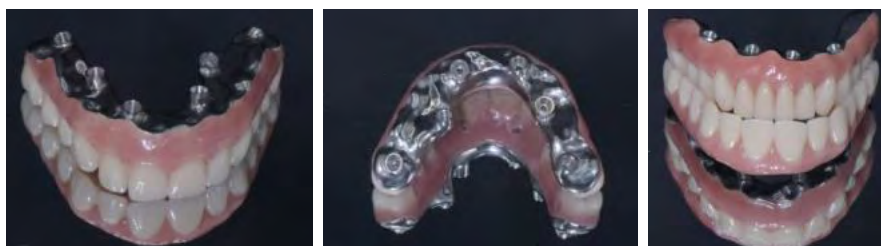


Fig. 17. Definitive prostheses. Observe that the portions contacting the mucosa are constructed from polished metal, facilitating improved hygiene both professionally and at home.



Fig 18. Final situation.

After analyzing the influencing factors, the authors determined that the most suitable prosthetic design was a Natural bridge with a CAD/CAM Chromium-Cobalt framework and customized composite teeth (Fig. 19, 20). Cr-Co was chosen due to its space-efficient characteristics compared to titanium.



Fig. 19. Final rehabilitation in situ. Note the absence of false gingiva, since no soft tissue compensation was necessary.

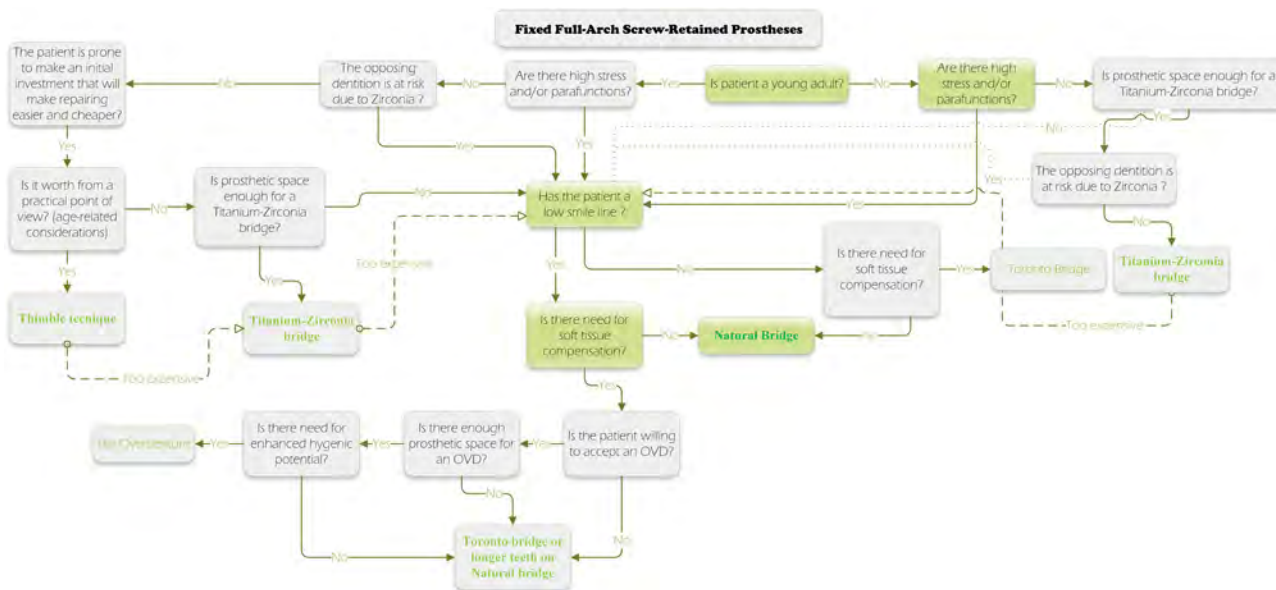


Fig. 20. Decision-making flowchart applied for a natural bridge.

CASE III: THIMBLE TECHNIQUE

In the case of a 54-year-old male seeking a durable and aesthetically pleasing fixed restoration for his upper jaw. The patient's failing dentition and unsatisfactory aesthetics and function were evident (Fig. 21, 22). Upon gathering all relevant prosthetic and anatomical information, surgery was performed, followed by a plaster impression and an occlusal registration (Fig. 23).



Fig. 21. Extraoral photos of the initial situation.



Fig. 22. Intraoral photos of the initial situation.

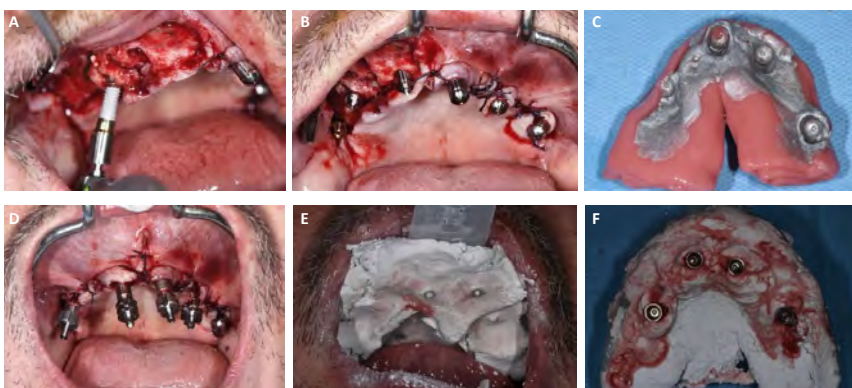


Fig. 23. Surgical implant placement and provisional registrations. **A):** Placement of implants (Biomax UNIPLANT with a diameter of 4.0 mm). **B):** Securing of the healing cups in position. **C):** Establishment of occlusal registration by guiding the patient to a centric relation using the “Chin Point” technique, coupled with the use of pink wax and Aluwax (Aluwax, Aluwax Dental Products). **D):** Positioning of the open-tray transfers. **E, F):** Capture of a detailed plaster impression.

After the completion of the osseointegration period, another impression was taken, and a PMMA try-in was 3D printed. It's worth noting that the dental midline was slightly shifted during this phase (Fig. 24). The final restoration design was then evaluated (Fig. 25). Given the patient's youth, desire for long-lasting results, aesthetic requirements, and absence of cost constraints, the Thimble technique was chosen as the most suitable prosthetic solution.



Fig. 24. PMMA try-in and small adjustments to the dental midline.

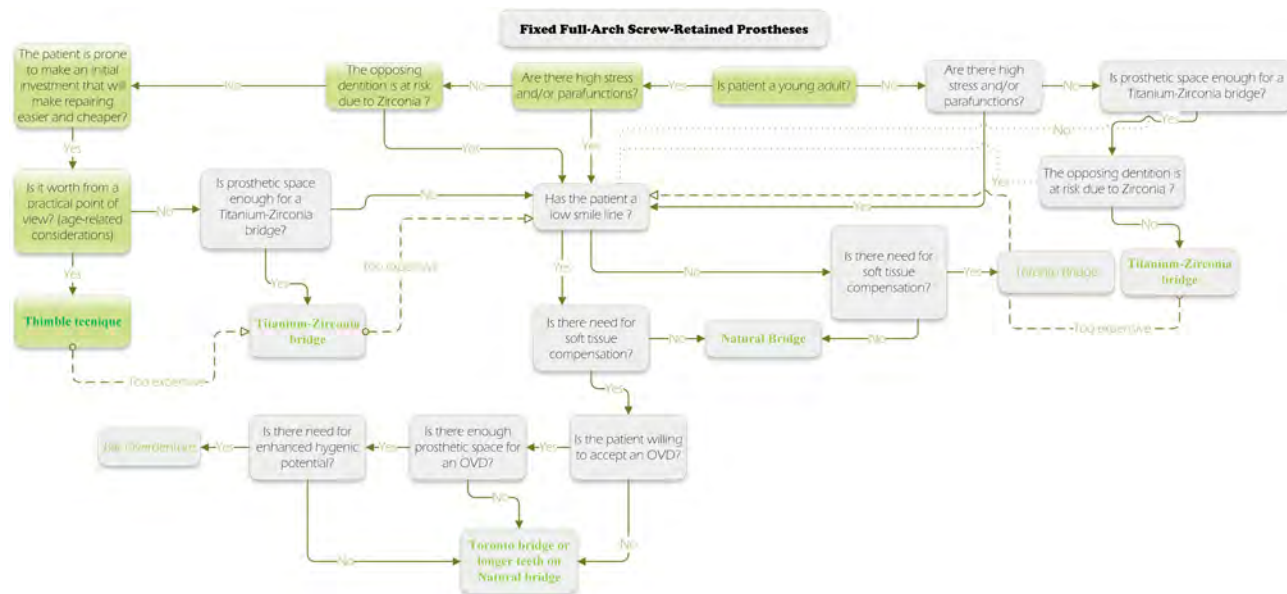


Fig. 25. Decision-making flowchart applied for a Thimble technique.

The fabrication process for a full-arch screw-retained implant-supported prosthesis using the Thimble technique commences with the construction of a Titanium framework, featuring stumps for the individual Zirconia crowns (Fig. 26).

Once the framework is delivered to the dental laboratory usual passivity tests are executed before luting each prosthetic crown in place. At last,

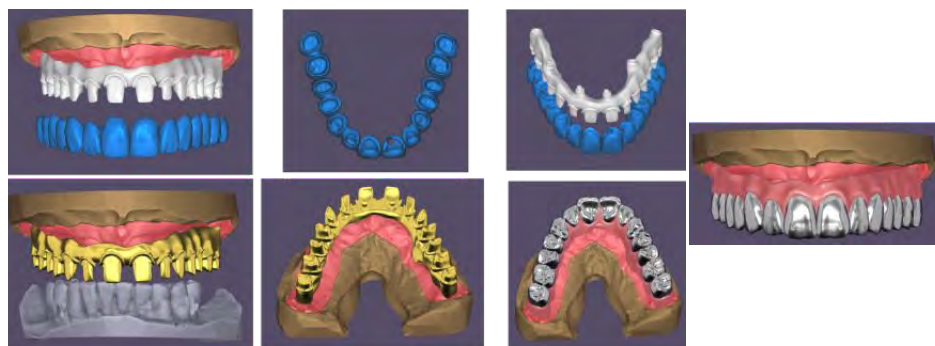


Fig. 26. CAD designing of a full-arch prosthesis using the Thimble technique CAD-On.

the final restoration is delivered (Fig. 27).

CLASS IV: TITANIUM-ZIRCONIA BRIDGE

A 75-year-old female patient has sought our expertise with a request for a fixed upper jaw rehabilitation. This case closely resembles the previous one, with the primary difference being the patient's age.

While the ease of repair is less critical for a 75-year-old patient, stringent aesthetic requirements remain a priority. After a comprehensive evaluation, a Titanium-Zirconia bridge was chosen (Fig. 28). The Thimble technique was ruled out due to its high cost and diminishing returns in meeting the patient's specific needs. Similarly, a Toronto bridge was not considered because it would not meet the patient's desired aesthetic standards. This illustrates why the authors advocate for an interpretive classification rather than a strict flowchart.

In this technique, a Titanium framework is meticulously designed to perfectly match a monolithic Zirconia superstructure. These two components are then bonded using an anaerobic cement, which requires some extra space but ensures mutual passivity (Fig. 29). The clinical results are briefly presented (Fig. 30).



Fig.27. Final restoration delivery.

CASE V: BAR OVERDENTURE

In a clinical case involving a 72-year-old male patient, both jaws rehabilitation was necessary as he had previously relied on a removable denture. The primary concern for this patient was functional improvement, with less emphasis on aesthetic considerations. Economic constraints and his suboptimal oral hygiene also played a role in the decision-making process (Fig. 31).

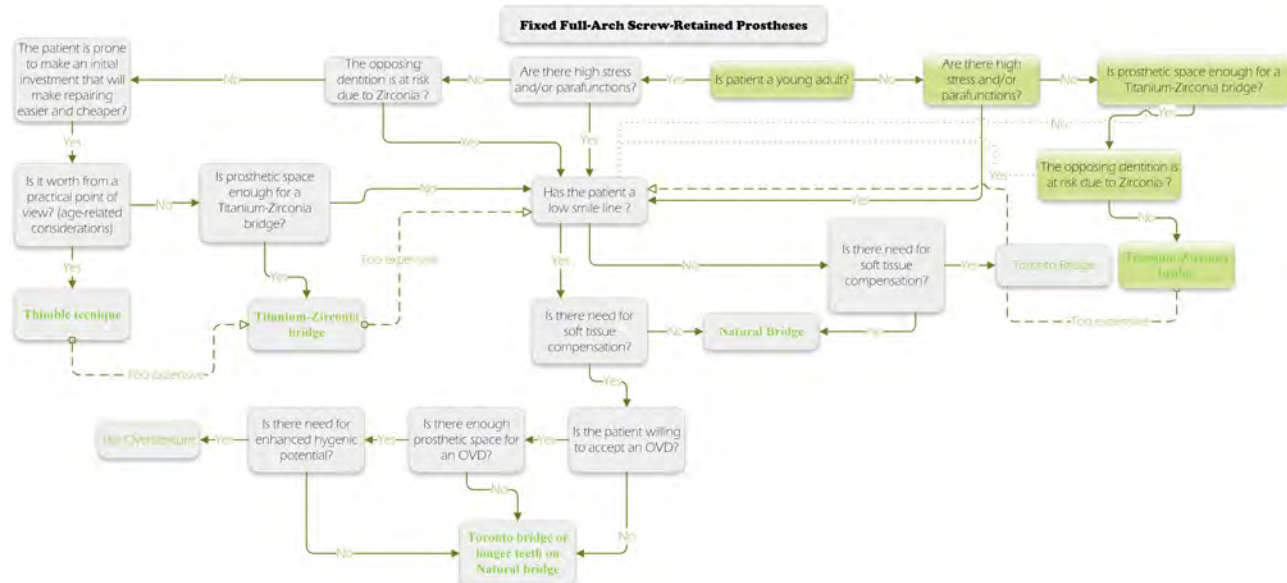


Fig. 28. Decision-making flowchart applied for a Titanium-Zirconia luted bridge.

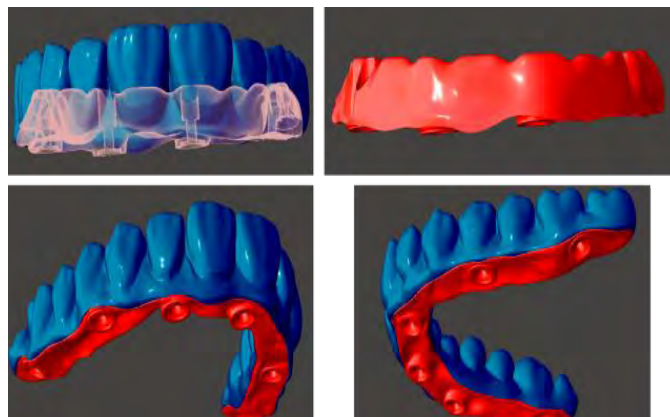


Fig. 29. This illustrates the two steps process of designing a prosthesis using CAD software and Blender. Initially, the entire prosthesis is assembled as a single piece in the CAD software to enhance aesthetics, function and harmony with soft tissue. Subsequently, the design is uploaded into Blender where a dedicated dental plugin is used to create the mesostructured, facilitating better management of luting spaces and passivity.

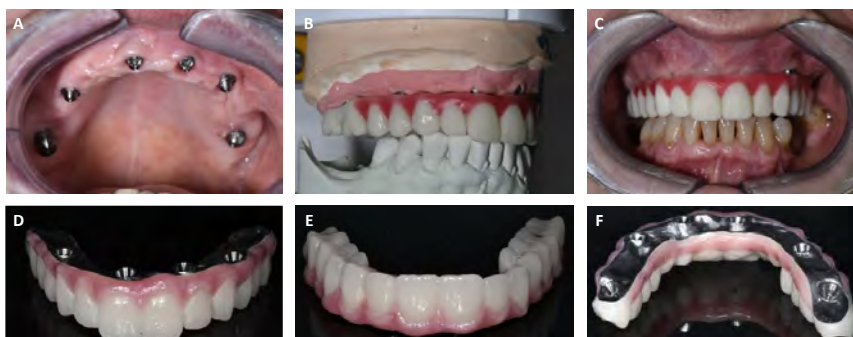


Fig. 30. Patient panel. **A):** Angled abutments in situ showcased with a soft tissue view. **B, C):** Intraoral trial of PMMA and pink wax gingiva. **D-F):** Different perspectives of the final restoration, assembled through manual luting of previously digitally designed components, adhering to the Titanium-Zirconia bridge luting technique.

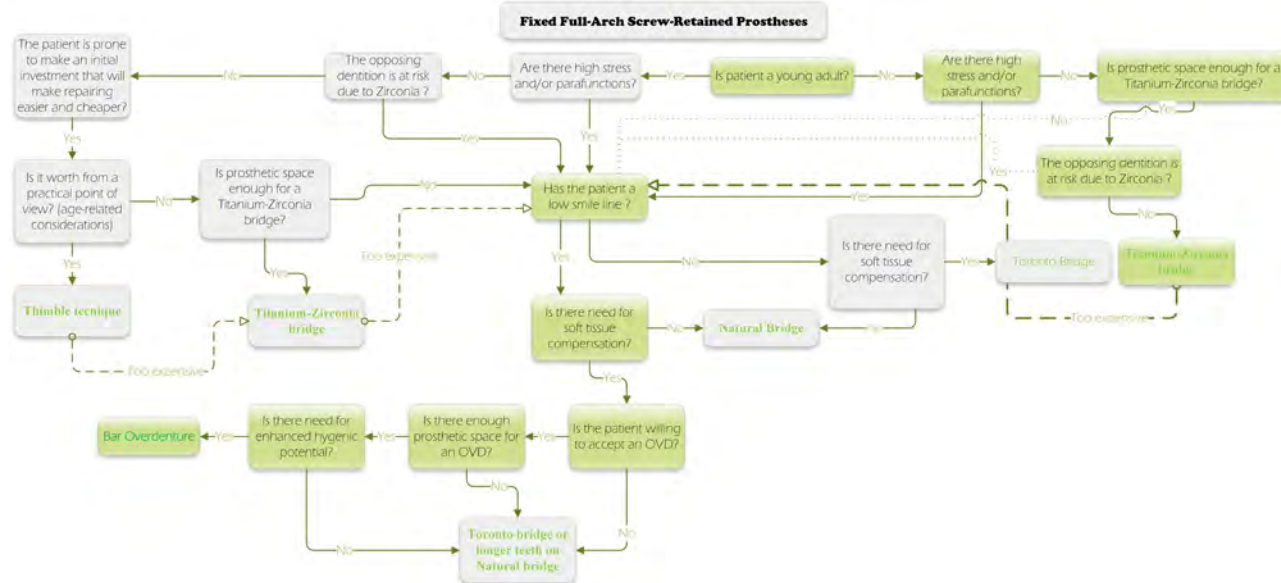


Fig. 31. Decision-making flowchart applied for a bar overdenture.

After a thorough assessment of all relevant factors, the authors concluded that a bar-supported overdenture (OVD) was the most suitable choice (Fig. 32). As reported earlier this design involves creating a primary bar with ball attachments to it, to be coupled with a second metal structure embedded into the removable OVD (Fig. 33).

Throughout the decision-making process, careful consideration was given to balancing various factors. As part of the comprehensive care provided to the patient, detailed information was offered regarding the potential need for maintenance associated with this type of prosthesis. Maintenance may become necessary due to the gradual wear and tear of attachments resulting from routine cycles of insertion and removal.

CASE VI: FULL ZIRCONIA

As previously noted by the Authors, the deployment of a full Zirconia bridge is generally discouraged due to the

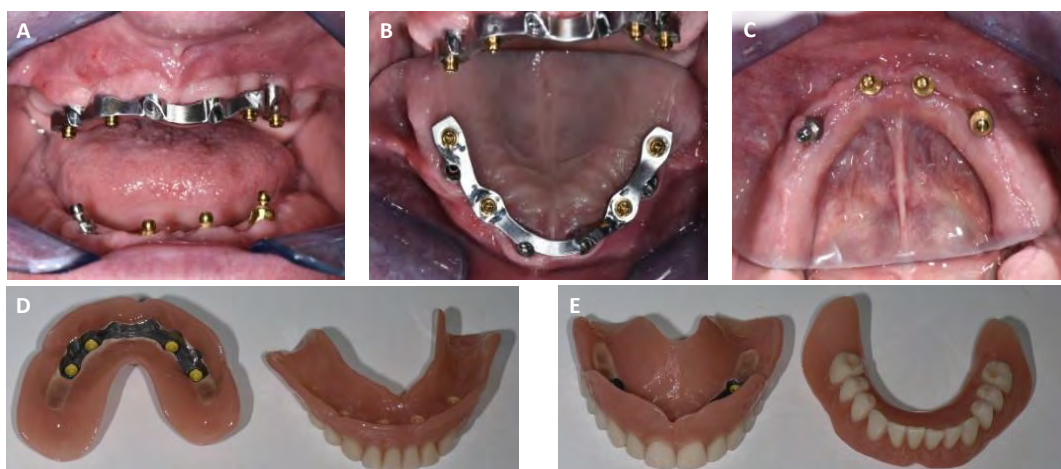


Fig. 32. Overdenture delivery. *A-C*): show the bar structure in situ. *D, E*): provide a complete view of the prostheses.

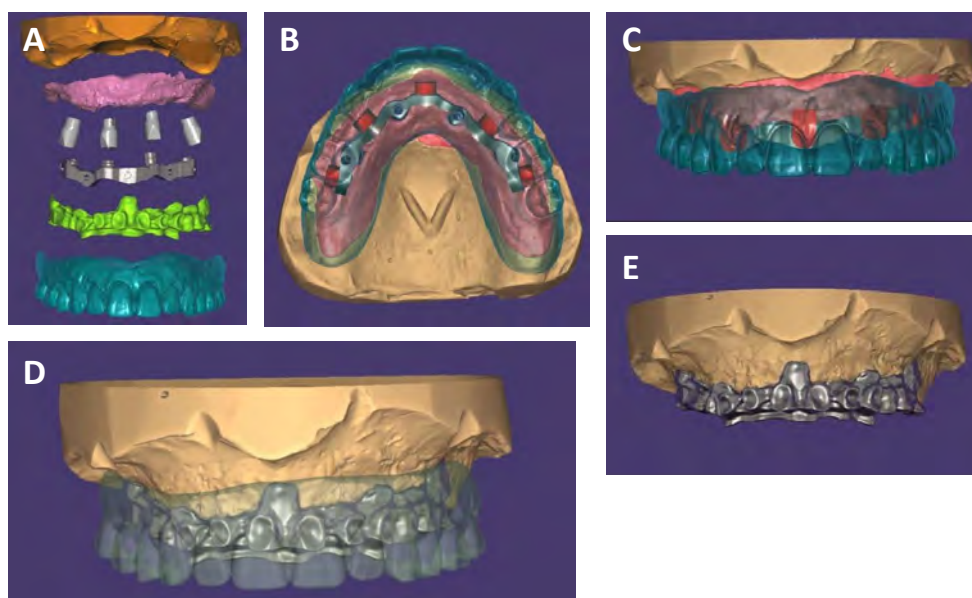


Fig. 33. Upper overdenture designing. *A*): shows the model base, the gingiva, the scan bodies, the primary structure, the secondary structure, and the aesthetic portion. *B, C*): show the overall prosthetic volume of the upper rehabilitation. *D, E*): show the volumetric relationship between the secondary structure and the aesthetic volume.

substantial technical hurdles in realizing passivity. Despite these concerns, the report presents a clinical case exemplifying the use of this methodology. However, it should be noted that no flowchart will be furnished, as this procedure does not constitute a regular component of the authors' daily practice.

A 65-year-old male requested an upper jaw rehabilitation by the mean of osseointegrated implants and a fixed prosthesis. The fabrication process involves various steps to achieve high passivity (Fig. 34, 35).

As reported by Tirone et al. (49) in a recent systematic review the ratios between the cantilever extension and cross-sectional connector area should be <0.51 , while the ratio between the former and screw access opening length should be <1.48 .

