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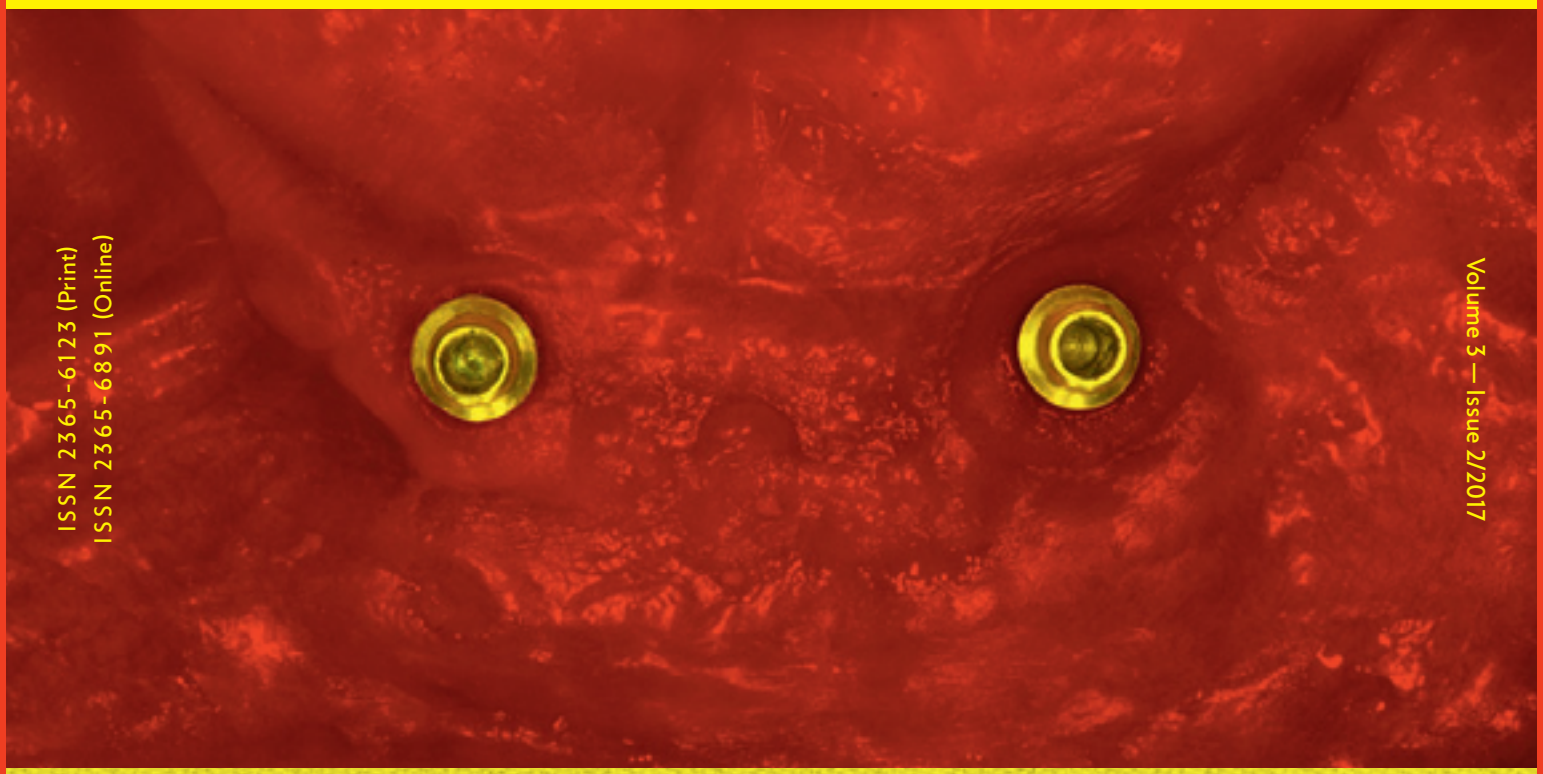
Journal for periodontology, implant dentistry, dental prosthodontics and maxillofacial surgery