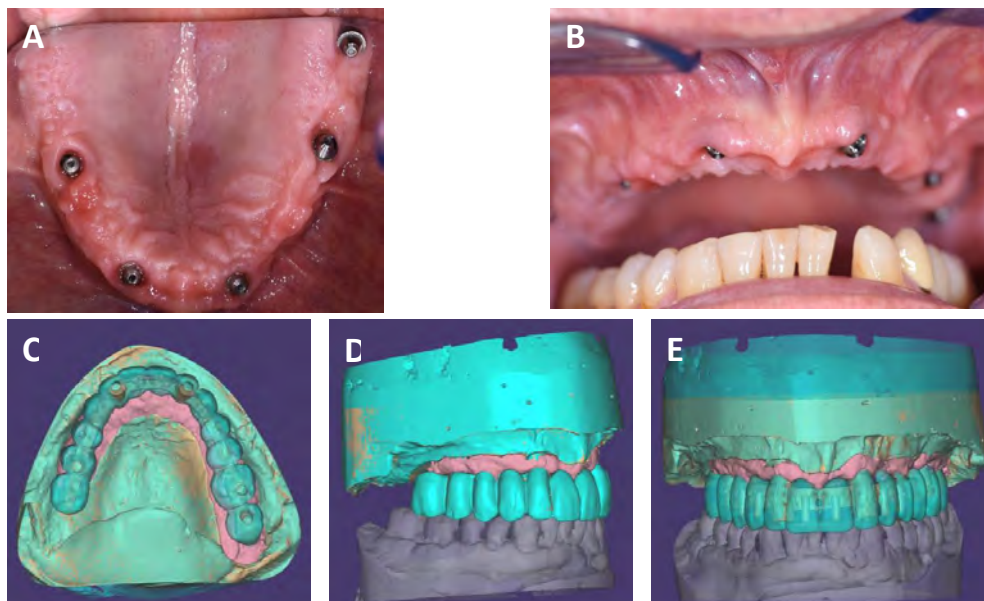


Fig. 34. *A, B): Soft tissue after a healing period of 4 month. C-E): partially report the various digital phases of prosthesis fabrication.*



Fig. 35. *Intraoral and extraoral views of the final restoration.*

DISCUSSION

The proposed classification of full-arch screw-retained implant-supported prostheses is a valuable tool for guiding clinicians in making informed decisions about the most suitable final restoration for their patients. This paper systematically considers a wide range of factors influencing the decision-making process and provides a case series to illustrate its practical application. The case series demonstrates the versatility and adaptability of the classification system across various clinical scenarios. It emphasizes the importance of evaluating each patient's unique circumstances, including medical history, anatomical considerations, aesthetics, and economic constraints. This patient-centered approach allows clinicians to tailor treatment plans to meet specific needs and expectations.

Furthermore, the integration of digital technologies and advanced diagnostic tools is highlighted as a key aspect of the decision-making process. These tools enable clinicians to gather precise data, evaluate dynamic occlusion, and enhance treatment planning accuracy. Digital visualization and assessment of restorative designs offer significant advantages in achieving optimal outcomes. It's important to note that this classification system provides a baseline for decision-making but is not rigid or prescriptive. Clinicians can adapt and customize it based on individual patient profiles and clinical expertise. Flexibility allows for adjustments and deviations when necessary.

CONCLUSIONS

In conclusion, the proposed classification enhances the decision-making process for clinicians, facilitating the selection of the most appropriate prosthetic design for each patient. Through the case series, we've demonstrated its practical application and versatility in addressing diverse clinical scenarios.

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Conflict of Interest Statement

All the Authors declare no conflict of interest.

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Original Article

FOCUSED MECHANO-ACOUSTIC VIBRATIONS: BIO-PHYSICOMETRIC APPROACH IN NEUROMUSCULAR DISEASES

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KEYWORDS: *physiotherapy, rehabilitation, neurological disorders, vibration*

ABSTRACT

This analytical retrospective observational study aims to demonstrate the effects of Focused Mechano-Acoustic Vibrations (FMVs) on people affected by neuromuscular diseases. A total of 11 patients (age 58 ± 11) underwent a protocol consisting of three weekly sessions of FMVs for one month, applied to patients affected by neuromuscular disease. Assessments made through a stabilometric platform before and after the rehabilitation protocol revealed positive, although not statistically significant, variations of the characteristics of the Center of Pressure and of the Romberg Index of patients recruited for the study. Our experience showed that the application of FMVs could be a useful tool in the rehabilitation of neuromuscular diseases. These new integrated approaches can be used in the rehabilitation field in a multidisciplinary and multispecialistic way.

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INTRODUCTION

Over the past decade, many studies have been conducted to better understand the effects of whole-body and focused vibrations on the central nervous system and the related control capabilities of the musculoskeletal system. The deepening of the effects of vibrations on the central nervous system would allow to improve the understanding of the pathophysiological mechanisms underlying many neurological pathologies characterized by musculoskeletal and motor manifestations.

This study builds on previous experiences that highlighted the effects of focused vibratory stimulation in neuro rehabilitation, including neurological diseases or neurological disorders. This kind of therapy was well tolerated, effective and easy to use. Independently of the etiology of neurological pathology, it could be used to reduce spasticity, to promote motor activity and motor learning within a functional activity (1).

This study focuses on the effect of Focused Mechano-Acoustic Vibrations (FMVs) in neurorehabilitation.

MATERIALS AND METHODS

This analytical retrospective observational study was conducted at the Castelnuovo della Daunia Thermal Center (Foggia), Italy. The data relating to 11 (age 58 ± 11) patients were considered. Subjects underwent a similar rehabilitation protocol from June to September 2021.

Inclusion criteria were:

- neuromuscular disability;
- balance disorders;
- gait disturbances.

Exclusion criteria were:

- inability to maintain an upright position;
- open wounds;
- varices and telangiectasia of the lower limbs.

The data collection is part of the operative routine of the professional team involved in this study. According to this operative routine, patients are frequently assessed across their rehabilitation path. Therefore, clearance regarding the subjects, according to the Declaration of Helsinki for this study was not required (2). All patients underwent 3 weekly sessions of FMVs treatment, for a total of one month of treatment.

The technology used for the administration of the FMVs therapy is VISS (Vibration Sound System) (Vissman S.r.l., Rome, Italy). The device works through fast moving air cones to produce a square wave mechanical vibration. This vibration is transferred to the skin by means of a self-supporting transducer and, passing through the surface layers and adipose tissue, stimulates so-called “High Threshold Activation” receptors. The signals released by these receptors trigger interactions and biochemical processes, which are able to modify the course of various pathologies related to neuromuscular diseases.

The treatment was administered for twenty minutes for each session, with the transducers of the device focused on specific target muscles, which were identified in each patient according to the Bio-Physico-Metric Approach.

The Bio-Physico-Metric Approach can be defined as an operating mode based on a thorough functional evaluation which is performed to identify Key Myofascial Trigger Points KMTTrPs, the elimination of which, allows the suppression of major muscle dysfunction and postural compensation.

This manual and functional assessment process to identify the areas most in dysfunction also using a skin impedance measurement tool, named ENF (Electroneurofeedback) Physio, (Fast Therapies S.r.l., Carpenedolo, Brescia, Italy) which allowed to objectify and quantify what had been assessed by the operator through the use of his hands (3, 4). For this study, the myofascial structures identified in each single patient through the Bio-Physico-Metric Approach were treated through the VISS device.

To assess the results of the studied rehabilitation protocol, an evaluation of the plantar support was carried out through a stabilometric platform (Diasu Health Technologies by Sa.Ni Corporate S.r.l., Rome, Italy).

Stabilometry is an objective assessment of body sways during quiet standing in the absence of any voluntary movements or external perturbations. The method enables the collection of information on the steady-state functioning of the postural control system and its ability to stabilize the body against gravity. This evaluation is performed using specific computerized boards that record postural adjustments of the body with high grade of sensitivity. The stabilometry was performed at the beginning (T0) and at the end (T1) of the rehabilitation protocol.

RESULTS

The data collected report information on the movement of the CoP (Center of Pressure), defining its kinematic parameters over time and the frequency of the oscillations. The coordinates of the CoP, i.e. the average value of the abscissa and ordinates of the CoP on the referential of the state kinesiogram, the oscillations in the frontal plane (X axis, right-left movement) and on the sagittal plane (Y axis, antero-posterior movement), during the upright station maintained for about 30 seconds gives us the results of the so-called “Surface of the Ellipse” or “Confidence Ellipse”; that is, the dispersion of the oscillations in relation to the precision of the system, which contains 90% of the sampled positions of the CoP. The value corresponds to the quantization of the segmentary tonic deviations of the body axis which are in direct relation to the vestibulo-spinal pathways.

In our experience, the surface of the Confidence Ellipse of the CoP decreased with eyes closed (without statistical significance), testifying a slight increase in the accuracy of the postural tonic system to stabilize the body.

The length of the CoP Sway Path traveled during the recording per unit of time represents an indicator of the energy spent by the body to stabilize itself. In our study, at the end of the rehabilitation protocol, this parameter recorded a slight reduction, which may highlight a slight reduction in the energy expenditure of the postural tonic system to maintain the upright position.

The Romberg Postural Test allows to evaluate the antigravity postural dynamics, and therefore the proprioception (ability to identify the position of the body in space), the vestibular function (the ability to recognize the position of the head in space) and the sight (in relation to the position of our body and the perception of the space where our posture manifests itself). After the rehabilitation protocol through FMVs, the Romberg Index showed a reduction (not statistically significant), which demonstrates how peripheral receptor stimulation played a fundamental role in minimally improving the parameters of proprioceptive function (Table I).

Table I. *Stabilometry: statistical analysis and data variations from T0 to T1.*

Variable	Count	Mean \pm SD	p value*
ES (T0) - Opened Eyes	11	234 \pm 121	
ES (T1) - Opened Eyes	11	326 \pm 296	ns
ES (T0) - Closed Eyes	11	581 \pm 923	
ES (T1) - Closed Eyes	11	340 \pm 401	ns
SP (T0) - Opened Eyes	11	415 \pm 147	
SP (T1) - Opened Eyes	11	406 \pm 103	ns
SP (T0) - Closed Eyes	11	566 \pm 394	
SP (T1) - Closed Eyes	11	560 \pm 302	ns
Romberg Index (T0)	11	197 \pm 216	
Romberg Index (T1)	11	122 \pm 112	ns

*p value shows the differences between T0-T1 of the group (Wilcoxon Matched-Pairs Signed Rank Test)
 ES: Ellipse Surface
 SL: Sway Path

DISCUSSION

Documented scientific experiences regarding the therapeutic use of mechanical vibration can be found as early as the year 1880. The French neurologist Jean-Martin Charcot observed that patients affected by Parkinson Disease experienced a reduction in tremor at rest and an improvement in sleep quality after a carriage ride or after a horse ride. Drawing inspiration from this observation, he modeled a chair vibrator that simulated the rhythmic shaking of a carriage. Georges Gilles de la Tourette extended these observations and modeled a helmet that made the head vibrate, assuming that the brain responded directly to the pulse, signaling schizophrenia and migraine.

Over the years, many scientists have perceived vibration as a suitable method to interact with the central nervous system (CNS) through stimulation of the peripheral nervous system (PNS). Indeed, numerous studies have been conducted to understand the effects of focal vibratory stimulation at various levels of the CNS. In those studies, particularly interesting were the effects demonstrated on the pathophysiological mechanisms of neurological disorders, as well as the therapeutic effects of focused vibrations in neurological disability. Based on the growing number of systematic reviews, whole body vibration and focused vibration appear to play a considerable role in reducing spasticity and improving gait, balance and motor function in patients with neuromuscular disabilities. Focal muscle vibration seemed to be more useful when applied to non-spastic antagonist muscles with reciprocal inhibitory action on spastic muscles in those individuals (5-7).

Vibration seems to be a powerful activator of the entire neuromuscular and skeletal system. In 1969, Hagbarth and Erklund, used vibrations to reduce the spasticity in stroke patients (8). Subsequently, it was used in neuro rehabilitation as well. Murillo et al. observed a significant reduction in spasticity in patients with Spinal Cord Injury, using a vibratory stimulation at 50 Hz applied to the quadriceps muscle for 10 minutes; in addition, they observed a reduction of the amplitude (H-Max) of the Soleus Muscle and the Achilles Tendon reflex (9). Ribot-Ciscar et al. observed, in quadriplegic patients, an increase in maximal isometric contractions in the Brachial Triceps while a 80 Hz vibratory stimulation was applied to the agonist muscle (7).

A study on individuals with Multiple Sclerosis combined botulinum toxin with focal vibration (at 120 Hz), in Gastrocnemius and Soleus Muscles. The study showed an improvement in spasticity and a reduction in fatigue symptoms, either with focal vibration alone or in combination with botulinum toxin, which was maintained during the 3-month follow-up period after treatment (10). In another study the authors reported the effects of vibration on the muscles Soleus and Erectors of the Spine in patients with Parkinson's during walking, showing that cadence and speed were increased (11). Pacinian Corpuscles are found in the deepest layers of the skin, consist of a single unmyelinated afferent neuron, wrapped in 20-60 concentric lamellae. They are, no doubt, the mechano-receptors most involved in the response to the perception of vibration, with the highest sensitivity at a frequency of 300 Hz. At this frequency, at 1 μ m of pressure, there is an activation of different receptors:

- Type 1 Sensory Receptors, which are nerve endings, covered with two red layers of collagen, able to turn on external stimuli;
- Unimodal Receptors, which are activated only by direct pressure;
- Phasic Receptors, which are very fast and follow the "all or none" principle, which means that they are activated or not.

A greater intensity of the afferent signal (charge capacity) determines a greater efferent response of the CNS. An intense efferent nerve response allows the recruitment of multiple motor units, thus the activation of multiple motor neurons which will result in more muscles being activated, and therefore a stronger muscle twitching. This results in a better engine performance, in a shorter time. After activation of the neurotransmitter receptors, various nerve and biochemical signals are activated, thus allowing persistent forms of synaptic plasticity, including, *inter alia*, structural synaptic plasticity, in order to maintain information in a long-term memory. This cellular mechanism for storing information in the Central Nervous System is likely to create new synapses in selected networks (12).

CONCLUSIONS

In accordance with the scientific literature, our experience showed that the application of FMVs could be a useful tool in the rehabilitation of neuromuscular diseases. Vibratory stimulation is well tolerated, effective and easy to use, with no side effects in the field of neurorehabilitation. Focal vibration could promote motor activity and motor learning

within functional activity, including in gait training, regardless of the etiology of the neurological pathology. These new integrated approaches can be used in the rehabilitation field in a multidisciplinary way.

Conflict of interest

This research received no external grants or funding. The Authors declare no conflicts of interest.

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Original Article

RADIOGRAPHIC EVALUATION OF BUCCAL BONE REMODELLING FOLLOWING IMMEDIATE IMPLANT PLACEMENT AND GRAFTING OF THE FACIAL GAP USING CALCIUM PHOSPHOSILICATE PUTTY

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ABSTRACT

Loss of teeth often leads to buccal plate bone left unsupported along with lack of blood supply further causing resorption of alveolar bone for which a myriad of procedures is available to refrain post-extraction bone loss including immediate implant. This study is aimed to evaluate radiographic outcomes of the alveolar ridge following immediate implant placement associated with the use of a calcium phosphosilicate (CPS) putty bone graft placed between the implant and the inner surface of the buccal alveolar plate. 15 implants were placed with a lingual/palatal orientation immediately after atraumatic extraction. The gap between the internal surface of the socket and the implant surface gap was filled with a CPS putty bone graft. Finally, a healing abutment was placed. CBCT analysis was carried out after immediate implant placement and 6 months post-operatively to assess the horizontal bone changes at the implant platform (L1), the mid implant (L2), and implant apex (L3) levels. Vertical bone height was measured from the implant platform to the buccal bone crest. CBCT analysis was assessed for buccal bone width at L1, L2, and L3 and was decreased at 6 months, similarly palatal bone width at L1 showed no change whereas L2, and L3 showed a decrease at 6 months along with bucco-palatal bone width significantly decreased at 6 months and lastly a minimal decrease was observed in vertical facial height at 6 months. The results were statistically significant. Minimal horizontal peri-implant

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buccal, palatal, and bucco-palatal bone dimensional changes were noted at 6 months after placement of immediate implant and use of Calcium Phosphosilicate putty bone graft. Moreover, minimal vertical facial bone height loss was observed.

KEYWORDS: *immediate implant, peri-implant, bone graft, CPS putty bone graft*

INTRODUCTION

Tooth loss often results in soft and hard tissue changes within the alveolar ridge leading to a reduction in horizontal and vertical dimensions (1). The buccal bone contour loss expected within 3 months after extraction is around 50% (2).

Different techniques have been proposed to prevent ridge resorption such as alveolar ridge preservation (ARP), guided bone regeneration using bone grafts and collagen membranes as barriers with or without immediate implant placement (IIP) (3-7).

Schulte and Heimke in 1976 proposed IIP. Today well-accepted terminology of immediate implantation includes immediate, early, and late placement of implants at the post-extraction sockets (8). Immediate implant placement means implantation at the same time after extraction into the extraction socket. The demand for it has increased especially in anterior sites due to benefits like the decline in the number of surgical interventions, the possibility of immediate provisional restoration, and improved short-term aesthetic outcomes (8, 9). Despite its advantages, it remains a challenge to place an implant matching the extracted tooth dimensions. The gap between the implant and bone is required to be filled in three dimensions with a biocompatible material for enhanced osseointegration (10, 11).

Several graft materials are used for this purpose and these include the use demineralized freeze-dried bone allograft (DFDBA), freeze-dried bone allograft (FDBA), autograft, hard tissue replacement polymer, connective tissue barriers, expanded poly tetra fluoro ethylene (ePTFE) membranes, bio-absorbable membranes, hydroxyapatite (HA), xenografts, use of growth and differentiation factors, particulate and block grafting materials and guided bone regeneration (GBR) (12, 13).

Recently a new generation of putty graft materials has been utilized in bone regeneration procedures with promising results. Putty bone grafts enjoy significantly superior handling characteristics in comparison to particulate grafts. These include ease of placement, enhanced particle containment, and a viscous consistency that has allowed for unique delivery systems to be developed. Calcium Phosphosilicate (CPS) putty bone graft is a pre-mixed composite of bioactive calcium-phospho-silicate particulate combined with polyethylene glycol and glycerine binder. Even though CPS putty is used extensively in regenerative procedures, there is not enough scientific literature about its use in immediate implants (14, 15).

Therefore this study is aimed to evaluate radiographic changes of the alveolar ridge following flapless immediate implant placement associated with the use of a CPS putty bone graft placed between the implant and the inner surface of the buccal alveolar plate.

MATERIALS AND METHODS

This study was a prospective clinical and radiographic investigation. Clearance from the institutional ethical committee of Sinhgad Dental College and Hospital, Pune was obtained (SDCH/IEC/OUT/2014-15/83, Ref No. SDCH/IEC/IN/2014-15/83).

Sample size determination

Sample size determination is done based on mean and standard deviation values using the following formula:

Sample size formula used:

$$N = (\sigma_1^2 + \sigma_2^2 / \kappa) (Z_1 - \alpha / 2 + Z_1 - \beta)^2$$

$$\Delta 2 = \frac{2 \times 1.96 \times 1.96 \times 0.65 \times 0.65}{0.5 \times 0.5} = 12.98$$

The notations for the formulae are:

N = sample size

σ_1 = standard deviation of Group 1

σ_2 = standard deviation of Group 2

Δ = difference in group means

κ = ratio = 1

$Z_{1-\alpha/2}$ = two-sided Z value (eg. $Z=1.96$ for 95% confidence interval).

$Z_{1-\beta}$ = power

Hence the minimum sample size is 13. Considering a 10% attrition rate we considered the total sample size as 15 in the present study.

Inclusion criteria

Systemically healthy patients between the age group 20 – 45 years.

Patients in need of extraction and implant placement of any incisor, canine, or premolar tooth.

Indications for extraction include trauma, endodontic treatment failure, or non-restorable carious teeth.

Teeth with healthy periodontium.

Alveolar sockets with 4 wall architecture and intact labial plate.

Patients willing to participate and sign an informed consent.

Compliant patients.

Exclusion criteria

Patients who are systemically compromised.

Current smokers and patients have a history of smoking.

The patient has a history of bone disorders.

Teeth having acute periapical or periodontal pathology.

Pregnant and lactating females.

Parafunctional habits.

Compromised soft tissue conditions at the surgical site.

Extraction sockets with one or more bony walls damaged.

Informed consent was obtained from all selected patients, and they were informed about the study verbally as well as a written information sheet before extraction and implant placement. A pre-operative CBCT scan (Promax 3D, Planmeca, Helsinki, Finland) was taken to study the bony architecture and for the selection of the implant size.

The implants used for this study were tapered implants (Touareg-S, Adin Dental Implant Systems, Israel) with a spiral tap having SLA alumina oxide blasted/acid etched surface treatment.

Pre-surgical procedure

All procedures from pre-operative assessment to post-operative follow-up were carried out by a single operator. All the patients recruited for the study underwent oral prophylaxis.

Pre-operatively, the patients received an antibiotic regimen (1g Amoxicillin 1 hour before surgery, followed by 500 mg three times a day for 5 days).

Surgical procedure

Atraumatic extraction of the indicated teeth was carried out by the operator without elevation of the periodontal flap under local anesthesia (2% Lidocaine with 1:100000 adrenaline) using periostomes, elevators and extraction forceps as required (Fig. 1, Fig.2).

Dimensions of extracted root pieces were measured before implant placement. The extraction socket was assessed to confirm the integrity of the alveolar socket (Fig 3).



Fig. 1. Pre-operative photograph



Fig. 2. Novabone Dental Putty Cartridge delivery system

The osteotomy preparation was carried out using sequential drilling without raising a flap towards the lingual/palatal wall of the socket. The required size of the dental implant was placed to a level 1-2 mm apical to the buccal alveolar crest and with a lingual/palatal orientation. This resulted in a gap between the internal surface of the socket and the implant surface. The gap was further filled with a synthetic particulate graft material using a cartridge delivery system (Novabone bioactive synthetic bone graft dental putty, Osteogenic Biomedicals, Lubbock, USA) (Fig. 4).

Finally, a healing abutment that occupied most of the socket and reflecting coronal to the gingival margin was placed.

Subsequently, a cone beam computed tomography (CBCT) scan was carried out post-operatively (Day 0 / Baseline) using Carestream CBCT Machine 9000 3D, USA, with exposure time 13 – 18 sec, with 60 – 90 Kvp, 8 mA-s and repeated after 6 months.

Patients were advised to follow the standard post-operative instructions and were advised to rinse with 0.12% chlorhexidine twice a day for 14 days postoperatively.

Following CBCT measurements were done at baseline (day 0) and at 6 months (Fig. 5, Fig. 6, Fig. 7).

Horizontal measurements: Buccal wall thickness, palatal wall thickness, and total bucco-palatal width from the external surface of the buccal and palatal/lingual alveolar plates to the implant surfaces were carried at the platform (L1), middle (L2), and apical (L3) levels of the implant.

Vertical measurement: Vertical facial bone level was measured on the facial surface of the implant as the perpendicular distance from the implant platform to the most coronal point of the facial bone.