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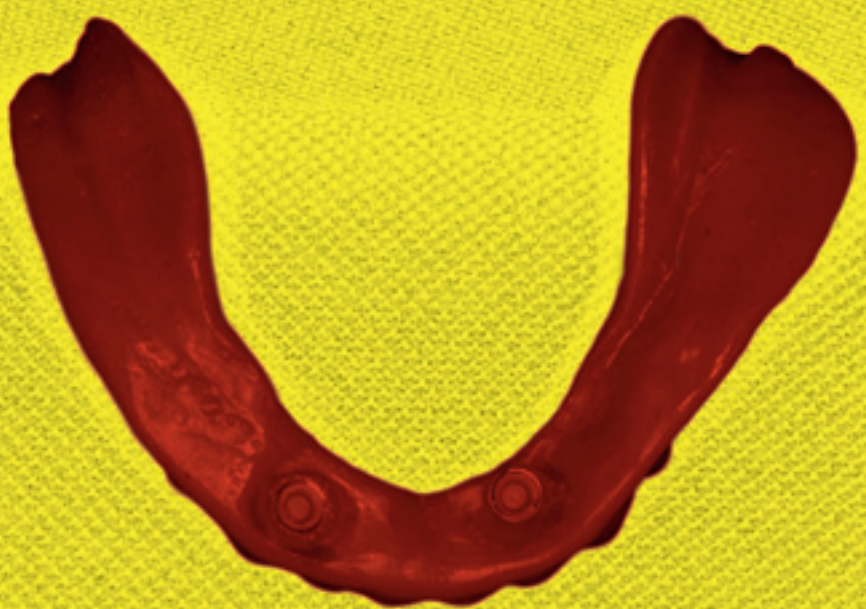

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Digital dentistry revolution: Should we ride the wave and where is it taking us?

Today, the digital revolution is changing the world, and dentistry is no exception. Clinicians have to rapidly assimilate these new technologies into their daily routine to keep up with these changes. However, many clinicians find themselves struggling to make the transition to a digital workflow.

In recent years, many technologies have been introduced on the market that allow the dental team to use new materials and devices in the production of dental restorations, in order to make dental care easier and faster and improve communication with patients and their dental team.

There are many areas of digital dentistry from which a general practitioner can benefit, and many more are being researched and constantly introduced. Among these, CAD/CAM technologies, intraoral imaging, guided surgery (including design and fabrication of surgical guides), digital radiography, occlusal and temporomandibular joint analysis, and photography are only a few examples.

Today, CAD/CAM technologies have become part of our daily practice, allowing the dental team to effect prosthetic rehabilitation with an accuracy and precision previously difficult to obtain using well-established conventional protocols. Similarly, guided surgery has become increasingly popular owing to its ability to render improved diagnosis and facilitate planning, followed by higher transfer accuracy of the virtual plan to the patient's mouth. Hence, it has undoubtedly been a major achievement to provide optimal 3-D implant positioning and higher patient satisfaction. CAD/CAM technologies and guided surgery allow full integration with other digital devices, such as intraoral scanners, to provide for accurate and faster patient-centered solutions. Digital impression taking is one of the most exciting new areas in dentistry for a wide range of procedures in prosthodontics, restorative dentistry and orthodontics.

Although there is no doubt about the potential and accuracy of established digital solutions, there is still a lack of evidence that recent digital technologies available on the market are superior to conventional protocols. Certainly, the evidence, by itself, does not determine the decision, but it can help support the patient care process. Evidence-based medicine has always required integration of three key components: research-based evidence, clinical expertise, and the patient's values and preferences. The Journal of Oral Science & Rehabilitation publishes original research in the field of digital dental science, and the recommendation for further research is to conduct unbiased long-term randomized controlled trials aimed at making a fair comparison between a new treatment and the existing treatment to see which works best. Moreover, in spite of increasing demand for easier and faster dental treatments, and growing penetration of digital marketing in dentistry, the clinician's experience, training and reasoning skills are needed in each field of new dentistry to accelerate the accumulation of the requisite knowledge and skills.

In conclusion, the digital dentistry revolution is changing the workflow and consequently changing operating procedures. Hence, clinicians should reason in this way, but not blindly ride the wave.

Dr. Marco Tallarico
Statistical Adviser

Contents

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Use of argon plasma to enhance soft-tissue integration of prosthetic components: a randomized, controlled animal study

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Abstract

Objective

This paper aimed to assess histologically the soft- and hard-tissue changes after insertion of cleaned and activated titanium implant abutments.

Methods

Three months after tooth extractions, four implants were inserted in one side of the mandible. Before connecting the abutments to the implants, two of them were detoxified (test group), while two were left untreated (control group). The abutments were randomly placed on the two distally or on the two mesially located implants. After one month, the same procedure was repeated on the other side of the mandible. The animals were euthanized one month after the last surgery. Histological analysis was performed to identify the shoulder of the implant, the most coronal bone-to-implant contact, the top of the adjacent bony crest, the top of the periimplant mucosa (PM) and the apical termination of the junctional epithelium (AJE).