The healing abutment remained in place during the entire 6-month observation period. All the participants were instructed to maintain oral hygiene and were seen at regular intervals of 1 week, 15 days, 1 month, 3 months, and 6 months. During the 6 months, all participants were given fiber reinforced acrylic provisional restorations, which did



Fig. 3. Integrity of the alveolus checked post-extraction



Fig. 4. Novabone Dental Putty synthetic bone graft material placed between the implant surface and buccal bone

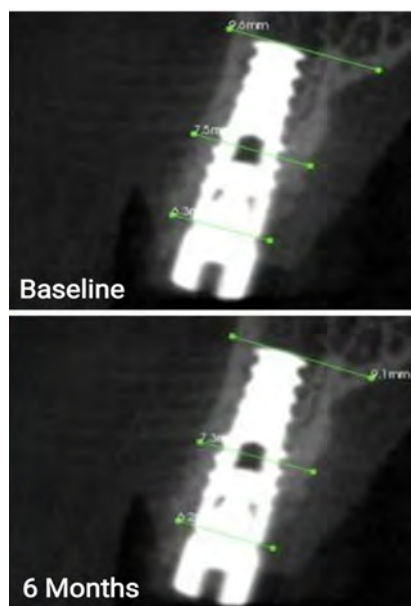


Fig. 5. Bucco-palatal CBCT measurements recorded at Baseline (Day 0) and 6 Months

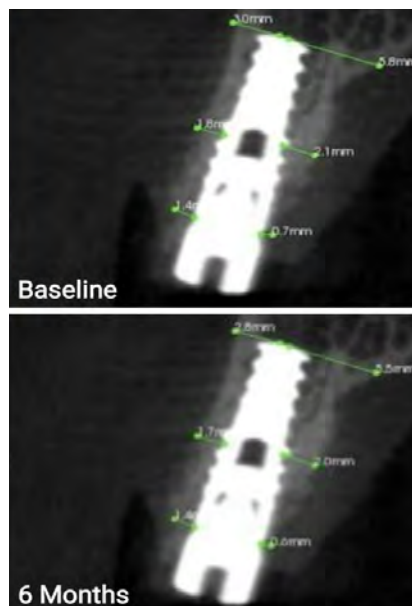


Fig. 6. Buccal and Palatal CBCT measurements recorded at Baseline (Day 0) and 6 Months

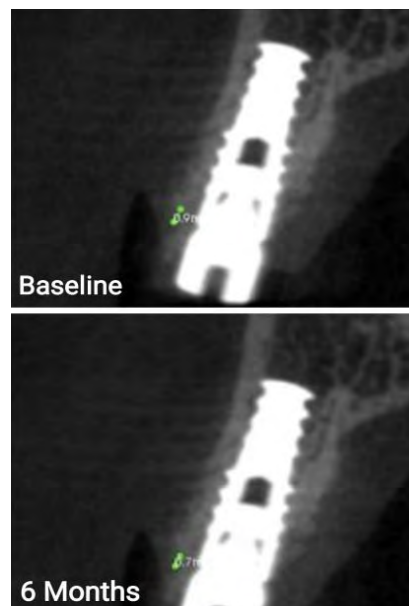


Fig. 7. Vertical CBCT measurements recorded at Baseline (Day 0) and 6 Months

not encroach on the gingival former. After 6 months post-extraction, all participants were recalled for the radiographic measurements. The implants were restored 6 months after the placement.

Statistical analysis

Data collected was compiled into an MS Office Excel worksheet and was subjected to statistical analysis using Social Sciences (SPSS) version 21.0. Descriptive statistics like frequency (n) and percentage (%) of categorical data, mean and Standard deviation of numerical data in each group were depicted.

The normality of numerical data was checked using the Shapiro – Wilk test or Kolmogorov-Smirnov test. Since the data was normally distributed, parametric statistical tests were used in the study. Keeping alpha error at 5% and Beta error at 20%, power at 80%, $p < 0.05$ will be considered statistically significant.

The data was collected by measuring buccal wall thickness, palatal wall thickness, total bucco- palatal width, and vertical facial bone alveolar ridge height at baseline (day 0) and after 6 months in mm. The comparison between time intervals i.e., 0 and 6 months was calculated using Paired 't'-test. A frequency distribution table was used for teeth distribution and gender distribution. Descriptive analysis was used to evaluate the mean and standard deviation for bone height and width.

RESULTS

A total of 9 patients (5 males and 4 females; average age – 31.2 years, with a total of 15 extraction sites in the upper jaw and lower jaw (13 sites and 2 sites respectively; Central incisors – 4, Lateral incisors – 3, Canines – 1, Pre molars – 7) were treated with palatally placed immediate implants along with the CPS putty bone graft placed in the gap between implant and buccal/ labial plate.

No postoperative complications were recorded at any included site. All patients completed the study. The CBCT measurements (Baseline and 6 months) were carried out and are summarized in Tables No 1,2,3,4 and Graph No 1,2,3,4.

The CBCT findings for buccal bone width (Table I) showed that there was a slight decrease in the buccal bone width at L1, L2, and L3 levels after immediate implant placement.

The CBCT findings for palatal bone width (Table II) showed that there was no change at L1 while slight decrease in the palatal bone width at L2 and L3 levels after immediate implant placement.

The CBCT findings for bucco-palatal bone width (Table III) showed that there was a slight decrease in the bone width at L1, L2, and L3 levels after immediate implant placement.

The CBCT findings for vertical facial bone height (Table IV) showed that there was a slight decrease in the vertical facial bone height after immediate implant placement.

The correlation coefficient showed a high correlation and statistically significant difference between baseline and 6 months for buccal, palatal, and bucco-palatal width at L1, L2, and L3 levels (Graph 1,2,3,4).

Vertical facial bone height difference showed less correlation and was not statistically significant. Comparison of mean differences in measurements of buccal bone width for baseline and 6 months showed statistically significant change at L1, L2, and L3 levels. Comparison of mean differences in measurements of palatal bone width for baseline

Table I. Comparison of mean differences of buccal bone width at baseline and 6 months

<u>Level Measurements</u>		<u>Mean difference</u>	<u>t value</u>	<u>P value</u>
<u>L1</u> (Coronal of implant)	<u>Baseline</u>	<u>0.28</u>	<u>6.54</u>	<u>P < 0.05</u>
	<u>6 months</u>			
<u>L2 Level</u> (Middle of implant)	<u>Baseline</u>	<u>0.20</u>	<u>5.12</u>	<u>P < 0.05</u>
	<u>6 months</u>			
<u>L3 Level</u> (Apical of implant)	<u>Baseline</u>	<u>0.18</u>	<u>5.33</u>	<u>P < 0.05</u>
	<u>6 months</u>			

Table II. Comparison of mean differences of palatal bone width at baseline and 6 months

Measurements		Mean difference	t value	P value
L1 Level (Coronal of implant)	Baseline	0.00	0.00	1.00
	6 months			
L2 Level (Middle of implant)	Baseline	0.20	3.94	0.001
	6 months			
L3 Level (Apical of implant)	Baseline	0.22	3.97	0.001
	6 months			

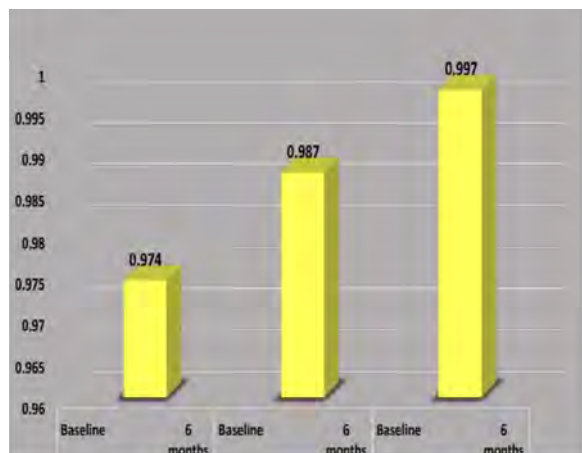
Table III: Comparison of mean differences of bucco - palatal bone width at baseline

Measurements		Mean difference	t value	P value
L1 Level (Coronal of implant)	Baseline	0.67	4.25	0.001
	6 months			
L2 Level (Middle of implant)	Baseline	0.68	4.71	P<0.05
	6 months			
L3 Level (Apical of implant)	Baseline	0.54	4.93	P<0.05
	6 months			

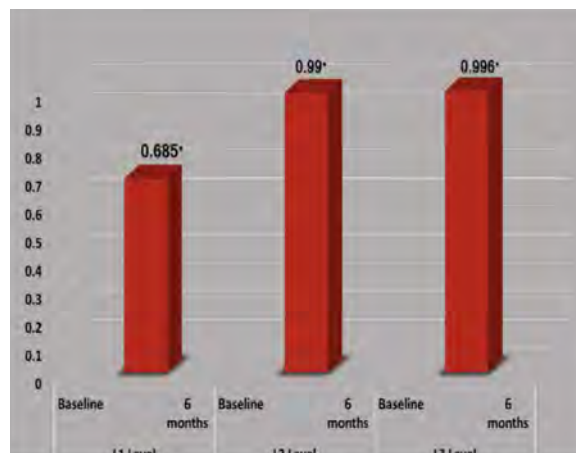
and 6 months showed no significant difference at L1 while statistically significant change at L2 and L3 levels. Comparison of mean differences in measurements of Bucco-palatal bone width for baseline and 6 months showed statistically significant change at L1, L2, and L3 levels. Comparison of mean differences in measurements of vertical facial bone height for baseline and 6 months showed statistically significant change.

Table IV: Comparison of mean differences of vertical facial bone height at baseline

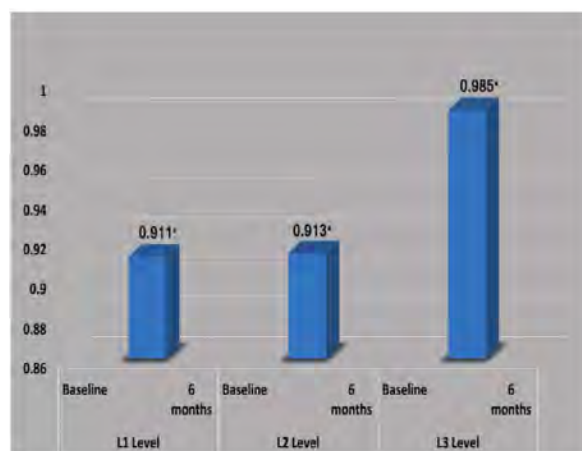
Measurements		Mean difference	t value	P value
L1 Level (Coronal of implant)	Baseline	0.67	4.25	0.001
	6 months			
L2 Level (Middle of implant)	Baseline	0.68	4.71	P<0.05
	6 months			
L3 Level (Apical of implant)	Baseline	0.54	4.93	P<0.05
	6 months			



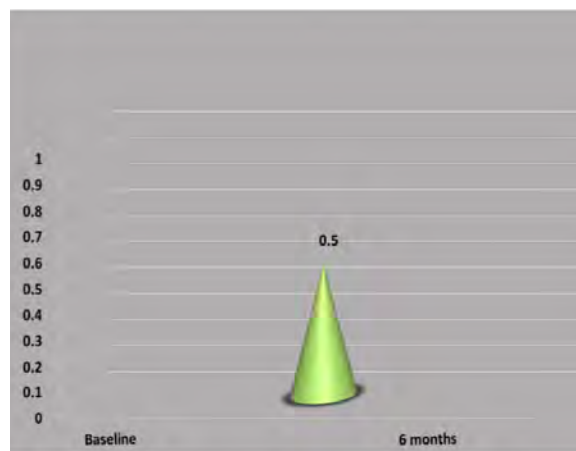
Graph 1. Correlation of buccal bone width at baseline and 6 months



Graph 2. Correlation of palatal bone width at baseline and 6 months



Graph 3. Correlation of bucco-palatal width at baseline and 6 months



Graph 4. Correlation of vertical bone height at baseline and at 6 months

DISCUSSION

The present radiographic study was carried out to assess the horizontal alveolar ridge changes on facial and palatal cortical plates, total bucco-lingual dimensional changes, and the vertical buccal alveolar ridge changes after placement of immediate implant associated with synthetic bone graft. The data clearly demonstrated preservation of the buccal alveolar bone thickness up to a 6-month period. Several studies have demonstrated similar results.

Roe et al. (16) evaluated the changes in horizontal facial bone thickness (HFBT) at 7 different levels compared to 3 in our study. The vertical facial bone level (VFBL) measurement was similar to our study. The mean HFBT changes ranged from -1.23 to -0.08 mm while the mean VFBL change was -0.82 mm. In comparison, the present study showed mean difference of facial bone height as 1.28. The mean difference in facial bone width changes was more at the implant platform level (0.28) than at L2 mid-implant level (0.20) and L3 apical level of the implant (0.18).

The horizontal facial bone width measurements taken in our study were similar to the study by Lee et al. (17). However, we also added palatal bone width, bucco-palatal width and the vertical measurement. The graft used in Lee et al. was bovine derived particulate graft. The study interval of baseline and 6 months CBCT was similar to our study. However, we did not use immediate implant supported provisional as in Lee et al. Results of both studies are similar in showing non significant resorption of buccal bone.

In a study by Botticelli et al. (18) no membranes or filler material was used. The flaps were subsequently replaced and secured with sutures in such a way that the healing cap of the implant was exposed to the oral environment. No radiographic measurements were done and the clinical measurements were done at baseline and 4 months after re-entry surgery. They noted that the horizontal resorption of the buccal bone dimension amounted to about 56%. The corresponding resorption of the lingual/palatal bone was 30%. The vertical bone crest resorption amounted to 0.3 ± 0.6 mm (buccal). In our study also the immediate placement of dental implant with bone graft materials did not prevent the peri-implant bone remodelling.

Lee et al. checked alteration of bone dimension following immediate implant placement in a systematic review and meta-analysis. A total of 6 studies were included. The weighted mean buccal horizontal bone dimensional reduction was 1.07 mm and buccal vertical bone dimensional reduction was 0.78 mm. The weighted mean palatal bone dimensional reduction was 0.62 mm horizontally and 0.50 mm vertically.

Another study carried out by Assaf et al. (2) assessed computed tomographic alterations of the buccolingual width of the alveolar ridge after immediate implant placement associated with the use of a synthetic biphasic calcium sulphate in 20 extraction sites in 20 patients. They used a healing cap like the current study. Buccolingual measurement was done at 1mm and 3mm apical to the bone crest. In accordance with our study, the authors concluded that calcium sulphate was capable of preventing the loss of buccolingual dimensions (2).

Tarnow et al. (7) showed that bone grafting at the time of implant placement into the gap in combination with a contoured healing abutment or provisional restoration resulted in the smallest amount of ridge contour change.

These results may be of clinical significance because the maintenance of the buccal wall and buccolingual dimensions of the alveolar ridge after dental implant placements has a positive relationship with the maintenance of the gingival margin, significantly reducing the risk of gingival recession.

Few recent studies have thrown light on multiple aspects of immediate implant placement. Ahmed Ibrahim Aboul Fetouh et al. (20) examined vertical and horizontal changes 1 year following flapless immediate implant with and without xenograft at sites with thin labial plate. This investigation suggested that immediate implants with or without grafting the labial gap preserved alveolar bone dimension and that bone formation labial to the implant was related to initial labio-palatal socket dimension.

Perez A et al. (21) showed that the customized healing abutment group showed the most favorable outcomes (in terms of papilla index and marginal bone level) in case of immediate implant that received a periimplant bone grafting procedure.

Mao et al. (22) included 4 randomized controlled trials and 12 nonrandomized controlled trials for systematic review and meta-analysis. This study demonstrated that immediate implant placement in the esthetic zone does not prevent buccal bone from resorption.

Levine et al. (23) showed that sites with wider gap (>2mm) exhibited a significantly thicker newly formed buccal bone wall and, a higher percentage of its buccal aspect covered by bone than sites in the wide gap group (<2mm).

The possible reasons for preservation of the buccal and palatal bone in our study are flapless technique and use of a CPS putty graft. Limitations of the present study were limited sample size, randomization, and split-mouth design was not considered, no histomorphometry analysis was performed to check the bone formed, and no soft tissue assessment and abutment-supported provisionalization of the implant was not considered.

CONCLUSION

Overall minimal horizontal peri-implant buccal, palatal, bucco-palatal, and vertical bone dimensional changes were observed at 6 months upon placement of immediate implant placement along with simultaneous use of CPS putty bone graft.

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Original Article

VINYLSILOXANETHER®: REDUCTION OF THE INTRA-SURGICAL IMPRESSION'S SETTING TIME AND ENHANCEMENT OF AESTHETIC PREDICTABILITY IN IMMEDIATE LOADING

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ABSTRACT

The impression affects the accuracy of the definitive cast thus an accurate impression is essential to fabricate a prosthesis with a good fit. In implant prosthodontics, a successful result can be achieved only when passively fitting prostheses are fabricated. The aim of the present report is to the evaluation of Vinylsiloxanether® (VSX) for the reduction of the intra-surgical impression's setting time and enhancement of aesthetic predictability in immediate loading. VSX was used in four clinical cases of immediate implant loading, (two cemented and two screw-retained) to verify the predictability of transfer of soft tissues on a plaster model and the predictability of impression transfer. VSX gave a predictability transfer of both systems reducing the intra-surgery setting time of the impression and ensuring an immobilization of the transfer impression copings, with accurate intra-oral implant position to the working cast. VSX is an excellent impression material, reducing the intra-surgical impression's setting time and enhancing aesthetic predictability in immediate loading.

KEYWORDS: *intra-surgical impression, immediate implant-loading, Vinylsiloxanether®, aesthetic predictability*

INTRODUCTION

A dental impression is a negative imprint of an oral structure used to produce a positive replica for a permanent record or for producing a dental restoration or prosthesis (1). Since the accuracy of the impression affects the accuracy

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of the definitive cast, an accurate impression is essential to fabricate a prosthesis with a good fit. In dentistry, prosthetic work has traditionally been an intra-oral impression that is subsequently poured into dental stone. The model from dental impression forms the basis for manufacturing crowns, fixed partial dentures and frames attached to natural teeth. Stone models are also used for producing frameworks for implant cases.

Dental implants have been proven successful in the treatment of edentulism (2, 3). Osseointegrated implants were used for the rehabilitation of edentulous patients with the principle objective of replacing conventional complete dentures with an implant-supported prosthesis (4, 5).

In implant prosthodontics, a successful result can be achieved only when passively fitting prostheses are fabricated (6-8). Although there is some evidence that prosthesis misfit may not affect osseointegration, there is evidence that prosthesis misfit is likely to increase the incidence of mechanical component loosening or fracture. The causes of component failure and loosening are multifactorial, but it must be assumed that prosthesis misfit plays an important role in complications such as occlusal and abutment screw loosening and fracture in implant restorations (2, 9-13). Because of these, prosthesis misfit must be minimized.

The position of dental implants is recorded and transferred to a working stone cast for the manufacturing of implant-supported prostheses (14). The correct transfer of each implant position in relation to neighbouring implants or teeth is of paramount importance for the design and fit of an implant-supported prosthesis and therefore for the long-term success of implant therapy avoiding mechanical and biological complications (15-17).

The conventional workflow for dental implant impressions involves screw-retained impression copings that are attached to the implant and impression trays loaded with impression material. Impression copings are either retained in the cured impression material (pick-up method) (18-20) or remain in the implants and are repositioned in the respective regions in the impression after it is removed from the mouth (transfer method) (21, 22). Replacement of transfer copings after removal of the impression from the mouth may be facilitated by plastic caps seated on transfer copings that are retained in the impression (23, 24).

The pick-up method is performed with open impression trays. To remove the impression with copings, the screw retention must be loosened. This is achieved through holes in the impression tray that are located on top of the impression coping. The transfer method is performed with closed impression trays, as no access to the screw-retained copings is required. Pick-up impression copings are frequently splinted to each other with acrylic resin or other materials or structures (bars, straws, or dental floss) before adding impression material (25-27). The rigid connection of multiple impression copings is applied to avoid movement of impression copings in the elastic impression material. A higher impression accuracy with splinted impression copings compared to non-splinted copings has been reported (27-30).

Today the majority of dental impression make use of polyether and additional silicone impression materials (31-33). Polyether is well known for its fluidity and precision. Casts obtained from polyether impression material are more accurate than casts obtained from other impression materials (34).

Silicon impression materials, on the other hand, secure a better elasticity: the impression can be easily removed from the oral cavity after a quick setting time. In addition, patients better tolerate this type of impression material since it is odourless and tasteless. The most recent review supports the supremacy of these two impression materials, especially in implantology (14).

The aim of the present report is the evaluation of Vinylsiloxanether® for the reduction of the intra-surgical impression's setting time and enhancement of aesthetic predictability in immediate implant loading.

MATERIALS AND METHODS

The impression material used combines the advantages of polyether and additional silicone impression materials: Identium® (IDT) which is named Vinylsiloxanether® (VSX). VSX was used in four clinical cases of immediate implant loading, two of them with a cemented technique and two with a screw-retained implant, to check the predictability of transfer of soft tissues on the plaster model and the predictability of impression transfer. IDT is available in three different viscosities: we chose the intermediate one (IDT medium) for the clinical cases of immediate loading with the cemented technique and the material with superior viscosity (IDT heavy) in the screw-retained technique.

The two clinical cases rehabilitated with immediate loading with the cemented technique were female patients aged 54 and 63; patients treated with immediate loading with the screw-retained technique were females of 37 and 47 years old (Fig. 1).

Patients underwent an implant prosthetic surgery with the insertion of n. 6 implants (patient 1, already supplied with 3 osteo-integrated implants on overdenture) or with the insertion of n. 8 implants (patient 2) with transmucosal technique. Patients underwent regional anaesthesia, then bone thickness was measured by a surgical feeler gauge and Intralock® implants with self-tapping thread profile were inserted. The required tightening torque was 50 N. Patients underwent intra-surgery impressions with IDT medium. It was not necessary to splint all the transfer impression copings together with pattern resin. A fixture-level impression was taken using an open tray. After 12 hours from surgery, the check of the structure was made on the screwed titanium abutments and after 72 hours a Co-Cr alloy and composite framework with cementation technique was delivered.

Screw-retained group of patients underwent regional anaesthesia (35). Then bone thickness was measured by a surgical feeler gauge, and Intralock® implants with self-tapping thread profile were inserted. The required tightening torque was always 50 N. Flat abutments were screwed at 35 N/cm at the peri-implant mucosal collar profile. Afterwards, an impression was taken with IDT heavy. It is not necessary to splint all the transfer impression copings together with pattern resin (Fig. 2).

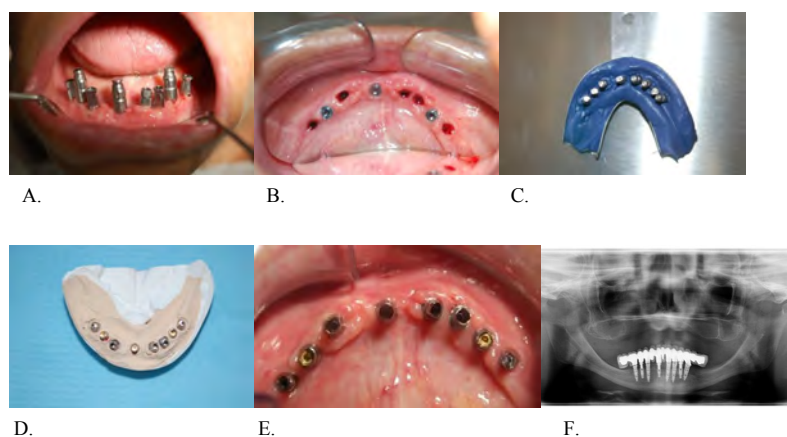


Fig. 1. *Cemented Technique.* A): Transfer impression; B): Flapples technique; C): Impression. D): Plaster Model; E): Abutments 0°; F): Final X-ray.

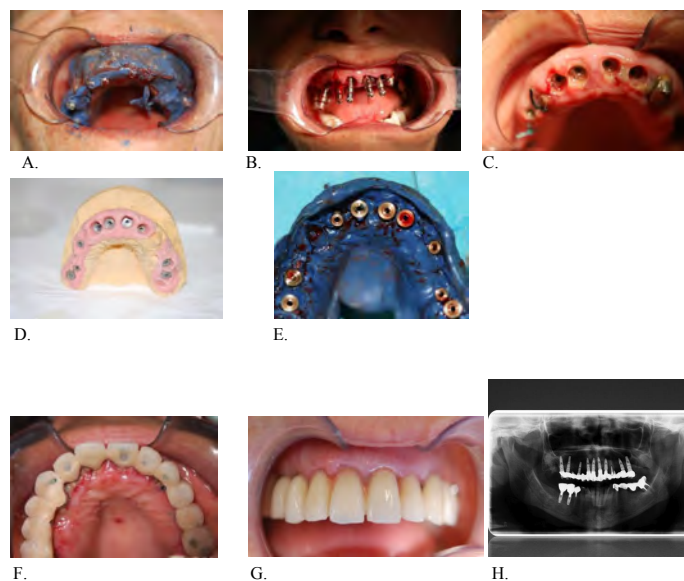


Fig. 2. *Screw-Retained Technique.* A): Intrasurgery impression; B): Transfer Impression; C): Multi-unit abutments and transmucosal tissue after 48 hours; D): Plaster model; E): Intrasurgery impression; F): Occlusal view; G): Front view; H): Final x-ray.

After 12 hours from surgery, the structure was checked for a completely passive fit. After 72 hours from surgery, a Co-Cr alloy and composite framework with screwed technique was delivered. The torque of fixation was 25 N.

RESULTS

VSX gave a predictability transfer of both cemented and screw-retained systems, reducing the intra-surgery setting time of the impression and ensuring an immobilization of the transfer impression copings, with accurate intra-oral implant position to the working cast. The consistency of the material and its considerable hydrophilic behaviour allowed to obtain an excellent closure of the peri-implant transmucosal collar profile without affecting periodontium (Table I).

DISCUSSION

Today available impression materials have advantages and disadvantages: VSX is the result of a combination of the two most widely used impression materials, e.g. polyethers and silicones. VSX combines the advantage of polyether and an additional type of silicone impression material (36).

Baer stated that VSX has been optimized for the one-step impression technique or monophasic technique (37). This material is considered reliable for the impressions of the dental arches. It is used as the material of choice for studies on the accuracy of 3D scanners (38) and other oral digital impressions (39) compared to other types of materials. One notable finding was the better taste rating of the polyvinyl ether in comparison with the polyether material (36).

The differences in impression precision can likely be attributed to the fact that because of the lighter colouring of the IDT, it proved easier to assess than the darker "Impregum". From a clinical point of view, good legibility is an advantage because it allows rapid assessment of the impression quality and eventually makes a new impression if the first one is poor (36). Furthermore, Enkling et al. (36) claim VSX as a good alternative for polyether materials: based on the results of their study, it allows users to achieve excellent fits for dental prostheses and simultaneously achieves very positive ratings in terms of its clinical handling.

The results of Enkling's study demonstrated that VSX with respect to dentists, patients, and technician assessment was ascertained to be similar or superior to the polyether (36). The results of the study conducted by Vojdani et al. were the same as in the study of Enkling et al. (36, 40) demonstrating no difference between polyether and VSX for multi-implant impressions with parallel implant placement. Also, Ender et al. confirm that conventional impressions using VSX material showed the highest precision to obtain the complete-arch impression (41).

The study of Tolidis et al. (42) agrees that newly formed VSX material exhibited no significant differences when compared with other polyvinylsiloxanes. Instead, Gupta et al. (39) conclude that the casts obtained from impressions made with polyether impression material proved to be more accurate statistically than casts obtained from VSX impression material.

Table I. Predictability of transfer.

	Cemented technique	Screw-retained technique
	Identium® medium	Identium® heavy
Years old	54 - 63 ± 2.12* y/o	37- 47 ± 2.37* y/o
Viscosity	1.5 ρ** (g/cm³)	1.5 ρ** (g/cm³)
Density	36** μ (kg × m⁻¹ × s⁻¹)	32** μ (kg × m⁻¹ × s⁻¹)
Torque	30 - 35 ± 2.5* Nm	20-25 ± 2.5* Nm
Total (N):	10 pz	10 pz

*Standard deviation applied to the reference samples. **values reported by the Safety Data Sheet.

VSX impression material quickly develops its hydrophilicity and provides an accurate impression in narrow spaces even in the sulcus after 1 second. Because of the hydrophilicity, it can produce a well-defined impression with crisp marginal details (37). VSX allows an immediate impression-taking procedure due to its hydrophilic and elastomeric properties in the peri-implant area. It doesn't have retraction and thus there is no need to splint the impression copings together with resin. This procedure simplifies the traditional technique and assures the total immobilization of the transfers in the impression. Soft tissue predictability, e.g., excellent transport, is another characteristic we appreciated during the reported clinical cases. In 2009 another paper compared several impression materials, acknowledging best results to IDT (43).

CONCLUSIONS

VSX is an excellent impression material with the following advantages: fluidity and stability, hydrophilic behaviour and viscosity at the same time, details precision, easy removal from the oral cavity and resistance to split without deformation, long processing time with short intra-oral setting time, universality of use, odourless and tasteless.

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Systematic Review

IMPACTED TEETH AND TEMPORARY ANCHORAGE DEVICES, A MODERN APPROACH: SYSTEMATIC REVIEW AND CLINICAL CASES

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ABSTRACT

Dental impaction is a prevalent dental condition characterized by the improper eruption of a tooth, becoming trapped within the gum or jawbone. Detecting impacted teeth early is crucial for effective treatment. Temporary Orthodontic Anchorage Devices have brought about a transformative shift in the management of dental impactions, furnishing supplementary support and stability during the process of tooth repositioning. The research method involved a thorough search of PubMed, Web of Science, and Scopus databases from August 2013 to August 2023, using keywords “Miniscrew OR TADs” and “impacted OR included teeth,” yielding 825 studies. After meticulous screening, 19 relevant articles were chosen for analysis. The review encompasses three case studies demonstrating successful tooth impaction resolution using miniscrews. The integration of skeletal anchorage with Temporary Orthodontic Anchorage Devices in orthodontic interventions has significantly expanded the treatment spectrum while concurrently enhancing efficiency. Notably, these modalities have exhibited promising outcomes in facilitating the repositioning of impacted teeth to their anatomically correct locations, thereby ameliorating both aesthetic and functional aspects. The use of Temporary Orthodontic Anchorage Devices offers several advantages, including a wider range of action, faster tooth movement and greater stability and accessibility without requiring the patient’s cooperation.

KEYWORDS: *impacted teeth, canine, molars, TADs, miniscrew, included teeth, traction, dislocation, disimpaction, skeletal anchorage*

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INTRODUCTION

Dental inclusions are a common problem in dentistry, attracting interest and attention from practitioners and researchers. They occur when a tooth fails to erupt properly in its natural position within the dental arch, becoming partially or completely trapped in the gum or jawbone. This condition can affect deciduous teeth and permanent ones (1, 2).

The eruption of permanent dental elements is the final stage in a complex series of genetically controlled events. Through these phenomena, a tooth bud develops in the maxilla or mandible by migrating in a coronal direction and erupts in the arch in its functional position according to predetermined times and paths. During this developmental process, however, numerous events can occur that interfere with the eruption of the tooth, leading to its inclusion, defined as a pathological condition that causes the failure to erupt in the oral cavity of a tooth element beyond the physiological limits of the eruption time, which represents a frequently encountered clinical picture, often associated with a transverse deficit of the upper jaw. Tooth retention must be distinguished from tooth inclusion: the latter is devoid of eruptive potential, the tooth root is fully formed, and the periodontal ligament is inactive (3, 4).

Epidemiological studies show an average incidence of dental inclusion of 20% in developed populations, with a slight prevalence for the female sex (5). The lower third molar (M3) is the most frequently included tooth, followed by the upper M3 and upper canine; the lower canines and other teeth follow less frequently. The upper canine is second only to the mandibular M3 in frequency of inclusion (6).

The prevalence of canine inclusion fluctuates from one epidemiological study to the next, depending on the composition of the groups examined in terms of ethnicity, gender and other variables; in fact, the disease is more represented, for example, in European populations than in Asian populations, in the female sex than in the male, and manifests itself much more frequently in the upper jaw; in 8-10% of cases, it is bilateral (7-9). The prevalence of canine inclusion varies from a minimum of 0.92% to a maximum of 4.3%. The incidence of permanent canine inclusion is approximately 2% of patients undergoing orthodontic treatment (10-16).

Inclusion is much more frequent in the upper than the lower jaw with a ratio of 10:1 (17), canine inclusion in deciduous teeth is very rare (18), in the mandible, dental inclusions occur more frequently in the vestibular area (19), mandibular canines included have a prevalence ranging from 0.05% to 0.4% (20), The female sex has a higher incidence of inclusion, with a ratio ranging from 2:1 to 3:1 compared to the male sex (21, 22), Inclusion or retention of second molars (M2) is a relatively rare condition (23).

Dental inclusion can be caused by several factors, including limited space in the dental arch, incorrect position of the dental germ during embryo development, physical obstacles, or other skeletal abnormalities (24-27). In addition, genetic factors, dental trauma, or inflammation may increase the risk of tooth inclusion (3). The diagnosis of tooth inclusion, or the suspicion that it may occur, must be made early, because many of the causes that contribute to hindering eruption can be removed if detected earlier than the average age of eruption, facilitating and reducing treatment time (10, 28).

Confirmation of the diagnosis of tooth inclusion is done through panoramic radiographs and 3D computed tomography (CT) scans to obtain more detail on the position of the included tooth and its relationship to adjacent teeth (29-32). Panoramic radiography can also detect any dental abnormalities associated with malposition of the canine in the palatal direction. Cone-beam CT (CBCT) is a 3D imaging technique that provides detailed and dynamic images of the skull and face, allowing a more precise assessment of the position of the included tooth (33-35).

Temporary Orthodontic Anchorage Devices (TADs) provide additional support and stability during tooth movement. The incorporation of TADs into orthodontic treatment has revolutionised the management of the most difficult malocclusions and significantly expanded the range of orthodontic movements that can be achieved (36). Several authors have demonstrated the effectiveness of TADs in the treatment of dental inclusions, proving to be a valuable aid in the resolution of included teeth by guiding the element into its correct position, with significant aesthetic and functional improvement (37-39).

The lack of osseointegration of titanium TADs contribute to instability and a relatively high failure rate, miniscrews are usually subjected to immediate loading and have a success rate of 50% to 89% (40, 41).

Immediate failure occurs when the insertion site is unsuitable such as areas with poor cortical bone or alveoli that have recently undergone extraction or due to incorrect handling during insertion such as a sudden change of insertion. Delayed

failure, on the other hand, includes overloading of the helix component or a sudden blow to the head of the TADs during mastication (36, 41-46).

In this article, we will examine the effectiveness of TADs as an anchorage method for dental inclusions. We will analyse the various treatment techniques using TADs that various authors over the years have used to resolve dental inclusions to improve dental function and aesthetics. The field of orthodontics has long been dedicated to achieving optimal occlusion and aesthetic results for patients. The advent of TADs has opened new possibilities, enabling more precise and efficient treatment approaches.

CLINICAL CASES

Case report 1

A 40-year-old patient at the start of the treatment. Contraction of the upper arch and palatally impacted and mesioinclined 1.3 and 2.3 were diagnosed. 2.3 elements presented an unfavourable position for recovery. The mechanics used involved two orthodontic TADs (1.6 mm diameter × 8.0 mm length) positioned in the lower arch in 35 and 45 areas. After disinclusion surgery, an elastic band (1/2 " - 16 ounce) was applied with the function of pulling the canine by anchoring it to the TADs. The patient wore the elastic all day long, removing it only during meals. The elastic was changed every 15 days. Disinclusion with miniscrews took place over the course of 10 months during which time the upper multibrackets therapy was placed to reposition the 13 and 23 in the arch after upper tooth alignment. The patient is currently still undergoing treatment. Patient records are reported in Fig. 1-3.

Case report 2

A 21-year-old patient with 13 and 23 inclusions in palatal position. The disinclusion of both dental elements was carried out at the same time as the orthodontic multibracket therapy with the use of orthodontic miniscrews in the lower premolar area (35-45). The use of daily and overnight elastic traction allowed the dental to reposition over the course of 12 months in the correct area to allow correct intercuspation. The traction elastics used in this case are 1/2 " - 16 ounces replaced every 2 weeks. Patient records are reported in Fig. 4-6.

Case report 3

The procedure, used in the clinical case of a 14-year-old patient, allowed the palatally included maxillary canines to be disengaged using two TADs and an elastic chain. The patient's medical history did not show anything relevant. Intraoral examination revealed the presence of two deciduous canines, a molar class I and an inferior crowding.



Fig. 1. Pretreatment X-ray orthopantomography showing the two impacted upper canines.



Fig. 2. Intraoral patient's photos collage: right side view with TAD and upper multibrackets therapy (A), initial frontal view (B), left side view with TADs and metallic button (C), initial upper occlusal view (D), and lower occlusal view (E).



Fig. 3. In treatment X-ray orthopantomography.

The patient's need was to resolve the inclusion of the two canines. The treatment plan involved the use of an orthodontic-surgical technique combined with orthodontic miniscrews and an elastic chain. The patient was informed of the risks, advantages and disadvantages of this treatment approach and provided written informed consent to forego the procedures. The advantage is the presence of an orthodontic device in the oral cavity that allows good oral hygiene to be maintained without restricting chewing. In addition, orthodontic traction requires minimal patient collaboration (Fig. 7, 8).

The main disadvantage was the need for surgical exposure of the included canines. The surgical-orthodontic treatment involved exposing the included canines with a diode laser and placing the two TADs.

LITERATURE REVIEW

Protocol and registration

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used in this systematic review and submitted to PROSPERO with ID CRD 483337 (47). The information flow across the several stages of a systematic review is shown in the flow diagram. It illustrates how many records were found, how many were included, how many were excluded, and why. The article was structured following the main points of the PRISMA checklist and the division into paragraphs.

Data sources and search strategy

Three reviewers (V.S., L.R. and V.C.) performed an online search to set the topic. We used PubMed, Scopus and Web of Science as online databases, in which we searched for publications that matched the topic of the review. The search method was developed by analyzing articles that referred to fixed and mobile appliances used after orthodontic treatment and the occurrence of relapse after their use. After several searches, the final search was referred to a range of time from October 2013 to October 2023 using the keywords "miniscrew", and "TADs" with the Boolean variable "OR", "impacted" and "included" teeth with the Boolean variable OR. The two research are linked by the Boolean variable "AND" (Table I).

Inclusion and exclusion criteria

This research studies the use of TADs for the treatment and traction of impacted teeth. Articles that met several criteria were included:



Fig. 4. Pretreatment X-ray Orthopantomography showing the two impacted upper canines.



Fig. 5. Intraoral patient's photos: initial frontal view (A), in treatment frontal view (B), final frontal view (C), initial occlusal view (D), in treatment occlusal view (E), and final occlusal view (F).



Fig. 6. Post-treatment X-ray orthopantomography.

Table I. Article Screening Strategy.

Articles strategy	screening	Keywords: (miniscrew OR TADs) AND (impacted OR included teeth) Boolean Indicators: (“A” OR “B”) AND (“C” OR “D”) Timespan: 10 years (2013-2023) Electronic Database: Pubmed, Web of Science, Scopus
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1. Study design: Randomized Clinical Trials (RCT), case series (CS), clinical trials (CCT), retrospective studies (RS), prospective studies (PS); observational study (O).
2. Human participants of any age
3. Any impacted tooth
4. English language
5. Only full text is available

Studies characterized by one of the following exclusion criteria were excluded:

1. Study design: reviews, letters, or comments, book, fee-paying pdf
2. In vitro studies
3. Animal models or dry skulls

Data processing

We excluded articles that did not fit the topic by reading the manuscripts’ titles and abstracts. The full text of the remaining articles was read to assess the relevance based on the inclusion criteria. The study data was selected by analyzing the study design, number of patients, average age, intervention, type of treatment disimpaction and outcome. Disagreements between authors on article selection were discussed and resolved.

Data extraction

A standardized form was used to capture data on research design and locations, population characteristics (e.g., sex, age), type of intervention and comparison, baseline measurements, and reported results. Each study was also evaluated for its handling of missing data and effect measurements. For extraction accuracy, two reviewers (V.S. and F.P.) worked separately; divergences were resolved by consensus. Because of the substantial variability in the treatments and outcomes reported, meta-analysis was not possible; consequently, papers were synthesized qualitatively.

Data analysis

For homogeneous research, the fixed effect model was used, whereas, for heterogeneous studies, the random effect model was used. In all analyses, the effect size was calculated using the standardized difference of means.

PICOS requirements

The PICOS (Population, Intervention, Comparison, Outcome, Study Design) criteria, which are used in this evaluation, encompass population, intervention, comparison, outcomes, and study design (Table II).

Quality assessment

The quality of the included papers was assessed by two reviewers, R.F. and E.I., using the ROBINS, a tool developed to assess the risk of bias in the results of non-randomized studies that compare the health effects of two or more interventions. Seven points were

Table II. PICOS criteria.

Criteria	Application in the present study
Population	Young and adults
Intervention	Disimpaction of teeth by means of TADs
Comparisons	Comparison with other techniques
Outcomes	Analysis of timing and results of the traction
Study design	Clinical Trials

evaluated, and each was assigned a degree of bias. A third reviewer (F.I.) was consulted in the event of a disagreement until an agreement was reached.

RESULTS

The electronic database search generated 825 results by entering the keywords (miniscrew OR TADs) AND (impacted OR included teeth) in three databases, including Pubmed (294), Scopus (129) and Web of Science (402). Following duplication elimination (274), 551 studies were screened reading title and abstract. After the abstract screening, 496 papers were rejected (10 reviews, 3 in vitro, 17 on animals, 7 weren't in English, 404 off-topic). Among the 55 articles selected, 2 texts were not retrieved, therefore 53 articles were chosen for the eligibility evaluation. Following the full-text examination, manuscripts were eliminated: 29 off-topic and 5 wrong settings. Finally, 19 papers were chosen for the systematic review. Fig. 9 summarizes the selection procedure.

The study data was selected by analyzing the study design, number of patients, average age, intervention, and outcomes (Table III).

Quality assessment and risk of bias

The risk of bias in the included studies is reported in Fig. 10. Regarding the bias due to confounding most studies have a high risk. The bias arising from measurement is a parameter with a low risk of bias. Many studies have a low risk of bias due to bias in the selection of participants. Bias due to post-exposure cannot be calculated due to high heterogeneity. The bias due to missing data is low in many studies. Bias arising from the measurement of the outcome is low. Bias in the selection of the reported results is high in most studies. The final results show that 9 studies have a high risk of bias, 3 have a very high risk of bias and four have a low risk of bias.

DISCUSSION

Molars

Several methods have been devised for mounting impacted teeth angled mesially with direct or indirect anchorage with miniscrews. The larger wire width allows a wider range of action in the treatment



Fig. 7. Digital upper arch impression with TADs

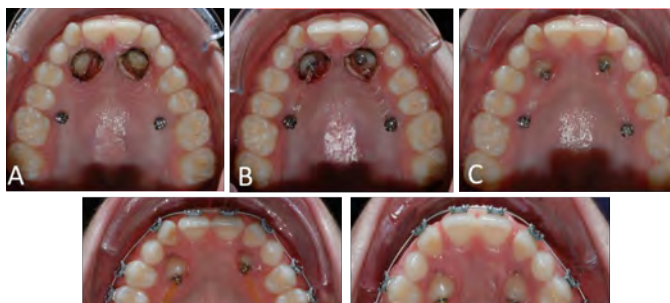


Fig. 8. Intraoral occlusal view photos: After surgical explosion (A), elastic chain positioning (B), after 1 month check (C), after 2.5 months check with multibrackets therapy (D) and after 4 months check (E).

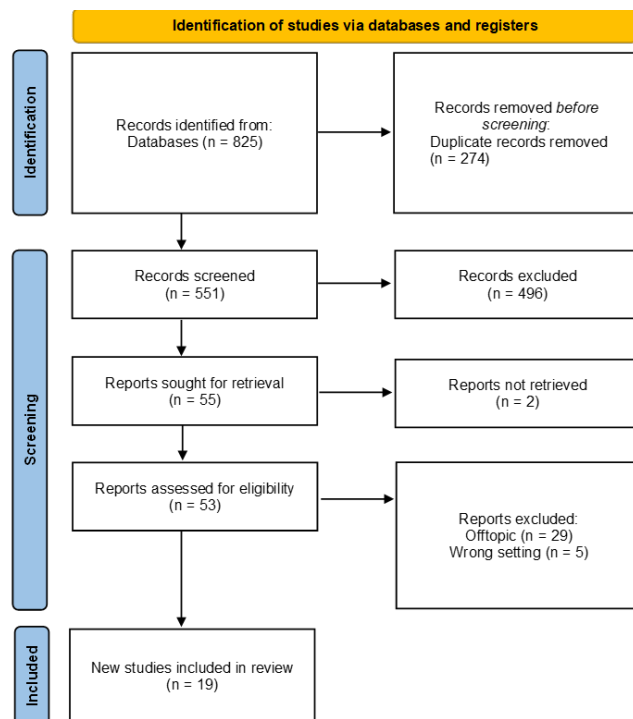


Fig. 9. Literature search Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

Table III. Characteristics of the studies included in the analysis.

Authors (Year)	Type of the Study	Aim of the Study	Materials	Results
Lorente et al. (2018) (48)	Case series	To induce the eruption of a profoundly impacted molar	A Cantilever arm supported by a miniscrew and a dental anchoring unit is used in a straightforward surgical approach. A "pole" functions as a first-order lever, with the resistance or charge represented by the unerupted molar and the fulcrum represented by the section of wire joined to form an anchoring unit. The force is generated by the miniscrew.	In both clinical cases, the use of the miniscrews caused the impacted molars to extrude, bringing them into balanced occlusion with the remaining dental parts.
Morita et al. (2020) (49)	Case report	The objectives of the treatment were creating a class I molar relationship, correct occlusion between the two arches, including the maxillary first molar (M1) and the impacted mandibular molars.	Two miniscrews were used, the first between the left second premolar and M1, the second miniscrew between the mandibular left canine and the first premolar. A transpalatal arch was used to prevent the molars from buccally tilting during intrusion.	Overjet and overbite were adequate, resulting in maxillary and mandibular occlusal interdigitation and a Class I molar attachment. The left maxillary first tooth was 3 mm intruded, whereas the left mandibular M1 was 60° upright and 6 mm extruded, according to a cephalometric superimposition. The total therapeutic period lasted two years and eleven months.
Baena et al. (2016) (50)	Case report	This study reports a case in which the lower M1 was recovered with orthodontic therapy combined with miniscrew, alloy Beta titanium (TMA) sectionals and oral surgery.	A 12-year-old female patient with an enclosed lower M1 had two miniscrews placed, one in the upper arch and a lever arm in (TMA 0.017x0.025) to intrude and create space in occlusion and one lower miniscrew between the first and second premolars and an extrusive lever arm in (TMA 0.017x0.025).	The miniscrews and sectional were removed after 24 months of therapy, the tooth was extruded and correctly brought into occlusion, also improving aesthetics.
Lorente et al. (2021) (23)	Two clinical cases	Conservative orthodontic treatment of eruption disorders of the permanent M2 in order to improve the occlusion of young patients. Treatment with TADs and TMA.	The two cases were solved by the use of a TADs acting as an anchor and a (TMA 0.019x0.025 inch) sectional arch exerting an extrusion force of 150-200 grams. the fulcrum of rotation of the TMA sectional arch is a (0.019x0.025) steel sectional arch bonded on the teeth adjacent to the tooth to be extruded.	This technique is a surgically performed orthodontic procedure to force the eruption of included M2s. This device uses mesial TADs that allow the application of an extrusive force in a short period in the first case 45 days in the second case four months.
Lorente et al. (2022) (51)	A prospective follow-up study	The study objective was to analyse the effectiveness of the author's "orthodontic technique to facilitate M2 eruption in the presence of complex molar inclusion indicators.	During 2 years, an observational prospective study was conducted. Baseline (T0) measurements of sociodemographic, clinical, and low-dose scanner characteristics were made. The follow-up variables (T1) included the interval between the procedure and the eruption of the M2, radiographic measures, button debonding, miniscrew failure rate, and success rate of eruption. 13 of the 24 molars were maxillary	The technique applies forces that succeed in extruding the included M2s in a short period and with a low failure rate. the treatment time variable depends on the severity of the infraocclusion of the tooth and the inclination of the tooth.
Alteri et al. (2020) (37)	A case report	The author presents a combined orthodontic-surgical technique for the disinclusion of the mandibular second molar M2. using orthodontic TADs and an elastic chain.	Orthodontic surgical technique on a 12-year old female patient, involving the use of a 13 mm long, 2.3 mm wide TADs placed in a retromolar area after removing the M3, and an elastic chain pulling the two included molars connected to two buccal and lingual buttons.	In a single surgical time, surgical removal of the lower M3, insertion of the miniscrew and orthodontic traction are performed, allowing a conservative treatment approach. After 3 months, the included tooth has achieved a good occlusion.
Mah et al. (2015) (38)	Case series	To demonstrate a biomechanical system that employs two miniscrews and a connecting wire to straighten mandibular teeth.	The procedure employs two miniscrews with an area for an orthodontic wire.	The impacted molar was effectively uprighted without interfering with the original occlusion or the alignment of the surrounding teeth.
Zhao et al. (2023) (52)	Clinical Trial	The current surgical procedure for extracting such Impacted lower M3 is either ineffective or time-consuming. A more effective surgical design is required.	Dr. Zhao retrieved Impacted lower M3 from 23 people who were found to have impacted lower M3 around the IAC between August 2019 and June 2022. These patients had their impacted lower M3 extracted by coronectomy-miniscrew traction.	The interval between coronectomy-miniscrew insertion and impacted lower M3 removal was much shorter compared with regular orthodontic traction.
Cortes et al. (2014) (53)	Case report	To prevent the danger of Inferior Alveolar Nerve (IAN) damage, the lower M3 was extruded using an orthodontic miniscrew prior to surgical removal.	An orthodontic miniscrew was placed between the first and second antagonist maxillary molars in the buccal cortex. Two orthodontic elastics were used to apply traction between the miniscrew and the orthodontic hook positioned on the lower M3 occlusal surface.	A CBCT imaging follow-up validated the lower M3 orthodontic extrusion's success.

Baik et al. (2016) (54)	Randomized Controlled Trial	To examine if vertical eruption of affected M3 improves after second molar mesialization and what factors influence vertical eruption of impacted M3 when lacking molar space is effectively repaired by second molar mesialization using miniscrews.	The study comprised 52 patients with missing mandibular M1 or missing deciduous mandibular M2, initially impacted mandibular M3, and effective edentulous gap closure with orthodontic. The control group (Group 2) included 46 individuals with impacted mandibular M3 who did not receive molar protraction therapy.	M3 in Group 1 erupted vertically an average of 2.54 mm compared to 0.41 mm in Group 2.
Greco et al. (2022) (55)	Case report	The study aims to treat impacted canines with a combined approach using TADs and aligners	In the first scenario, the affected canine's space is recreated, the malocclusion is corrected using an aligner device, and TADs are then used to attempt to de-impact the canine. The second clinical scenario involves a de-impaction stage that occurs right away and relies only on the use of TADs and sectional wires, followed by a finishing phase with aligners. It is connected to the canine-first strategy.	Both methods of treating impacted canines are effective, but which one is chosen depends on the initial malocclusion and the amount of space that is available in the upper arch.
Noroozian et al. (2022) (56)	Case Report	This study analyses a method to guide palatally impacted canines into the dental arch	Two possible scenarios have been analysed: a first -canine approach and a first phase of space creation approach, depending on the needling of the space	The drawbacks of the traditional technique are not present with this technique. Additionally, compared to the conventional approach, the overall treatment time and the time that orthodontic appliances are in the mouth cavity are shorter.
Venugopal et al. (2020) (57)	Case Report	This study aims to assess the validity of the miniscrew for the treatment of labially impacted canine	It has been used a power arm on the exposed canine and a TAD on the opposite arch	The use of TAD in the opposite arch is a valid solution in the traction of the upper canine. The referred problem is the discomfort of the patient
Venugopal et al. (2021) (58)	Case Report	The study aims to assess the validity of TAD to disimpact a palatally impacted canine	17 years-old patient was treated with TAD on the opposite arch and a power arm on the exposed canine	In less than 11 months, the impacted tooth was successfully brought into occlusion.
Jung et al. (2021) (59)	Case report	Before surgical removal, the lower M3 was extruded with an orthodontic miniscrew to reduce the risk of inferior alveolar nerve injury.	Orthodontic extrusion of the lower M3 using a miniscrew inserted on the maxilla and an intermaxillary elastic band without bracket connection to the surrounding teeth.	Cross-sectional CBCT pictures taken 3 months following the first application of the orthodontic force revealed that the nerve and root had been separated, and extraction was conducted. We discovered a 3-mm upward migration from the mandibular canal, equal to 0.75 mm each month. Furthermore, because traction was administered on the palatal side, the teeth were inclined 5 degrees toward the lingual side.
Bellot - Arcis (2021) (60)	Case report	Use of miniscrews to distalise the entire mandibular arch and canine disinclusion.	TADs for canines included	The miniscrews were placed in the retromolar area to straighten the mandibular molars, distalise the entire mandibular arch and prevent the maxillary incisors from tilting excessively.
Chang et al. (2016) (61)	Case report	Canine disinclusion	Two palatal TADs were used to distalise the maxillary dentition.	The inclusion of canines caused significant root resorption in four maxillary incisors. In 25 months of treatment, two palatal TADs were used to distalise the maxillary dentition.
Galluccio et al. (2021) (62)	Case report	Approach with the bone tunnel technique	TADs and canines included	The subperiosteal tunnel access technique with vertical incision (VISTA) is an effective method about the direction of forces and periodontal conditions of the included canine. It is done by means of an elastic chain connected in the posterior area with a temporary anchoring device (TAD).
Migliorati et al. (2021) (63)	Case report	Evaluation of two anchoring systems	Miniscrews and palatal bar	The study conducted canine disinclusion using two techniques. The test group received treatment using a mini-screw as anchorage, the control group was treated using a trans-palatal arch anchorage unit.

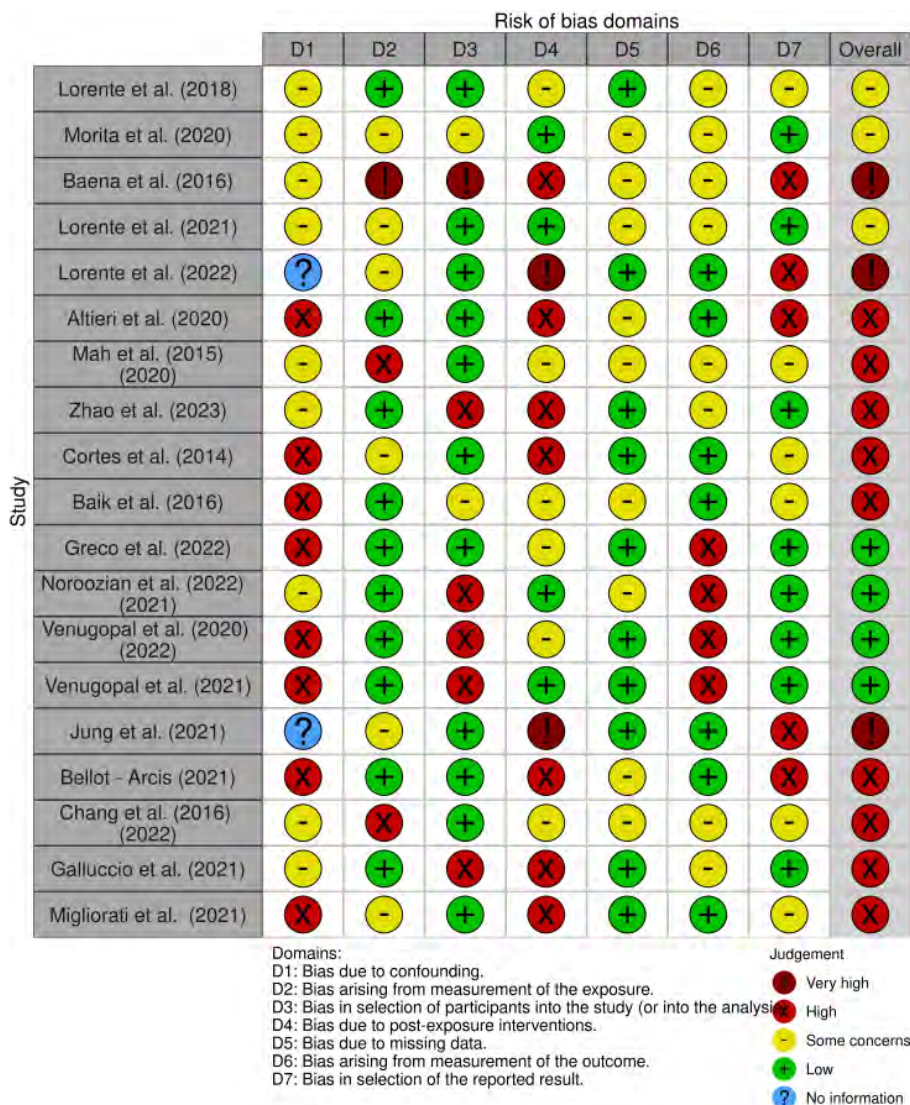


Fig. 10. Risk of bias evaluated through ROBINS tool.

mentioned by Lorente et al. and enables effective tooth movement. As the force used in the described technique is equal to the 50-150 g used in other procedures, the molar eruption can occur more quickly. The cantilever fits easily on the miniscrew for fast activation (48). After the procedure, there is no need to replace chains, elastic wires, or springs. If the miniscrew is placed mesially to the ectopically erupted molar, stability and accessibility are improved. If the miniscrew is inserted distally, in most cases, removal of the M3 and a healing time will be required before the necessary anchorage can be fixed. The M3 is only removed if the miniscrew blocks the crown of the second molar and the lack of space prevents the eruption of the second molar.

According to the author, the cantilever approach is used to resolve the dislocation of difficult molars and guide the tooth correctly into the arch without complications. Although this technique has mainly been used on M2, it has also been performed on M1 and lower canines (48). The approach presented by Mah et al. employs two miniscrews as orthodontic brackets and employs a rectangular connecting wire to manage the affected molar position in three dimensions (38). With

miniscrews, this approach combines the benefits of direct and indirect anchoring.

Without several brackets on teeth, different creative wire patterns (loops or helices) may be used to erect and regulate the molar position. The appliance system is less complicated and provides for improved oral hygiene without the danger of decalcification or gingival issues. They also demonstrated a three-dimensional force being applied to the tooth through a wire connected to a bracket with a specific orthodontic abutment attached to a miniscrew with a particular inner thread pattern on its head (38). The built-in rectangular groove that links the two miniscrews is used in their system. In patient 1, one of the two miniscrews on the left side came out before the procedure of uprighting the molar began, therefore only one miniscrew was used. The left miniscrew was strong enough to bear the uprighting force: the moment produced by uprighting the molar was clockwise, which helped tighten the miniscrew into the bone (38).

The main results in this situation were twofold: the miniscrew may survive if the thread direction can endure the moment induced by the uprighting force, and the molar position may be appropriately managed if the slot length of the miniscrew head is long enough to firmly grasp the wire. In the three patients, vertical and horizontal wire loops were used. Initially, distalizing tension was applied to the crown of the impacted or mesially pointed molar using several vertical looped wires. An open-coil spring can be used instead of vertical loops to enable the distalizing force of patient 1's molar. Their observations show that loops outperform coil springs (38).

M1 and M2

The inclusion of the M1 is an extremely rare event. In the case of Morita et al., an uprighting cantilever was utilized to upright and extrude the M1 because the cantilever mechanics provide an uprighting moment and an extrusive force simultaneously, which is suited for correcting the angulated and inferiorly positioned molar (49). A miniscrew was placed between the canine and the first premolar, and the cantilever was hooked over the miniscrew head. The connection of a tube in the buccolingual direction, rather than the mesiodistal direction, was the most unusual component of the molar uprighting mechanics applied in this case. By twisting the distal end of the cantilever, an efficient distal tipping moment may be imparted to the molar. As a result, a miniscrew was placed between the canine and the first premolar to create a longer cantilever mechanism (49).

The clinical case described by R. Rodriguez Y Baena concerns a 12-year-old patient who presented with a delayed eruption of the mandibular M1 on the right.

The treatment involved an intrusion of the right upper M1 with subsequent extrusion of the lower M1 including using TADs (50-64). On the mandible, TADs were placed between the first and second premolars connected to a cantilever in TMA 0.017x 0.025 exerting a vertical extrusive force on the lower molar included (65, 66). After 24 months, the tooth achieved proper occlusion with its antagonist. The TADs were removed at the end of the treatment (27, 67-69).



Fig. 11. Insertion site of miniscrew for molar uprighting.

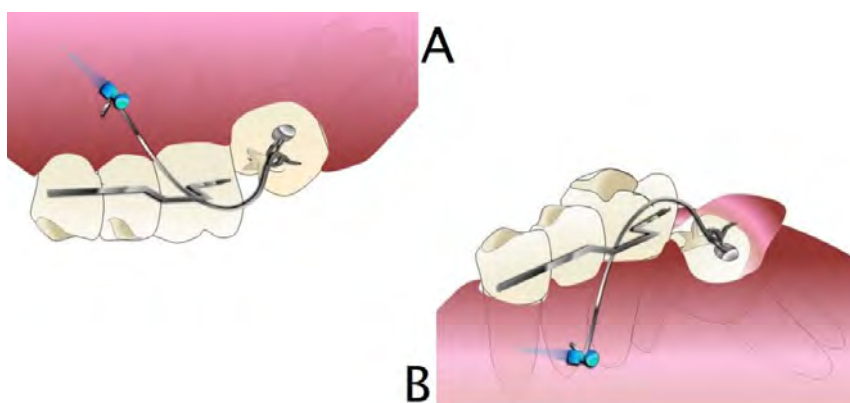


Fig. 12. Traction of the impacted tooth using the Lorente technique. A: upper molar. B: lower molar with surgical exposure.

Second molar inclusion is a rare condition. Lorente et al. in this paper describe two cases of included molars, in a 15-year-old and a 13-year-old (70). The authors opted for conservative orthodontic treatment with TADs between the first and second premolars. A 0.021 “x0.025” steel sectional was bonded to the three teeth adjacent to the included molar. This acted as a mesial step through which a Ni-Ti cantilever, exploiting its memory effect, generated an extrusive force of 150-200 grams to the included tooth (Fig. 11). The maxillary tooth included in the first case reached occlusion after 45 days, while in the second case after four months due to the increased mandibular bone density (23, 71).

Bereket et al., in their work, conducted a prospective observational study over two years, focusing on the eruptive technique of Lorente for M2 using TADs and Ni-Ti (Nickel Titanium) cantilevers (72) (Fig. 12). The study was carried out on a sample of 21 patients, with an average age of 13.9 years. Between the starting time (t_0) of the study and the ending time (t_1), the following variables were compared: the time elapsed between the surgical intervention and the eruption of the included tooth, the failure rate of TADs, radiographic measurements between the bone margin and the cusp of the included tooth, and the treatment success rate (51). Three cantilevers of different lengths were used to extrude the included tooth, selected based on the point of force application relative to the centre of resistance of the tooth. According to the authors, the angle and degree of infraocclusion of the included molar are variables that can particularly influence treatment times. Thanks to the adopted technique, all teeth were correctly erupted into the arch, except for two cases where perfect occlusion was not achieved (51). The failure of one TADs was also recorded. Compared to others, one advantage of this technique is that it can be performed on both the upper and lower jaw, providing good comfort to the patient. Finally, the main limitation of the study is the small sample size of included molars considered (51).

Altieri et al. present an orthodontic technique for the eruption of impacted lower M2 in a 20-year-old patient (37). The technique involves the surgical removal of the M3, the placement of TADs in the retromolar area, and an elastic chain connected to the second molar, bonded with two buttons, one on the buccal side and one on the lingual side. An early diagnosis and prompt treatment are the keys to success in the eruption of M2. The advantages of this technique are the absence of bulky devices that hinder chewing, the maintenance of good oral hygiene, and the lack of patient cooperation (37).

M3

Zhao et al. used a procedure comprising coronectomy, modified pericoronal osteotomy and improved orthodontic extraction (52). Coronectomy reduces the resistance of the M3 extraction crown, provides sufficient space for miniscrew traction, and also creates a suitable surface for miniscrew implantation. The duration of extraction with this approach can be significantly shorter than that of standard orthodontic extraction, which can take months, after precise coronectomy, removal of the pericoronal bone and implantation of the miniscrew, and with adequate extraction force produced by the spring (52). In the case of Jung et al., the inferior M3 was close to the IAN, but it was still possible to remove it without causing nerve damage by using TADs and a cross band for 4 months (59). In this study, only one TADs was placed on the maxillary palatal side and only one button was connected to the inferior M3 to enable its traction. The use of a bone anchor in the opposite arch made it easier to manage the direction of traction and the angle of the teeth for the patient. When traction was applied to the palatal side of the maxilla, the teeth shifted lingually and the apex of M3 was separated from the canal horizontally and vertically. In this case, TADs were used as an anchoring device to provide a more predictable and safe therapy. Compared to other CT procedures, CBCT has several advantages, including lower effective radiation doses, faster acquisition times, simpler imaging and lower costs (59). In the case of Cortes et al., elastic traction was also employed, resulting in a 5-week orthodontic treatment duration to achieve lower M3 extrusion (53). The hook was positioned on the lower M3 occlusal surface in this example, resulting in less contact with the patient's cheek mucosa; two elastics were used, reducing traction time. However, an initial surgical treatment utilizing a piezoelectric surgical device, which has been discontinued, was required to remove the bone around the occlusal and buccal surfaces of the lower M3 crown (53). Baik et al. investigated the factors associated with the vertical eruption of impacted M3 when room is obtained by uprighting with mesialization of the second teeth (54). Even though horizontal angulation was significant, as demonstrated by the distance between the ramus and M3, vertical eruption was detected. This implies that initial vertical position and available space are important factors in the eruption of impacted M3. As a result of uprighting with second molar mesialization, impacted lower M3 arise vertically (54).

Canines

With an incidence ranging from 1% to 5.9%, canines are most typically added after the M3. Canine impaction is most frequently related to lack of space, wrong development of the tooth position, an atypical eruption path, extra teeth, and genetic factors, according to the literature (73). The placement of the lateral incisor may be affected by how close the upper canine is to being affected. The lateral incisor's root may be pressed by the palatal canine, which will cause it to migrate in the direction indicated by the canine. The crown of the lateral incisor may positively deflect as a result of the canine's vestibular location (74). Since most retained canines exhibit mesioinclination, they frequently have a greater impact on the position of the lateral incisor than the first premolar (75).

Several treatment protocols have been developed over the years to be able to treat palatally included upper canines, including Ballista springs, interarch tractions, and wires Kilroy springs (19,57,76-78).

The age of the patient, the physician's ability and experience, predicted patient compliance, and most importantly anatomical location all influence treatment options (79).

The traditional approach to treating impacted canines with orthodontic surgery entails surgical tooth exposure using either the "open exposure" or "closed exposure" method, bonding an orthodontic button with the attached chain intraoperatively, and connecting it to the arch of the permanent appliance (80).

To avoid changing the occlusal plane and straining the neighbouring teeth, impacted canines must be removed using optimal biomechanics during orthodontic eruption (73). For instance, if anchorage is only provided by the brackets and archwire, this could result in a lateral open bite and bone loss distal to the lateral incisor (81).

Anchorage of a miniscrew (1.6 mm diameter × 8.0 mm length) to the arch opposite that in which the impacted canine is present and the use of an intermaxillary rubber band brought the canine into occlusion in about 11 months. The patient had to wear the rubber bands (1/8", 4.5 oz) for about 8-12 hours a day, inserting one end of the rubber band into the miniscrew and the other end into the pre-welded hook into the button. The miniscrew is placed perpendicular to the occlusal plane so as not to create discomfort when inserting the elastic (57,58).

When TADs continuously provide the right amount of extrusive force in the proper direction without worrying about anchoring loss, the impacted canine will progress toward the dental arch as the other teeth are independently levelled and aligned at the same time. The regional acceleratory phenomena that develop as a result of mucosal retraction and bone removal can be advantageously used to apply orthodontic force as soon as possible after exposure surgery (82).

For the treatment of palatally impacted canine teeth, Heravi et al. proposed this unique procedure with a distinct appliance design that used two bracket-type mini-screws. The mini-screws were inserted between the first and second premolars as well as between the second premolar and the M1. The two bracket-style miniscrew slots on the rectangular TMA wire were used to create a cantilever spring, which was then ligated with ligature wire (83).

Noroozian et al., in three patients, after surgical exposure of the palatally impacted canine, for the traction phase of the tooth applied a cantilever anchored to two miniscrews inserted in the palate, before starting orthodontic treatment. The cantilever is made of 0.017-0.025-inch stainless steel wire with a hook or helix in the anterior area to ligate the ligature wire and a U-loop in the middle to change the load's direction (56). This disengages the root of the canine from that of the lateral avoiding resorption of the root of the lateral, the patient also has an aesthetic advantage because there is permanence of the milk tooth in place, at least at first. The treatment also lasts much less overall and the arch form is not changed. Fixed orthodontics begins at the moment when the canine cusp emerges from the palatal mucosa and aims to bring the tooth back into the arch (56).

Another therapeutic option for palatally included canines involves a hybrid approach that includes sectional wires (0.017 × 0.025 TMA), miniscrews (1.3 mm wide and 10 mm long) and aligners. Both a first-canine approach and a first-stage alignment and subsequent traction of the canine have proven to be equally valid techniques: the choice of one appurtenance over the other is dictated primarily by the space in the arch at the time of treatment initiation: a lack of space requires a first-stage opening and a simultaneous or subsequent traction phase (55).

Ballot-Arcis et al. in a paper published in 2021 described a multidisciplinary, non-surgical orthodontic treatment of an adult patient with Class III skeletal malocclusion, palatally impacted canine, treated with fixed appliances and skeletal anchorage (60). To straighten the mandibular molars, distalise the entire mandibular arch and avoid an excessive inclination of the maxillary incisors to improve dentofacial aesthetics, two miniscrews were placed in the retromolar area.

The treatment results were very satisfactory and remained stable after a reasonable retention period. Two TADs were placed distal to the mandibular M2. Distal traction was performed with elastic chains from the minivits. After distalisation of the mandibular arch, achieved by the use of miniscrews, the patient's malocclusion improved significantly within a reasonable treatment time (60).

Chang et al. describe a case of a 12-year-old boy with bilaterally included maxillary canines. Two miniscrews were used to space the arch and distalise the maxillary dentition. The treatment lasted 25 months. The maxillary canines were moved away from the short roots of the incisors by the miniscrews, and further root resorption was avoided (61).

Galluccio et al. present in their article for canine disinclusion including the subperiosteal tunnel access technique with vertical incision (VISTA) This technique shows good performance regarding the direction of forces and periodontal condition of the canine when erupted; it is usually performed using an elastic chain connected to a TADs in the posterior area (62).

Migliorati et al. compared the efficiency of two different anchorage systems to disinclude maxillary canines using a CBCT. Two anchorage systems, TADs and palatal anchorage, were used. The study was carried out on 22 patients and no major differences in results were observed with the two methods (63). This review has several limitations:

1. Heterogeneous study designs: the included studies vary in design, such as case-control, observational, retrospective, and prospective studies. Combining data from different study designs may introduce heterogeneity and affect the validity of the review's conclusions.
2. Limited sample sizes: some of the included studies have small sample sizes, which could limit the statistical power and generalizability of the findings.
3. Lack of quality assessment: the review does not mention whether a quality assessment of the included studies was conducted. Evaluating the methodological quality of the studies is essential to assess the overall reliability of the evidence.
4. Limited scope of analysis: the review mainly focuses on muscle activity following mandibular condylar fractures, but it does not discuss other potential outcomes or complications related to these fractures, such as pain, joint function, or psychosocial impact. A more comprehensive analysis of the implications of these fractures would provide a more robust understanding of the topic.
5. No meta-analysis: while the review mentions "qualitative analysis," it does not provide any meta-analysis or systematic synthesis of the findings. A meta-analysis, if possible, could help in pooling the results from multiple studies to draw more robust conclusions.

CONCLUSIONS

In our research, it has emerged that the resolution of dental inclusions can be achieved both with and without the use of TADs, resulting in a satisfactory and stable outcome over time. In general, the use of skeletal anchorage through TADs in orthodontic treatment has expanded treatment possibilities and improved efficiency. The utilization of TADs offers various advantages, including a wider range of action, faster tooth movement, and increased stability and accessibility. Several treatment protocols have been developed, including the use of TADs, cantilevers, elastic chains and coil springs to provide continuous extrusive force in the correct direction. In conclusion, dental inclusion is a significant issue in dentistry and with the progress of techniques and instruments it is possible to resolve dental inclusion cases more safely and predictably with accurate and reliable therapeutic protocols. Further research and advancements in the field of orthodontics will continue to enhance the management of dental inclusions, offering better outcomes to individuals with this condition.

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Case Report

MODIFIED CORONALLY ADVANCED TUNNEL TECHNIQUE (MCAT) FOR THE TREATMENT OF MULTIPLE ADJACENT GINGIVAL RECESSION (MAGR) USING SITE SPECIFIC DE-EPITHELIALIZED FREE GINGIVAL GRAFT (DGG): A CASE REPORT

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ABSTRACT

To evaluate the clinical outcomes of Multiple Adjacent Gingival Recession (MAGR) using Modified Coronally Advanced Tunnel (MCAT) technique in conjunction with site specific De-epithelized Gingival Graft (DGG). Root coverage of MAGR in Recession Type 2 (RT2) cases presents a treatment challenge due to papilla loss. There is a demand for interdisciplinary approach including surgical and restorative approach in RT2 cases especially when non carious cervical lesion (NCCL) is involved. Various surgical techniques have been described in the literature to treat MAGR. Coronally advanced flap with sub-epithelial connective tissue graft although efficacious, has its limitations. Tunneling techniques like MCAT are used due to their advantages like reduced morbidity and maintaining papillary blood supply. This case report aims to evaluate the clinical results in a patient with multiple adjacent RT2 gingival recession and NCCL using MCAT along with site specific DGG and restorative treatment. A 68-year-old male was referred for the treatment of MAGR on the buccal surfaces of teeth #21–25, with a diagnosis of RT2. MCAT surgery included the preparation of the recipient site with a tunnelling protocol, keeping the interdental papillae intact. A free gingival graft was harvested, de-epithelialized extra-orally, and the resulting connective tissue graft was sutured. Partial root coverage around 80% was achieved at 6 months, consistent with the initial diagnosis of RT2. There was also an appreciable increase in gingival thickness, gain in keratinized tissue as well as improved final aesthetic outcome.

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The results indicate that the use of MCAT may represent an alternative to conventional CAF by reducing surgical time and patient morbidity and yields root coverage in the treatment of MAGR defects (RT2) when used in conjunction with DGG.

KEYWORDS: *connective tissue graft, gingival recessions, tunnel technique, de-epithelized gingival graft, coronally advanced flap*

INTRODUCTION

As defined by the American Academy of Periodontology (AAP), gingival recession (GR) is a term that designates the oral exposure of the root surface due to a displacement of the gingival margin apical to the cemento-enamel junction, and it is also frequently related to the decline of dental (white) and gingival (pink) aesthetics as well as buccal cervical dentine hypersensitivity.

These defects were categorized following the 2018 World Workshop into three categories: (1) recession type 1 (RT1) with no loss of interproximal attachment, (2) recession type 2 (RT2) when the amount of interproximal attachment loss is lower than of buccal attachment loss, and (3) recession type 3 (RT3) if interproximal attachment loss is greater than buccal attachment loss (1).

In RT1, complete root coverage (CRC) is achievable; for RT2, some studies confirmed the limit of interdental CRC loss within which 100% root coverage is predictable applying different surgical approaches, whereas for RT3 CRC is not possible (2, 3).

In cases of Multiple Adjacent Gingival Recession (MAGR), the surgical management is more demanding and usually requires a longer surgical time, while the wound healing process is more prone to complications and influenced by numerous factors such as, for example, the extended avascular surface area, limited blood supply, or/and unfavorable tooth position (4). RT2 MAGR frequently needs the dual approach of surgery and restorative treatment especially when non-carious cervical lesion (NCCL) is present.

Among the plethora of treatment strategies for root coverage, sub-epithelial connective tissue graft (SCTG) with coronally advanced positioned flap (CAF) was proven to be an effective treatment for multiple gingival recessions defects in areas with esthetic concerns (5). RT2 recession cases may benefit at short term when SCTG based procedures were used, but the predictability is less compared to RT1 (6).

To overcome the disadvantages of CAF like vertical incisions and disturbed papillary blood supply, new techniques like tunnelling have been proposed for the surgical treatment of MAGR. Recent literature shows that tunnelling is an effective and predictable procedure for treating MAGR (7). According to current systematic review and meta-analysis, the overall calculated average root coverage (ARC) of tunnel for MAGR is 87.87% whereas CRC could be achieved in 57.46% of defects (8).

The modified coronally advanced tunnel (MCAT) approach minimizes the surgical invasiveness and enhances wound and soft tissue stability, limiting patient morbidity and surgical chair-time (9). The procedure involves creating a partial-thickness flap by undermining the gingival tissue and alveolar mucosa without separating the interdental papillae. This technique allows clinicians to reduce the need for vertical incisions, which may enhance the esthetic outcome of the root coverage procedure. This technique has the advantage of blood supply from the overlying flap and underlying periosteal bed without compromise in vascularity due to dissection of papillae. However, this approach is technique sensitive (10).

The SCTG is a predictable and versatile technique in treatment of gingival recessions. Differences in hard palate anatomy and insufficient fibro-mucosal thickness may complicate harvesting connective tissue graft (CTG) and considering that healing by secondary intention is not associated with increased post-operative discomfort, Zucchelli and coworkers introduced the de-epithelialized gingival graft (DGG) (11) in which it is harvested as a free gingival graft, then extra-orally de-epithelialized. This technique permits palatal harvesting regardless of fibromucosa thickness (12). CT obtained using the DGG technique is considered more stable primarily composed of lamina propria with large amounts of fibrous CT and contains less fatty and glandular tissue than SCTG and longer graft can be harvested (13). MCAT technique in combination with DGG, has been introduced to as a treatment to increase gingival dimensions and to cover the exposed root surface effectively and with long-term stability. Additional gingival thickness (GT) increase, root coverage, and patient-based outcomes favored MCAT, though keratinized tissue (KT) change proved greater with DGG (14).

CASE DESCRIPTION

Clinical case presentation:

A 68-year-old male patient reported to the Department of Periodontology, Sinhgad Dental College and Hospital, Pune with esthetic concern and root sensitivity complaints in December 2022. Patient was non-smoker with no systemic health diseases, and ability to maintain good oral hygiene. Patient had no history of taking antibiotics within 3 months or more than 2 weeks of duration and no gingival surgery within 12 months at the defect site. The clinical examination of the patients revealed MAGR (RT2) and NCCL with #21-25 teeth (Fig 1, 2).

Clinical evaluation indicated plaque index (PI) of $\leq 15\%$ and gingival index (GI) of $\leq 13\%$ and probing depth of $\leq 3\text{ mm}$ (Table I).



Fig. 1. Baseline RT2 Gingival Recession defects

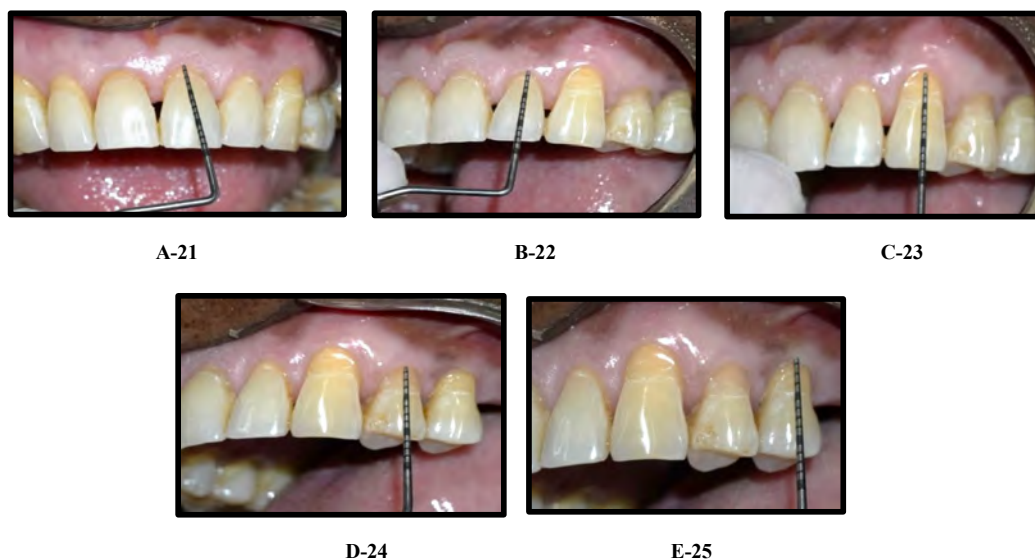


Fig. 2. Baseline measurement of gingival recession depth using UNC-15 probe

Table I. Clinical parameters at baseline; CEJ- Cemento-enamel junction; RD- Recession depth; RW-Recession width; WAG- Width of attached gingiva; KTW- keratinized tissue width; GT- gingival thickness.

Tooth no.	Class	CEJ	RD	RW	WAG	KTW	GT
21	RT2	Visible	2 mm	5 mm	3 mm	4 mm	Thick
22	RT2	Visible	1 mm	4 mm	3 mm	4 mm	Thick
23	RT2	Visible	4 mm	5 mm	4 mm	5 mm	Thick
24	RT1	Visible with step	3 mm	5 mm	3 mm	4 mm	Thick
25	RT1	Visible with step	4 mm	5 mm	2 mm	3 mm	Thick

The treatment plan finalized was an interdisciplinary approach of MCAT and cervical restorations after initial healing of 6 months. Patient selection, consent recordings, and surgical procedure were completed by a single clinician/Periodontist at Department of periodontology, Sinhgad Dental College and Hospital, Pune.

Pre-operative

Four weeks prior to surgery, a prophylaxis session was performed, and all teeth were supra-gingivally cleaned. Root planning of the exposed root surfaces using designated curettes was performed. To avoid further progression of the recessions, the patient was instructed to use soft tooth brush with limited pressure and Modified Stillman technique. Informed consent for the root coverage surgery was obtained.

Surgery

Local anesthesia (2% Lidocaine with 1:100000 epinephrine) was administered on both recipient and donor sites. For the recipient site preparation, sulcular incision with 15-D lance tip ophthalmic microsurgical knife was made through the gingival sulcus until the incisal tip of interdental papilla. A full-thickness mucoperiosteal flap was reflected, extending beyond the mucogingival junction with specific tunnel instruments preserving the integrity of the gingivo-papillae complex carefully (14) (Fig. 3).

The undermining of tissues was extended laterally, about 3–5 mm, to prepare the tunnel (4). The second step was site specific application of DGG at 23, 24 and 25 sites since they had more recession compared to incisors. Free gingival graft (FGG) was harvested from the palate and de-epithelialized to obtain a CTG (Fig. 4).

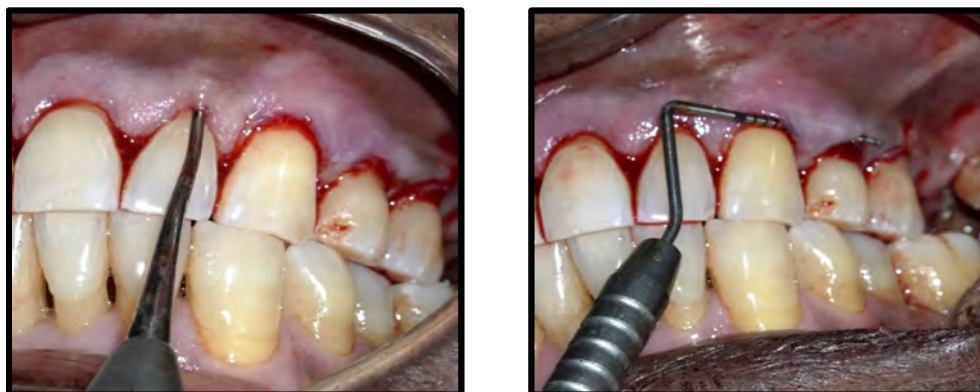


Fig. 3: *Sulcular incisions and tunnelling with specific tunnel instruments*

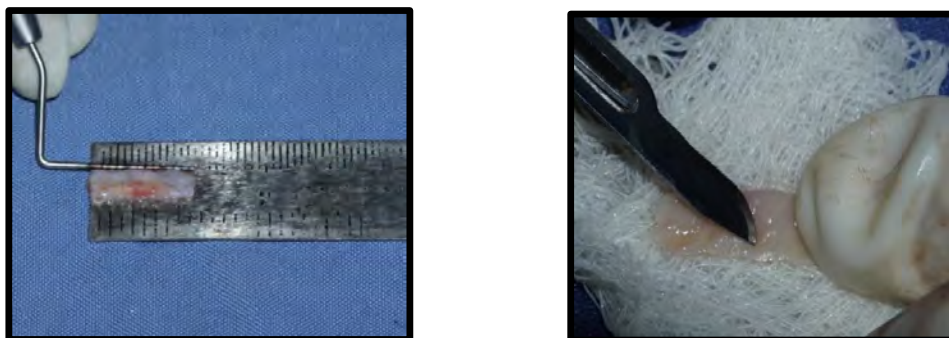


Fig. 4. *Free gingival graft harvested from the palate and de-epithelialized extra-orally*

Graft was carefully inserted into the tunnel with the help of 6-0 polyamide monofilament suture using graft positioning suture technique. Sling sutures were used to coronally reposition the flap 1 mm above CEJ (Fig. 5).

Donor site was secured with bovine collagen type I matrix (SURGICOLL-MESH Advanced Biotech Products (P) Ltd. Encoll Fremont, CA, USA) along with stabilizing sutures to reduce post-op discomfort (15) (Fig. 6).

Postoperative instructions and evaluation of morbidity

An analgesic was prescribed for post-surgical pain relief. Patient was instructed to avoid brushing and chewing in the treated area for a period of 2 weeks and rinse the mouth twice a day using 0.2% chlorhexidine solution. Palatal sutures were removed after 1 week. The recipient site sutures were removed at 2 weeks post-op (Fig. 7).

Patient was instructed to resume the brushing on the operated area using roll technique. Re-examinations were conducted at day 3 for evaluation using VAS scale which consisted of pain and swelling questionnaire in the operated areas (the scale was anchored by “no pain or swelling” as score 0 and “worst imaginable pain or swelling” as score 10).

Patient was further recalled after 1 and 2 weeks where all sites were clinically assessed for wound healing with the help of healing index (16), where the wound healing was scored from 1 (very poor) to excellent based on clinical assessment. At 1 month (Fig. 8) and 3 months (Fig. 9) and 6 months (Fig. 10), post-operative follow ups were conducted.

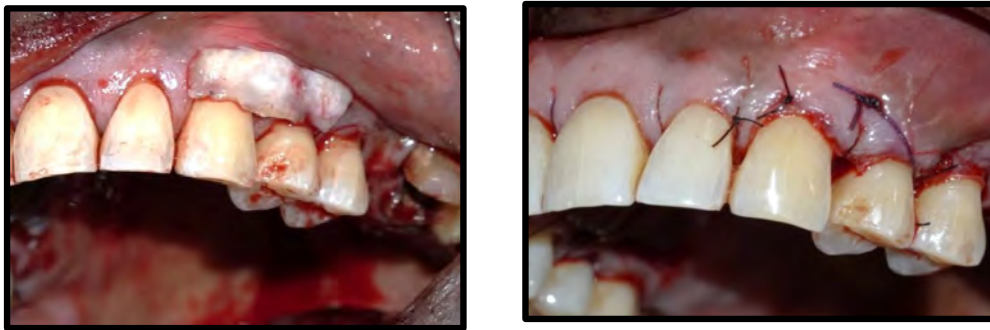


Fig. 5. Graft adaptation and recipient site suturing with sling sutures using 6-0 monofilament suture

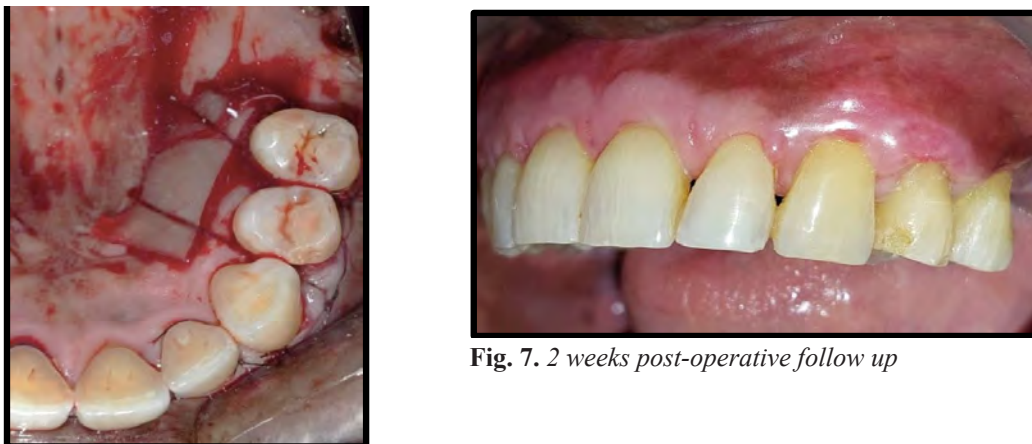


Fig. 7. 2 weeks post-operative follow up

Fig. 6. Bovine Collagen Sheet dressing to protect the donor site secured with 6-0 sutures

The Root Esthetic Score (RES) was assessed at 6 months (17). The definitive restoration of the remaining cervical lesion was done after 6 months using composite resin. During the follow up visits, supragingival plaque was removed when necessary and reinforcement for the proper brushing technique and oral hygiene were implicated.

RESULTS

Healing was uneventful with slight inflammation, some discomfort and swelling for the patient. At the day of suture removal, the level of the gingival margin was still about 1 mm above the CEJ. After 2 weeks, a coverage of about 80% of the denuded root surfaces was achieved which continued till 6 months post-operatively. Increase in keratinized tissue width and gingival thickness were observed. Hypersensitivity completely diminished after the procedure. Scar tissue formation was limited and became almost completely invisible after 1 month.

The VAS median (range) values of postoperative pain after 3 days were between 2–4 and by the end of 1 week there was a decrease in the VAS median (range) values showing 0–2 score.



Fig. 8. 1-month post-operative follow up



Fig. 9. 3-month post-operative follow up



Fig. 10. 6-month post-operative follow up

Healing index showed the scoring of 4 (very good) at all surgically treated sites

In RES system, five variables 6 months following the surgery were evaluated: GM, marginal tissue contour (MTC), soft tissue texture, muco-gingival junction. Alignment, and gingival color (GC). After clinical evaluation a score of 7 was recorded.

DISCUSSION

In the present article, a clinical case was reported in which the DGG was used with the MCAT technique to treat MAGR with NCCL. The primary objective of the case report was to evaluate a degree of GR reduction and soft tissue thickness gain. Improvement of clinical parameters reflecting reduced recession and increase in gingival thickness and keratinized tissue was observed.

The MCAT technique ensures sufficient blood supply to CTG and maintains its vitality and simultaneously, it maintains the gingival margin harmoniously. The tunnel technique provides an effective treatment plan, particularly in MAGR defects as it provides an excellent graft adaptation to the recipient site, produces favourable esthetic results, and increases the gingival biotype (18).

Aroca et al. reported ARC of 90% for the tunnel technique with CTG in treatment of multiple Miller classes I and II gingival recessions, and 83% in case of Miller class III gingival recessions after 12 months (7).

Treatment of MAGR with CAF resulted in 77.7% CRC when releasing incisions was used, whereas it amounted to 89.3% in the group treated without vertical releasing incisions (19).

According to Zucchelli et al. (11) a statistically greater increase in buccal soft tissue thickness may be achieved with DGG, owing to a better quality of connective tissue directly under the epithelium (11).

Regarding NCCL, whether restored with composite/ionomer materials or not, may be safely treated by SCTG+CAF and CAF. There is no evidence on the optimal timing for NCCL restoration (before, during or after root coverage procedures) (6).

The results also confirm the legitimacy of performing minimally invasive techniques of harvesting grafts from the palate as the thin grafts collected in this way are sufficient to obtain both, optimal gingival thickness and aesthetics Zucchelli et al. (20).

CONCLUSIONS

This case report demonstrated that MCAT with selective DGG might represent a promising method for root coverage in MAGR type RT2. At 6 months, this technique gives predictable results with uneventful healing of the surgical sites and has potential to increase soft tissue thickness, keratinized tissue gains and as well as to improve the final aesthetic outcomes. However, randomized controlled trials are needed using this method and focusing on evaluating the amount for root coverage, papillary gain, and the quality of the soft tissue attachment.

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Case Report

TYPE I DENTIN DYSPLASIA: A RARE CASE REPORT OF TWO SIBLINGS

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ABSTRACT

Dentin dysplasia (DD) is rare autosomal dominant hereditary disorder related to disturbance in dentin development. The common characteristics of DD are normal enamel, short roots, pulpal obliteration, atypical dentin, early exfoliation and occasional periapical cysts. Two cases of DD are reported and pertinent literature discussed.

KEYWORDS *Dentin dysplasia, hereditary, tooth, pulp, root*

INTRODUCTION

Dentin dysplasia (DD) is rare autosomal dominant hereditary disorder related to disturbance in dentin development. This rare condition was first described by Ballschmiede as “Rootless teeth” in 1922. The term “Dentin Dysplasia” was coined by Rushton (1). The common characteristics of DD are normal enamel, short roots, pulpal obliteration, atypical dentin, early exfoliation and occasional periapical cysts (2). Shields et al. (3) classified DD into two types. In type I the teeth are clinically normal in size, shape and consistency in both primary and permanent dentition. According to Shields et al. in-type II DD the roots are normal and coronal abnormalities are seen.

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CASE DESCRIPTION

Two siblings (18-year-old female and 19-year-old male), reported to the Dept of Periodontology with the complaint of missing teeth in the lower front region and mobility with upper and lower back teeth. Both patients gave history of exfoliation of few front teeth due to loosening. Both patients medical history was not contributory. There was no history of early teeth exfoliation with family members. Parents of the patients had consanguineous marriage and belonged to lower socio-economic strata.

On clinical examination, both the patients appeared to be well developed and well-nourished without any visible external deformity. All the vital signs were normal in both the patients. Extraoral examination (Fig. 1a and Fig. 1b) in both patients showed normal facial structure and no deformity involving scalp, hands and feet.

On intraoral examination, (Fig 2a) of the female patient, most of the anterior teeth were missing and the teeth which were present had varying degree of mobility.

The color of the teeth was normal. The oral hygiene status was poor. The mandibular right second and third permanent molar and lower left third permanent molar were cariously destroyed. The gingiva had normal colour except for the marginal gingiva which was seen reddish in colour. Ample amount of plaque and calculus was noted in the surrounding region. The contour of the gingiva was scalloped and consistency was firm. Resorbed ridge was seen in the missing teeth region. The size of the gingiva was normal. Generalized bleeding on probing was present. Mulberry molars were seen in mandibular right and left sides of the jaw.

Teeth present –

8 7 6 5 4	3 4 5 6 7 8
8 6 5 4 3	3 4 5 7 8

Grade I mobility –

7 6 5 4	4 5 6 7 8
6 5 4	4 7

Grade II mobility -

	3
	5

Grade III mobility -

3	3



Fig. 1a. Extraoral features of female patient



Fig. 1b. Extraoral features of male patient



Fig 2a. Intraoral features of female patient

In the male patient, intraorally, (Fig 2b) the color of the teeth was normal.

The oral hygiene status was fair. The gingiva was pale pink colour, scalloped contour and firm consistency. All incisors were missing and mobility was present in upper right premolar and lower left canine. Ridge resorption was seen in the missing teeth region. The size of the gingiva was normal. Mulberry molar were seen in lower right and left sides of the jaw.

Teeth present -

8 7 6 5 4 3	3 4 5 6 7 8
8 7 6 5 4 3	3 4 5 6 7 8

Grade I mobility -

4 3	
3	3

Investigation

Extraoral radiographs (Fig 3a, 3b), hand-wrist radiograph (Fig 4a, 4b) and intraoral radiographs (Fig 5a, 5b) were taken.

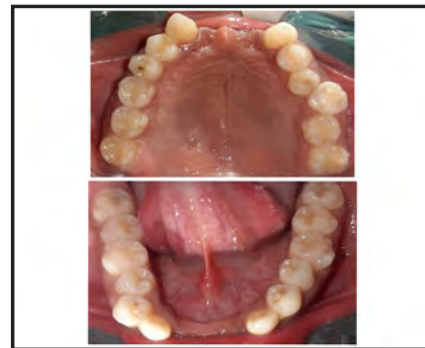


Fig. 2b. Intraoral features of male patient.



Fig 3a. Extraoral radiograph of female patient



Fig 3b. Extraoral radiograph of male patient.



Fig 4a. Hand – wrist radiograph of female patient



Fig 4b. Hand – wrist radiograph of male patient

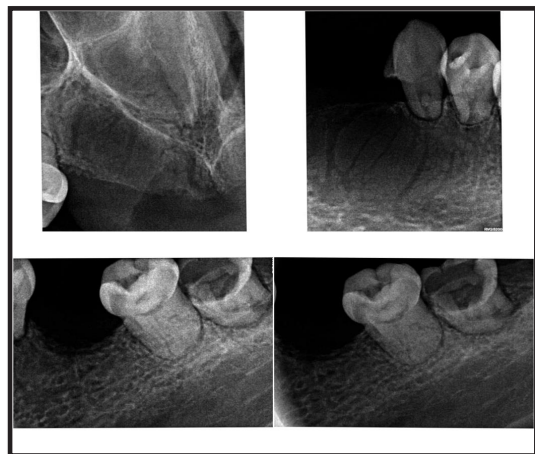


Fig 5a. Intraoral radiographs of female patient



Fig 5b. Intraoral radiographs of male patients

Radiographically, the teeth appeared to have normal enamel and shorter roots. Crescent shaped pulpal remnants were seen. Pulpal obliteration was clearly visible and open apices were seen. (Fig 3a, 3b) Taurodontism was noted with all molars. Periapical radiolucencies were noted in female patient with 38 and 48. Tests like complete blood count, serum phosphorous, serum calcium, blood sugar levels, bleeding and clotting time were performed. All the lab investigations were within the normal range for both the patients.

Differential diagnosis

Generally, diagnosis is based on history and the clinical and radiographic features of the patient (4). The features of DD I most commonly resemble with DD II and dentinogenesis imperfecta. Some systemic disorders like calcium deficiency, rheumatoid arthritis, vitamin D deficiency, sclerotic bone and skeletal anomalies (5) also needs to be differentiated. In patients with dentinogenesis imperfect, the root appears to be constricted and short (3) with translucent crown. The crown fractures and enamel chips off easily. In patients with sclerotic bone and skeletal anomalies, along with DD I features the sclerotic bone is dense and skeletal anomalies are seen in wrists and hand bones. Defective calcification of mineralized structures is seen in patients with Vitamin D dependent rickets (VDDR). Along with large pulp chambers and short roots VDDR patients also exhibit features like short stature, open fontanels, muscle weakness and convulsions (6).

Diagnosis

After careful evaluation of the clinical feature, radiographic features, lab investigations, and differential diagnosis, both patients were diagnosed with Dentin Dysplasia type I c.

DISCUSSION

DD is commonly associated with autosomal dominant inheritance (7). Dental papilla is associated with the abnormalities seen in root formation. Reduced growth and obliteration of pulp space is seen due to calcification of the multiple degenerative foci in the papilla (8). The condition is mainly caused due to abnormal interaction in ameloblasts and odontoblast and causing abnormal differentiation and function of odontoblast (9). Witkop (10) suggested that the dysplasia resulted from breaking off and migrating of the epithelial cells from the sheath of Hertwig into dental papilla, where they induce odontoblast differentiation and dentin formation. It is classified into two types i.e., Type I dentin dysplasia and Type II dentin dysplasia. In type I DD the colour, shape and consistency of the crown portion is seen normal in both deciduous and permanent teeth. Radiographically the primary dentition shows complete pulp obliteration (7). According to Carroll et al., in permanent dentition four slightly different radiographic appearances have been seen and are further classified based on those differences (7). DD1a has complete root obliteration, no root formation. In DD1b minimal remnants of pulp at CEJ are seen with short root and no visible canals. DD1c is seen with two crescent shaped pulp remnants and intermediate root length. DD1d has pulp chambers near CEJ, widened canals with pulp stones. Root bulge in anterior teeth is seen and normal root length with visible canals (7). In type II DD the roots appear to be normal in size and shape. The crown portion appears to be translucent and discoloured in nature. Radiographically in DDII the tooth is normal sized, but with thistle tube shaped canals where pulp chambers suddenly constrict at base into narrow canal. Pulp stones are seen in the chamber and no bulging of root is seen (7). Dentinogenesis Imperfecta is also associated with genetic inheritance like dentin dysplasia in which both deciduous and permanent teeth are affected (2). In this the crown appears to be amber and are translucent. The crown structure is more prone to fracture and the enamel readily chips off. The roots and the pulp chamber appear to be smaller than the normal size, and due to deposition of irregular dentin pulpal obliteration is seen (2).

Treatment of patients with dentin dysplasia is symptomatic and is mainly focused on retention of the teeth present rather than replacement. Extraction is suggested for the teeth with hypermobility, pulpal necrosis and periapical abscess (5). Procedures which reduce discomfort during mastication and prevent premature loss of the teeth are carried out (11). Patient should be recalled for regular follow ups due to unfavourable prognosis of affected teeth because of short roots and associated periapical radiolucency and conservative treatment such as prevention of caries should be done (12). For aesthetic purposes, composite crowns can be added (13). Periapical surgery and retrograde filling can be done in teeth having longer roots (12, 13). Placement of removable dentures or space maintainers can be done if necessary. Due to

pulpal obliteration and presence of pulp stones, endodontic therapy is difficult (12). Treatment combining onlay bone grafting and sinus lift procedure can be done for successful placement of the implants (14). The severity and the outcome of the treatment depends upon the patient's age. Acceptable results can be achieved with early diagnosis and proper treatment (7). Recently, three mutant genes have been detected in three affected pedigrees (15-17).

Oral prophylaxis was performed in both the patients. Dietary and oral hygiene instructions were given. Extraction was done in female patient for teeth which were cariously destructed and having grade III mobility. For the male patient, removable prosthesis was delivered in Dept of Prosthodontics with maxillary and mandibular anterior teeth. As for the female patient since there was mobility involved with maximum number of teeth, prosthesis could not be given. No comprehensive treatment including implants could be done due to the socio-economic status of the parents. Both patients were kept on regular maintenance protocol.

CONCLUSION

DD-1 is a rare anomaly related to genetic inheritance. It possesses various difficulties during the treatment of such patients. This abnormality of dentin is associated with early exfoliation of the primary as well as permanent teeth, rootless teeth, hypermobility etc. In patients with dentin dysplasia preventive care is most effective. Maintenance of oral hygiene and meticulous diet habits should be established for retaining the natural teeth for longer duration of time. In such cases the dentist plays a very critical role in early diagnosis and effective treatment for the patients. Although a series of pathogenic genes have been identified, detailed pathogenic mechanisms remain unclear. Further exploration of genetic function and signaling pathways is needed to acquire a comprehensive understanding of these diseases.

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Case Report

COMPLICATIONS ARISING FROM ODONTOGENIC INFECTION: A CASE INVOLVING DEEP NECK SPACE AND MEDIASTINAL IMPLICATIONS

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ABSTRACT

Odontogenic infections are a frequent illness that, if not treated right away, can swiftly spread to the rest of the body, and turn into infections that are life-threatening. As these infections may result in life-threatening consequences such as airway obstruction, mediastinitis, sepsis, and respiratory distress syndrome, early identification and knowledge of the deep neck areas and fascial planes are essential. The use of regular therapy for localized or severe odontogenic infections with little risk is now possible because of advancements in medical treatments and antibiotics that have decreased morbidity and death rates. Here we report, a lower right canine abscess that started as a phlegmonous neck collection with mediastinal involvement in a 70-year-old man with multiple comorbidities. To control the infection and protect the airways, prompt surgical treatments were necessary. This included drainage, tracheostomy placement, and tooth extraction. In managing life-threatening deep-neck infections, the case emphasizes the value of early discovery, vigorous

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treatment, and multidisciplinary management. Accurate diagnosis and prompt treatments depend greatly on knowledge of and use of trustworthy diagnostic techniques like CT scans and laboratory markers. To shorten hospital stays and speed patients' recovery without raising risks, it is crucial to use broad-spectrum antibiotics, early surgical drainage, and adequate airway care.

KEYWORDS: *odontogenic infection, oral health, oral surgery, dental abscess, dental infection control, phlegmon, head and neck infection, imaging, deep neck space infection*

INTRODUCTION

Odontogenic infections are among the most common in the mouth and are usually caused by periodontal disease and dental cavities (1). Numerous odontogenic infections have the ability to self-regulate and may even drain on their own. However, these diseases may spread to anatomical regions close to the oral cavity and across adjacent facial planes (2). Odontogenic infections, like those of the deep fascial spaces of the head and neck, not only hurt and cause discomfort; they can also cross boundaries and have catastrophic outcomes (3-7).

The interaction of the patient's health status and microbiological variables affects the transmission of an infection. The host's capacity to fend off infection depends on the strength of the germs as well as the patient's general local and systemic circumstances. Infections can spread due to systemic changes brought on by disorders like alcoholism, uncontrolled diabetes, immunological suppression, HIV/AIDS, or weakening of the immune system (8-12).

Suppurative odontogenic infections can travel to potential fascial gaps deep inside the head and neck. Examples of such infections include orofacial space infections and peripharyngeal space infections (3).

The upper aerodigestive tract is the first part of the neck that might be affected by deep neck space infections(13). Infections of the tonsils, pharynx, and upper respiratory tract are the next most common sources, after dental infections. Submandibular locations account for 36% of the locales, whereas 13% are sublingual, 12% are para-pharyngeal, and 3% are retropharyngeal (14-16). Oral pathogen infections have three crucial stages: Stage 1 (lasting 1 to 3 days) with modest swelling, Stage 2 (lasting 2 to 5 days) with excruciatingly painful and red swelling, and Stage 3 (lasting 5-7 days) with the formation of an abscess (17). The danger of disease and death from deep neck infections is particularly high when they coexist with conditions that impair the body's immune system. It is essential to comprehend the deep neck spaces and fascial planes because they are key to how the illness develops. Consequences that are frequent and potentially fatal include airway obstruction, jugular vein thrombosis, descending mediastinitis, sepsis, acute respiratory distress syndrome, and disseminated intravascular coagulation (18). The morbidity and mortality rates of odontogenic infections have significantly decreased over the past seven decades as a result of breakthroughs in antibiotics, better public health standards, and improved medical and surgical treatments. Today, standard treatment for localized or severe odontogenic infections is available with little risk of adverse events or mortality (19-21).

Securing the airway, maintaining efficient drainage, giving the right antibiotics, and boosting the immune system continue to be the main focuses of treatment. Additionally, patients should be ready for a lengthy hospital stay (18). The case of a 70-year-old man with lower right canine abscess-related unilateral phlegmonous neck collection and mediastinal involvement who also had diabetes, obesity, hypertension, ischemic heart disease, and a history of prior TIA is discussed in this paper. A distinguishing characteristic is the appearance of heterogeneous tissue with many gas bubbles in the right submandibular plane.

Case description

A 70-year-old Caucasian man presented to the Olyclinic of Bari with dyspnea, spontaneous and on-palpation pain, right mandibular edema with increasing volumetric increase, obesity, hypertension, type II diabetes, ischemic heart disease, chronic obstructive pulmonary disease, and prior transient ischemic attack (TIA) are among the patient's medical histories. The rectal swab revealed *Klebsiella Pneumoniae* Carbapenemase (KPC) infection.

The patient revealed that he had previously been admitted to another hospital where he had received antibiotic therapy with Tazocin and Targosid, followed by Metronidazole. This was after the onset of the right mandibular edema.

He was then quickly transported to the Bari Polyclinic's Intensive Care Unit due to significant mediastinal involvement

brought on by the spread of purulent phlegmon collection.

Leukocytosis was not present according to the most recent blood tests, and the C Reactive Protein (CRP) level was 6 mg/L. Due to the patient's renal insufficiency, a neck-chest Computerized Tomography (CT) was done without contrast material, which revealed signs of inhomogeneous tissue with many contextual air bubbles in the right sub-mandibular plane (Fig. 1). The first diagnosis was an abscess affecting the long muscles of the ipsilateral neck, including the muscles of the hypopharynx, including the common carotid artery, and the sternocleidomastoid muscle (SCM), up to the plane passing through the second cervical vertebrae C2.

Additionally impacted were the right thyroid lobe and the right submandibular gland. A more confined area in the right paraortic/lodge of Baretty and an inhomogeneous thickening of the adipose tissue of the prevascular anterior mediastinum were seen. In the left basal site, there was additional evidence of parenchymal thickening with contextual air bronchogram.

Using a 5.2 mm disposable bronchoscope and a strengthened Magill tube under fiberoptic guidance, intubation was carried out. Additionally, both bronchial hemisystems' copious mucous secretions were broncho-aspirated. To stabilize the airways, a surgical tracheostomy, right submandibular gland sialoadenectomy, and laterocervical abscess drainage were also performed (Fig. 2).

The subcutis and platysma muscle were flapped during surgery, which entailed a curvilinear incision from the right mastoid to the chin. Necrosis of the cervical fascia at the level of the right upper and inner parapharyngeal space was associated with abscess collections. It is desirable for the inferior pouch to communicate with the superior mediastinum. The right supraclavicular area contains additional subplatysmatic abscess collections.

These abscess collections underwent drainage. Blood vessels were ligated and dissected to protect the jaw muscle and the right submandibular gland. The nerves were protected while the gland was removed. Additionally, a supra-isthmic tracheotomy was performed, and the incision was patched and secured using a Porte n.9 cannula with a 130 mm cuff. The following antibiotic regimen was recommended: Targosid 400 mg Endovein (Teicoplanina) at 12:00 and 22:00, Rocefin 2 g Endovein (Ceftriaxone) at 8:00 and 22:00, and Desometasone 8 MG at 8:00 and 22:00 + gastroprotectives.

CT chest/mediastinum (without and with contrast) and CT neck (without and with contrast) procedures were carried on the day following the emergency surgery. The examination was conducted both before and after the injection of the contrast agent (Ultravist 370). Many beam hardening artifacts were present, which decreased the exam's ability to accurately diagnose. The neck CT revealed the existence of two contextual drainage catheters and a fluid collection with total measurements of around 8x2x1 cm in the right prevertebral, paratharyngeal, and anterior cervical area. Adipose tissue from the local area was seen to be ingested. From the aforementioned collection, an offshoot with maximal dimensions



Fig. 1. CT Chest/Neck/Mediastinum performed after the surgery: front (A), right side (B) and transverse plane (C-D) highlighting the presence of a chronic periapical inflammation at the dental element 4.3 and multiple gas bubbles in correspondence of the right submandibular plane.

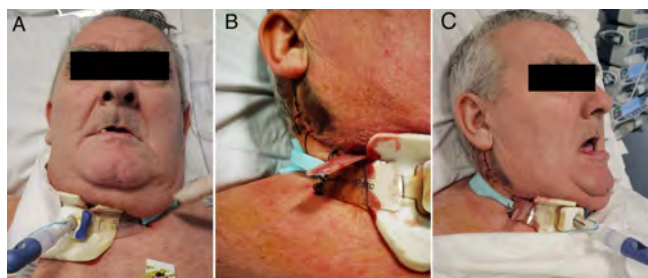


Fig. 2. Patient photos after the emergency surgery: front (A), right side (C) and a particular of the suture after the abscess drainage (B). Evidence of the tracheotomy and of placement of cannula type Porte n.9.

of 7x5x1 cm, right parathyroid retroclavicular development, and in the cranial region of the superior mediastinum, appeared to begin in a caudal orientation. Calcific plaques are seen at the carotid bifurcation, especially so on the right. An increased cardiomeastinal shadow, a hazy and inhomogeneous parallel thickening, a minor layer of ipsilateral pleural effusion, and a tracheostomy were all visible on the bedridden patient's chest X-ray. At the carotid bifurcation, which is further to the right, calcific plaques were seen. A bilateral pleural effusion layer was discovered

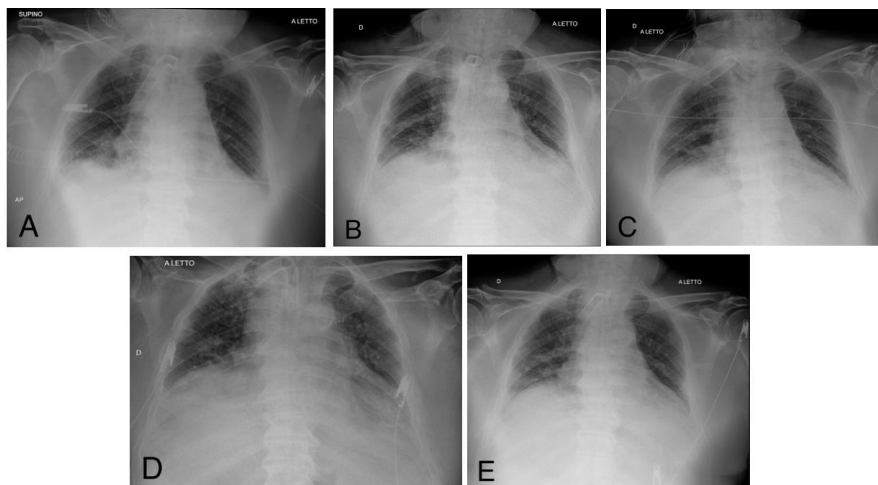


Fig. 3. Chest X-ray sequence: June 8 (A); June 13 (B); June 15 (C); June 17 (D); June 18, 2023 (E), that shows a blurred and inhomogeneous parallel and basal right thickening; a minimal layer of ipsilateral pleural effusion and enlarged cardiomeastinal shadow and tracheostomy.

along with lower lobe dysplasia in the right and left lungs (Fig. 3).

The patient's rectal and pharyngeal swabs, as well as the tracheobronchial aspirate, all tested positive for the bacterium *Klebsiella Pneumoniae*. Additionally, blood tests revealed that he had *Staphylococcus hemolyticus*. Three Penrose drains were present, and Rifocin flushing was carried out through the Penrose drains. The dressing was periodically changed, and the surgical incision was cleansed with betadine and H₂O₂. Chest X-rays taken afterwards indicated no difference from those taken before.

The patient underwent dental surgery to have the infected tooth extracted ten days following the emergency. The lone tooth in the oral cavity, tooth 4.3, was extracted under local anesthetic without the use of a vasoconstrictor. Volkmann spoons were used to execute alveolar curettage and phlegmon debridement. Hemostasis was carried out using Tabotamp (oxidized regenerated cellulose gauzes) after washing with a physiological solution. Fig. 4 shows the surgical extraction.

Five days following the tooth extraction, the CT Neck (without contrast) and CT Chest (with contrast) were done. After the elimination of two of the three laterocervical-submandibular drainages on the right, there was a volumetric reduction of the mediastinal and prevertebral components as compared to the prior CT scan. On the other hand, the right submandibular-jugulodigastric component (now measuring around 55x25x15 mm) appeared more structured and expanded in volume. With the pleural effusion resolved, bilateral pulmonary ventilation improved. The remaining conclusions remained mostly unchanged. The patient in Fig. 5 is shown without the requirement for assisted ventilation.

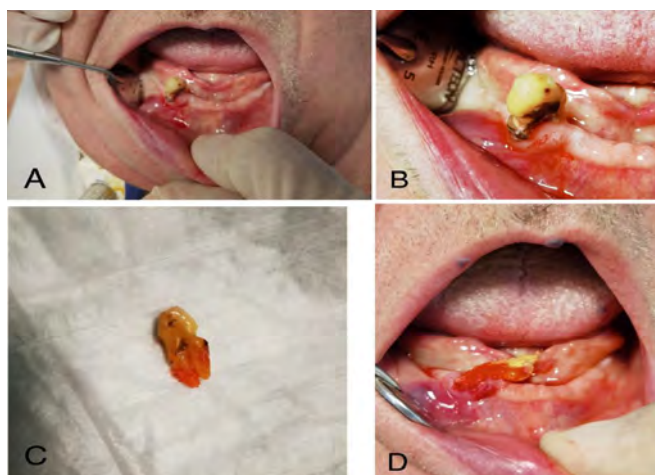


Fig. 4. Intraoral photo (A) and a detail of the dental element 4.3 (B) before the extraction; extracted 4.3 (C) and intraoral photo after the extraction in which haemostasis with Tabotamp was performed.

DISCUSSION

Prescription antibiotics are an excellent way to treat dental infections, which happen frequently. These infections can progress to the cervical and mandibular region, offering serious hazards to patients, if they are not properly treated. These side effects may eventually result in death, such as Ludwig's angina, respiratory obstruction, facial deep neck abscesses, cellulitis, cervical necrotizing fasciitis (CNF), aspiration pneumonia, septicemia, brain abscess, endocarditis, disseminated intravascular coagulation (DIC), jugular thrombophlebitis, and abnormalities in blood coagulation (22-24). The pharynx and oral cavity, particularly the teeth, are the most frequently affected areas by infection (15, 25). Odontogenic infections of the head and neck continue to be the leading cause of hospitalization in departments of maxillofacial surgery despite favorable socioeconomic situations, accessibility to dental care, and availability of antibacterial medications (14, 24, 26-28).

When deep fascial space infections are discovered, it might be difficult to make an early diagnosis and put off starting treatment, which raises the risk of consequences (27, 29, 30). Due to the particular structure of the head and neck, inflammatory illnesses there have distinctive characteristics (31-33). The key contributing elements to these distinguishing features are the intricate structure of the face and neck, the existence of teeth in the oral cavity, the close proximity of the paranasal sinuses, the robust blood supply, and the presence of critical organs for sight, hearing, smell, and taste (34, 35). Today, improvements in diagnosis and treatment have considerably decreased the prevalence of serious outcomes following odontogenic infections, largely because predisposing factors are present (36). The use of radiodiagnostic tools is essential for discovering infections, identifying abscesses, tracking their development, and, occasionally, administering drainage procedures (37, 38). The most crucial imaging test for accurately evaluating neck spaces impacted by deep neck infections is a computed tomography scan (39). According to recent suggestions, computed tomography scans may be useful in determining the extent of the infection's spread so that the best surgical strategy can be planned (40). With adequate surgical care, appropriate antibiotics, and removal of the odontogenic focus, the majority of patients experience full recovery (41).

To prevent tragic outcomes, prompt medical attention, often involving surgery, is imperative (18, 42). Early diagnosis and timely surgical therapy within the first twelve hours significantly decrease the mortality rate (43, 44). Unquestionably, the patient's treatment's initial strength was the rapid laterocervical surgical drainage, tracheostomy, and administration of an appropriate and sufficient antibiotic medication. In fact, the treatment for these infections includes the use of broad-spectrum antibiotics, airway management techniques (including tracheostomy), and surgical intervention. Additionally, the abscess may need to be surgically drained at first (16). All patients who were admitted to the hospital because of an odontogenic infection received surgical incision and drainage treatment (3). Either a general anesthetic with endotracheal intubation or a local anesthetic with premedication was used. Due to respiratory obstruction and problems with endotracheal intubation, head and neck odontogenic infections pose serious consequences. Trismus and anatomical anomalies pose particular difficulties.

According to a study described by Keswani et al. all patients received incision and abscess draining under local anesthetic and analgesia without respiratory assistance (45). Deep neck infections can lead to life-threatening consequences, including airway compromise, mediastinitis, pericarditis, cerebral involvement, and artery erosion (46-49). Another serious consequence that might occur is descending necrotizing mediastinitis (DNM), a serious infection that affects the chest and neck and progresses over time. This syndrome occurs when an infection that starts in the mouth, throat, or neck quickly spreads through the subcutaneous tissue and cervical fascia to the thoracic cavity, causing tissue necrosis (50). If this condition is not treated promptly and effectively, the death rate (10-40%) by sepsis and organ failure is high. The existence of comorbidities or other health disorders is another crucial factor to consider (51).



Fig. 5. Patient without assisted ventilation.

The person profiled in this article has diabetes, is overweight, and has high blood pressure. This patient has a number of risk factors for necrotizing fasciitis (NF), including diabetes mellitus (DM), alcoholism, liver cirrhosis, chronic renal failure, hypertension, and malignancy (52). The most prevalent comorbidity, DM, significantly raises the risk of Deep Neck Space Infection (DNSI) complications and mortality (53). In a study of 263 cases, a significant proportion of patients with DNSI also had DM, HIV infection, primary arterial hypertension, or coronary heart disease (14, 54). DNSI (Deep Neck Space Infections) are highly influenced by body mass index (BMI). Acute phlegmonous laryngitis as the underlying cause, neck phlegmon as the affected area, and a higher risk of sequelae are all clearly correlated with rising BMI (54). An important aspect of this instance was the presence of gas bubbles at the level of the cavernous sinus, as revealed by CT. Gas bubbles created by bacterial fermentation are typically present in a wide range of severe disorders.

The microbiome is a vital element that could influence how a patient develops. There are two types of CNF: suppurative and gaseous. The first exhibits an accumulation of purulent fluid, while the second exhibits gas production (55). Six patients with DNM (descending necrotizing mediastinitis) caused by pharyngolaryngeal and odontogenic infection were studied by Sakai et al. and required thoracic surgery, broad-spectrum antibiotic therapy, and forceful drainage (56). All patients exhibited gas bubbles on their chest CT scans and had polymicrobial infections involving both aerobic and anaerobic bacteria, including the *Streptococcus anginosus* group SAG (56). The bacteria that cause phlegmon, a purulent infection of the subcutaneous connective tissue, can come from the tonsils, pharynx, oral cavity, and other places. Phlegmon and abscesses can develop as a result of these bacteria spreading through the fascia's gaps and connective tissues.

Targeted antibiotic therapy may be useful when specific bacterial or fungal strains can be identified. Another noteworthy element of the patient's care that has been often noted in the literature was the empirical antibiotic therapy in this clinical case, which included a combination of drugs effective against gram-negative and gram-positive bacteria (57-65).

It is essential to develop and use a few reliable technologies in order to quickly detect and identify DNSI repercussions such as DNM, CNF, and systemic sepsis. The neutrophil-to-lymphocyte ratio (NLR), the Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score, and the LRINECxNLR scores are suggested by Fiorella et al. to predict septic complications and the risk of CNF during DNSI (66).

CONCLUSIONS

Despite major improvements in their detection and treatment, deep-neck infections still rank among the most seriously life-threatening illnesses. In order to effectively treat widespread cervico-mediastinal abscesses with an odontogenic etiology, early detection, intensive antibiotic treatment, and surgical treatments are essential. Any odontogenic infection must be treated right away since a missed or delayed diagnosis of a deep-space neck infection can result in dangerous consequences. Broad-spectrum antibiotic therapy, prompt odontogenic source extraction, appropriate airway management, and early surgical drainage have all been shown to speed up recovery and decrease hospital stays without raising hazards. For precise diagnosis, clinical presentation and instrumental techniques like CT scans are essential, but laboratory markers should also be taken into account for prompt and trustworthy support.

Author Contributions:

Conceptualization, G.D., A.M.I., and F.V.; methodology, V.E.S., S.G., and F.M.; software, A.P., and A.D.I.; validation, F.I., G.F. and L.S.; formal analysis, F.V., and A.M.I.; investigation, N.A.A.Q., A.I., and S.G.; resources, F.M.; data curation, N.A.A.Q., A.P., and G.D.; writing—original draft preparation, V.E.S., and F.I.; writing, review and editing, A.I., A.M.I., A.S. and G.D.; visualization, F.I., and G.F.; supervision, L.S., and F.I.; project administration, A.D.I.

Conflicts of Interest:

The authors declare no conflict of interest.

Informed Consent Statement:

Informed consent was obtained from the patient involved.

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Case Report

SINONASAL KERATINIZING SQUAMOUS CELL CARCINOMA: CLINICAL AND MAGNETIC RESONANCE IMAGING FINDINGS

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ABSTRACT

Sinonasal keratinizing squamous cell carcinoma is a rare malignancy originating from the paranasal sinuses and nasal cavity epithelium. This report details the clinical presentation, radiological insights, and management of a localized sinonasal keratinizing squamous cell carcinoma case in the maxillary sinus. A 47-year-old female patient with asymptomatic cheek swelling underwent comprehensive evaluation. Clinical examination, orthopantomography, cone-beam computed tomography, and magnetic resonance imaging were performed. Histopathological analysis showed poorly differentiated keratinizing squamous cell carcinoma. Clinical assessment revealed a firm, painless swelling in the posterior left maxillary region. Imaging studies exhibited opacity within the left maxillary sinus, evident as well-defined destruction of lateral and posterior walls. Magnetic resonance imaging delineated a heterogeneous mass extending into subcutaneous adipose tissue, characterized by constrained diffusion and pronounced contrast enhancement. Maxillectomy was performed, classifying the tumor as T3N0M0. The rare presentation of sinonasal keratinizing squamous cell carcinoma underscores the importance of timely diagnosis and appropriate therapeutic strategies. This case illustrates the crucial role of multidisciplinary collaboration involving clinical evaluation, advanced imaging, and histopathological analysis for effective management. Healthcare practitioners should remain vigilant, considering uncommon malignancies in the differential diagnosis of sinonasal lesions to ensure optimal patient outcomes.

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KEYWORDS: cone-beam computed tomography, head and neck neoplasms, magnetic resonance imaging, maxillectomy, squamous cell carcinoma

INTRODUCTION

Sinonasal keratinizing squamous cell carcinoma (KSCC) is a malignant epithelial tumour arising from the surface epithelium lining of the paranasal sinuses and nasal cavity that exhibits squamous differentiation (1–5). Sinonasal KSCCs are rare lesions as the sinonasal tract is the least frequent site for squamous cell carcinoma (SCC) in the head and neck area. Male:female ratio for the KSCCs was reported to be 2:1 according to the World Health Organization (WHO) and it is mostly seen in patients in the sixth and seventh decades (1). Industrial exposures, such as leather dust and wood dust, and smoking increase the risk for sinonasal KSCC. Presence of Human Papilloma Virus (HPV) infection is generally associated with non-keratinized SCCs rather than KSCCs (2, 3, 6–11).

Sinonasal KSCCs most commonly develop in the maxillary sinus, followed by the nasal cavity and the ethmoid sinus. Since sinus carcinomas are generally present later and at a higher stage, nasal cavity carcinomas have a better prognosis than paranasal sinus carcinomas. The 5-year overall survival rate for sinonasal SCC was reported approximately 50-60% and regional lymph node metastasis is not common for KSCCs (1).

The aim of this case report is to present the clinical, orthopantomography (OPG), Cone-beam computed tomography (CBCT), magnetic resonance imaging (MRI) with T1W, T2W, diffusion-weighted image (DWI-TRACE), apparent diffusion coefficient image (ADC) and contrast-enhanced image (+C) features of a KSCC case which was localized in the maxillary sinus.

CASE DESCRIPTION AND RESULTS

Informed consent

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from the patient included in the case report.

Medical anamnesis and clinical findings

A 47-year-old female patient was referred to our clinic with a painless swelling localized at the left cheek. The patient's medical anamnesis was unremarkable as the patient had no systemic diseases or a history of surgery. The patient was not distressed and her vital signs were stable. Extraoral examination revealed a firm and non-fluctuant swelling of her maxillary left posterior site with no overlying skin deformities. Cervical



Fig. 1. OPG of the patient shows calcification in the right maxillary sinus. Note that the lateral wall of the left maxillary sinus is not as evident as the right maxillary sinus.

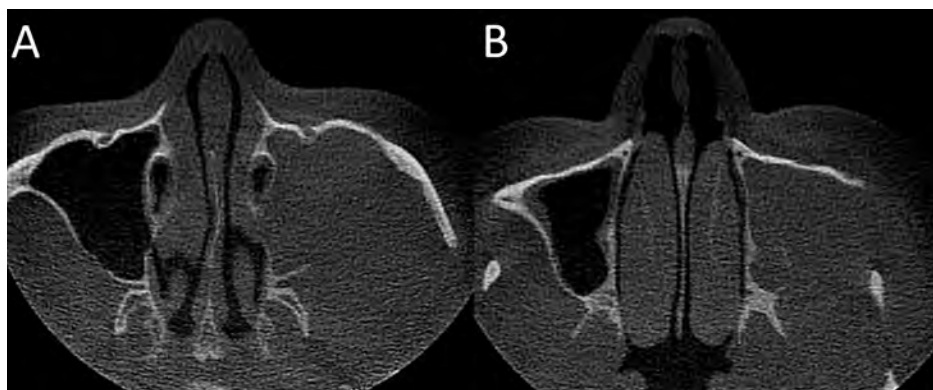


Fig. 2. CBCT Axial Slices of the patient show lateral and posterior wall destruction at the left maxillary sinus.

lymph nodes were examined and no palpable submental or submandibular lymphadenopathy was detected. Intraoral examination revealed moderate oral hygiene with several dentin caries and moderate horizontal alveolar bone loss. No obvious mucosal changes were present thus, an OPG was performed in order to initiate the radiological examination.

OPG and CBCT findings

An opacity that covers the internal structure of the left maxillary sinus with less evident maxillary sinus lateral wall and maxillary sinus floor was detected in OPG (Fig. 1). No pathological fracture or poorly-defined lamina dura was seen. In order to evaluate the opacity of the left maxillary sinus, a CBCT was performed. CBCT revealed total opacity of the left maxillary sinus with the destructions at the lateral and posterior walls (Fig. 2). Since CBCT examinations cannot differentiate soft tissue lesions from the surrounding soft tissue and cannot reveal the soft tissue invasion/extension MRI was performed.

MRI findings

In coronal plan T2W sections, a mass with high signal and heterogeneous internal structure was detected in the left maxillary sinus that caused destruction (Fig. 3). The majority of the mass had heterogeneous liquid-necrotic signal. In the pre-contrast T1W coronal plane fat suppression sequence, the mass was extending to the subcutaneous adipose tissue with a higher signal. DWI-TRACE MRI images (Fig. 4) demonstrated restriction and post-contrast images (Fig. 5) demonstrated contrast enhancement at the solid components of the lesion in axial slices.

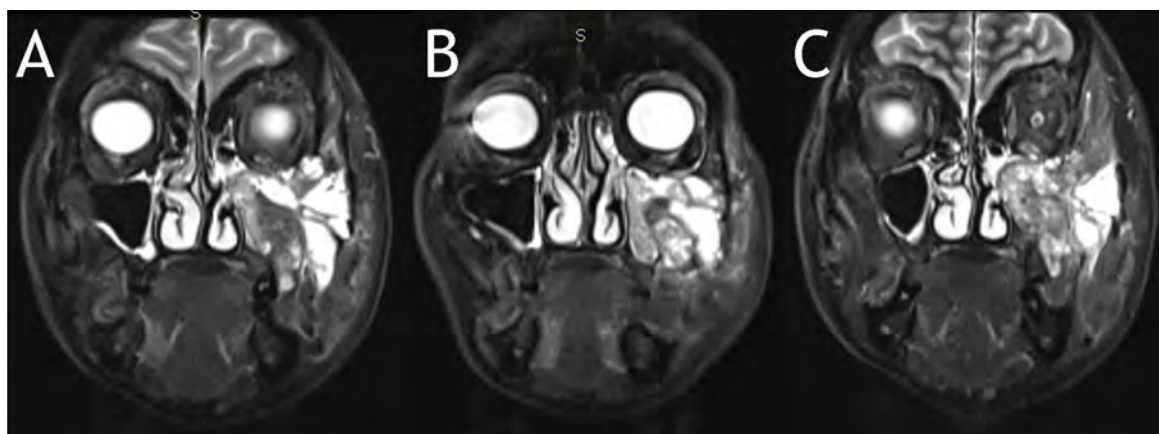


Fig. 3. T2W-TSE-STIR (TR: 5530, TE: 37.0, 3.5mm slice thickness) coronal slices demonstrate hyperintense cystic components of the lesion with relatively hypointense solid components. Note that the lesion is extending to the lateral side and invades superior portion of the left masseter muscle, inferior border of the left orbital rim and buccal mucosa.

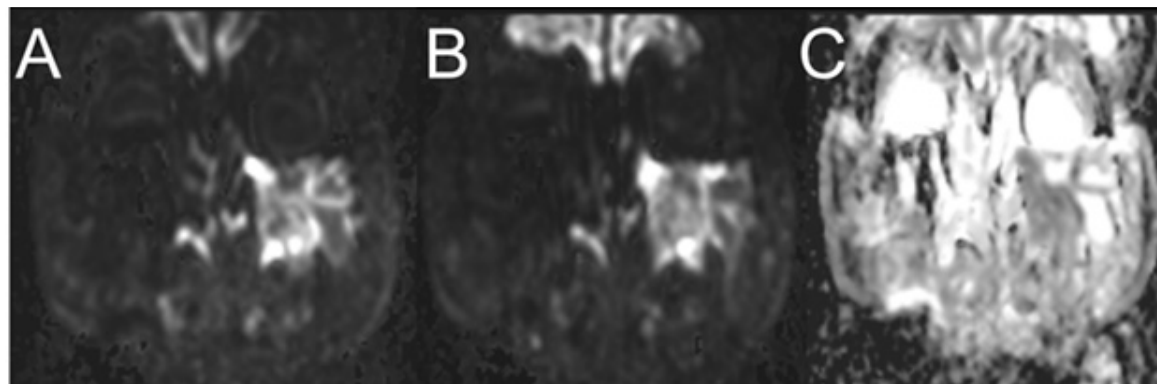


Fig. 4. DWI-TRACE ($b=800$) (A-B) / ADC (C) ($b=800$) / (TR: 6300, TE: 68, Slice Thickness: 5mm) coronal slices of the patient demonstrates diffusion restriction (A, B) and lowered ADC values (C).

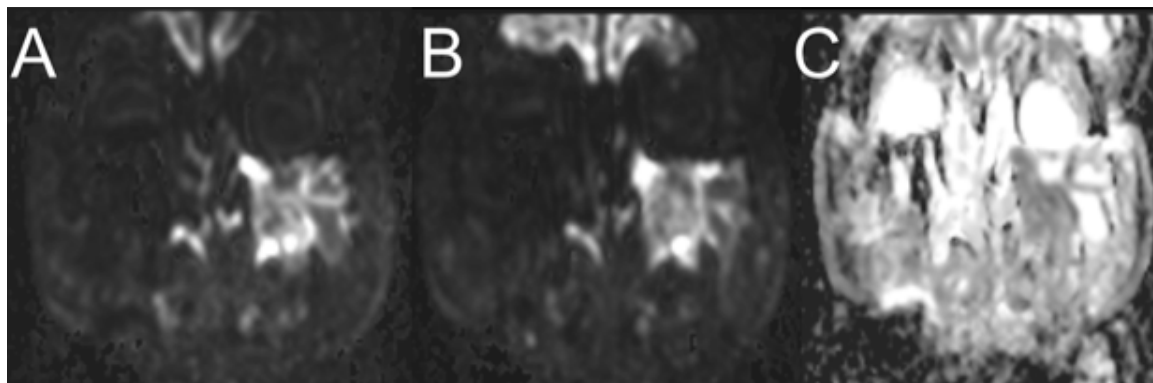


Fig. 5. *TIW-TSE-+C (TR: 733, TE: 13, Slice Thickness: 5mm) axial slices of the patient demonstrates enhancements at the tumoral sites of the lesion.*

Biopsy

Given the patient's clinical presentation and the lesion's ill-defined borders that were seen on images, our initial diagnosis was a squamous cell carcinoma originating from the surface epithelium of the maxillary sinus. An incisional biopsy was performed to evaluate the histopathological nature of the lesion. Histopathological analysis suggested poorly differentiated keratinizing squamous cell carcinoma. The multidisciplinary team of an oral and maxillofacial surgeon, an ENT specialist, a radiologist and an oral diagnosis and radiology specialist, recommended maxillectomy without selective neck dissection.

Tumor nodes metastases (TNM) classification of the tumours

As the maxillary sinus carcinoma in our case had grown into the posterior wall of the maxillary sinus, buccal mucosa and to the infraorbital rim without any spread to the neighboring lymph nodes or to a distant part of the body, the TNM classification for this tumour was T3 N0 M0.

Maxillectomy and peri-operative care

Following the oral intubation of the patient under general anesthesia, adrenaline was injected intraorally and extraorally to provide vasoconstriction at the relevant region. Two grams of cephalexin sodium (Cezol) was administered to the patient pre-operatively to avoid any sepsis table. The Weber-Fergusson incision with the Dieffenbach modification was planned. The Colorado tip diameter of the monopolar electrocautery was used to prepare the flap and hemorrhagic foci were controlled with a bipolar electrocautery. The flap was prepared with a wide field of view, extending laterally to the zygomatic arch area.

The maxillectomy borders were determined with a help of a physio dispenser and the surgery borders were as follows (Fig. 6):

- Superior-medial border: Nasolacrimal Canal
- Superior border: Infraorbital Rim
- Superior-lateral border: Arcus zygomaticus of the zygomatic bone
- Medial border: Distal inter-proximal area of left lateral incisor tooth

Following the maxillectomy, as there was tumour invasion finding in MRI slices, excision of the superior portion of the masseter muscle was also performed. The sections where the tumor invaded the buccal mucosa were excised, and the fascia lata, the deep fascia of the thigh, taken from the lateral femoral region was sutured to the excision area. The surgery was finalized after the muscle-skin and subcutaneous regions were stitched and 100 mg of tramadol HCl (Contramal) was given intravenously for postoperative pain control (Fig. 7). The post-operative temporary prosthesis was adapted to the defect area after the operation and a soft



Fig. 6. *Extraoral image of the patient following the Weber-Fergusson incision's Dieffenbach modification. Note that the tumor is seen at the buccal aspect.*

diet was suggested for post-operative 10 days for the patient who was fed nasogastric for 3 days. On the post-operative 8th day, the skin sutures were removed and the patient was consulted to a radiation oncologist.

Histopathology of Maxillectomy Specimen

The specimen was mainly intraosseous with surrounding soft tissue involvement (Fig. 8). Histopathological image demonstrates a malignant tumor with a disc-like, non-cohesive structure formed by atypical epithelial cells with hyperchromatic nuclei and broad eosinophilic cytoplasm. Dyskeratosis and keratin plugs are occasionally observed. The tumor also displays significant anaplasia and atypical mitoses (Fig. 9). An invasive SCC that extended from the maxillary sinus into the maxilla was confirmed. Focal mild dysplasia was noted signifying an origin from the maxillary sinus instead of an intraosseous origin. No malignancy was seen at the margins of the excised maxilla, surrounding soft tissue, and excised mucosa.

DISCUSSION

As most of the demographic features and habits of the patient do not correlate with the previous cases, we would like to state that our case will contribute to the literature. KSCC patients are mostly males in their 6th to 7th decade; however, our case was a female patient in her 5th decade. Cigarette smoking and industrial exposures were described in the etiology of KSCC however no smoking history or exposure to industrial materials was present as the patient was working in home care services in Cyprus where no such exposures are present. Localization of the lesion was compatible with the literature as the KSCC of our patient was also localized in the maxillary sinus, where it is most frequently localized in the literature. There was no palpable submental or submandibular lymphadenopathy which is compatible with the WHO's classification book as regional lymph node metastasis is uncommon. Clinical features of the patient were not characteristic as there was no epistaxis, nasal obstruction, rhinorrhoea, paralysis, facial pain, diplopia or proptosis; thus, the findings which led us to perform an MRI examination was just minimal expansion at the malar area and opacity of the left maxillary sinus on OPG (1-3, 12-15).

The role of DWI-TRACE MRI images in the diagnosis, lymph node staging and treatment outcomes of head and neck cancers were reviewed by Payne et al concluded that the diagnostic accuracy of DWI-TRACE images for grading head and neck cancers remains unknown but they are successful in the diagnosis (16-26). In a cohort study of 81 patients, Wang et al. showed that head and neck cancers have statistically significant lower ADC values compared to cystic lesions, and with an accuracy of 86% they were able to differentiate head and neck carcinomas from malignant lymphomas (20). Another study, in which they evaluated 16 malignant and 17 benign tumours, also showed that benign tumours had lower ADC values than malignant tumours of the head and neck region (28). Yun et al. (21), conducted another study to histologically grade different head and neck squamous cell carcinomas with 10 poorly differentiated, 10 moderately differentiated and 34 well-differentiated lesions using DWI-TRACE MRI and ADC values. They reported that there was a statistically significant difference between the ADC values of well-differentiated and poorly

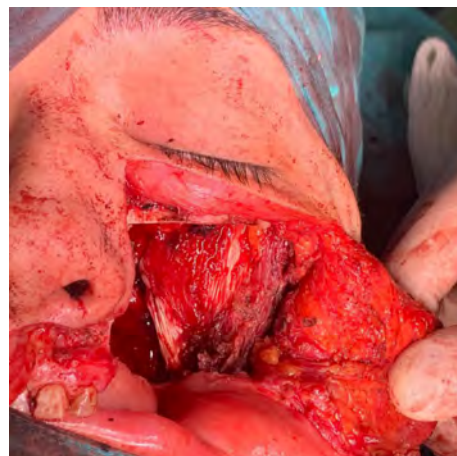


Fig. 7. Extraoral image of the patient following the maxillectomy. Note the excision of the masseter muscle that was attached to zygomatic bone.



Fig. 8. Maxillectomy specimen.

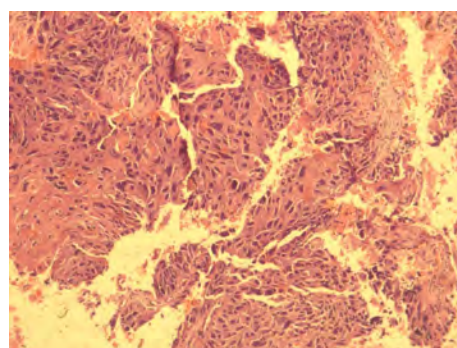


Fig. 9. x10 HE histopathological image demonstrates a malignant tumor with a disc-like, non-cohesive structure formed by atypical epithelial cells with hyperchromatic nuclei and broad eosinophilic cytoplasm. Dyskeratosis and keratin plugs are occasionally observed. The tumor also displays significant anaplasia and atypical mitoses.

differentiated lesions in standard and high b-value ranges. They also reported that as the lesion had poorer differentiation the lesion would appear brighter on DWI-TRACE MRI images and had lower ADC values. These generalizations were not applicable in moderately differentiated lesions (21).

CONCLUSIONS

In this case report, we presented the clinical, radiological, and histopathological features of a 47-year-old female patient with KSCC localized in the maxillary sinus. The diagnosis was made by a multidisciplinary team of specialists, and the patient underwent maxillectomy without selective neck dissection. The TNM classification for this tumor was T3 N0 M0, and the patient's postoperative follow-up was unremarkable. Timely diagnosis and appropriate treatment are crucial for the management of sinonasal KSCC, and healthcare providers should consider this rare malignancy in the differential diagnosis of sinonasal lesions.

Acknowledgments and disclosure statements

The authors report no conflicts of interest related to this study.

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Letter to the editor

HA DERMAL FILLER MIGRATED AFTER LIP AUGMENTATION

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To the editor,

Hyaluronic acid (HA) is extensively used for soft tissues augmentation procedures and it has become gradually more popular and common due to cultural tendencies and increasing association of the appearance of the lips with both beauty and youth. Many dermal fillers have been advised for lip augmentation, such as collagen, calcium hydroxyapatite, hyaluronic acid (1, 2), and polylactic acid, which are used as temporary fillers. Herein we would like to present a case of HA filler migrating into the superficial lip vermilion which caused discomfort by swelling.

A female patient, V.A., 45 years old, no smoker, with no allergies to drug and food substances, came to our attention. The patient was referred to the Department of Oral surgery of University of Chieti by her dentist for the removal of a mass present in the right lip secondary to lip augmentation procedure with HA. The clinical examination of the patient revealed a single mobile mass in the right inferior lip vermilion that mimicking a soft tissue tumor, mucocele, fibroma or angioedema (Fig.1).

The mass was palpable and approximately 1 cm long and was causing discomfort, pain and swelling. The lip vermilion appeared healthy without ulcer. After discussing the options with the patient, she agreed to the removal of the HA migrated into the superficial area of inferior lip vermilion. The filler which had migrated into the lip was removed with 20 G



Fig. 1. Clinical aspect of lip after HA migration (Arrow).

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needle (Fig. 2). The clinical diagnosis was swelling, and discomfort caused by chewing trauma and inability to give a kiss.

As reported in literature, the most common clinical presentation is characterized by filler migration associated to mild symptoms, swelling, fever (3-6) and abscess (4, 7) that could be involved at medium-long-term from the treatment. Moreover, the time of presentation of complications is very heterogeneous and can be immediate, after a few hours from the filler injection (8) to maximum of 14 years (3) from the treatment. On the other hand, the most common intervention for dermal filler migration was characterized by the surgical removal of the mass (5, 9, 10). An embolism represents a critical and very insidious early complication that could take advantage of hyaluronidase thrombolysis injection in the case of HA dermal filler (3).

In this case report the migration of dermal filler material to the superficial vermilion lip suggests that the filler may have migrated immediately as a result of an overfilled injection, high-pressure, high-volume, and orbicular muscle activity. This clinical case aims to increase awareness of a growing recognition of the risks of injectable dermal fillers. Possibility of complication exists less with experienced providers, and risks generally arise when the implant is performed by doctors with less experience and inappropriate techniques. Low-pressure and low-volume filler injections are recommended with more than one treatment per session to minimize dermal filler migration (11, 12). Probably the high-pressure and high-volume filler injections (1) caused a detachment of the tissues concurrently with the orbicularis oris muscle acting as a pump and moving the HA implant, causing migration into the area with a low-density tissue, such as the cheek. Indeed anatomically, lips are occupied by the orbicularis oris muscle which is a muscle capable of developing a lot of force. Also, unnecessary massaging after filler injection, an inappropriate distribution or deposition are responsible filler migration in the adjacent tissues. HA migration can be causing granulomatous inflammation or mimic a mucocele or tumor (13). In conclusion when performing dermal filler procedures in practice, is important physical recommends informing patients of the possible risks of filler migration.



Fig. 2. Two months after the lip augmentation procedure

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