Results

All of the animals remained in good health during the experimental period. No statistically significant differences were found between the test and control sites ($p > 0.05$). Between the first and the second time points, no statistically significant differences between the groups were found, except for PM–AJE of the test group, with higher values observed two months after implant placement. However, a trend of better marginal bone levels was found in the test group, compared with the control group, at the second time point.

Conclusion

Although differences between the test and control groups failed to reach significance, a trend of better marginal bone levels was found at the test sites compared with the control sites.

Keywords

Argon plasma, soft-tissue adhesion, animal study, titanium abutment.

Introduction

Periimplant soft- and hard-tissue stability is critical for the success of an implant-supported restoration, from a functional and esthetic point of view.[1] It has been described that the relationship between the implant–abutment connection and surrounding hard and soft tissue plays an important role in establishing such mechanical and biological stability.[2, 3] In fact, the literature has demonstrated that, when an implant is exposed to the oral environment after the connection of a prosthetic component, periimplant hard-tissue level changes may occur[4] and that the amount of bone remodeling, characterized by circumferential (horizontal and vertical) bone loss, should remain stable after one year.[5] Several factors and, in particular, disruptions occurring after prosthetic connections may affect periimplant resorption,[6] since the bacterial contamination of the implant–abutment junction from the oral cavity has been shown to trigger a hard-tissue response.[7]

Many strategies have been advocated to minimize the effect of this contamination clinically: mechanical improvement of the implant–abutment connection stability,[8] implant–abutment microgap shifting from the vital bone,[9–12] and reducing the number of abutment dis- and reconnections.[6] Nevertheless, minimal bone resorption (0.5 mm) has been observed in longitudinal analysis.[13]

Bone resorption might be related to the contaminants (bacteria, wear microparticles and pollution from laboratory procedures) present on the abutment at the time of implant–abutment connection. In fact, the presence of contaminants on the abutment surface can still be observed after the steam cleaning protocol after technical laboratory procedures.[14] Since the abutment comes into contact with both bone and connective tissue, abutment cleanliness appears to be important. In fact, the presence of contaminants at the platform–abutment level has been suggested to cause associated tissue-damaging inflammation.[14] Titanium wear microparticles have been demonstrated to activate osteoclastogenesis.[15] Additionally, it has been shown how interactions between cellular components and implant–abutment materials influence the healing process around implants and how these interactions are regulated by the state of the surface.[16]

In order to protect abutments against such pollutants, plasma cleaning of customized abutments has recently been advocated.[17] Plasma cleaning has been demonstrated *in vitro* to have a triple effect on titanium: cleaning, corrosion protection and increased surface energy.[18, 19] However, there is a lack of evidence in the literature regarding the clinical relevance of a plasma cleaning procedure performed on dental implant abutments.

Although there are certain differences in the inflammatory response and in the bacterial population, the beagle dog model has been extensively used in experimental study because of its size and its extremely cooperative nature. Although some major differences exist between dogs and humans, all periodontal tissues and the size of the teeth are quite similar to those observed in humans. Furthermore, they are a very inbred type of animal with very limited anatomical differences between the various dogs.

The aim of this animal study was to assess histologically soft- and hard-tissue adaptation after insertion of cleaned and activated titanium implant abutments. The null hypothesis was that argon plasma cleaning treatment of abutments does not have any positive or detrimental effect on periimplant bone remodeling and soft-tissue adhesion.

Materials and methods

Subjects

This study followed the ARRIVE guidelines.[20] The research protocol was approved by the local ethics committee for animal research at the University of São Paulo, Ribeirão Preto, Brazil.

Eight beagle dogs were used for the experiment. The animals were pre-anesthetized for all surgical procedures with Acepran 0.2% (0.05 mg/kg; Univet-vetnil, São Paulo, Brazil) and sedated with Zoletil (10 mg/kg; Virbac, St. Louis, Mo. U.S.), and the maintenance of the anesthesia was performed with inhalation of Forane (Baxter Hospitalar, São Paulo, Brazil).

All mandibular premolars and the first molars were extracted bilaterally and after three months, a crestal incision was performed in the premolar–molar region of one randomly selected side of the mandible. Full-thickness mucoperiosteal flaps were elevated, and four experimental sites were selected in the edentulous alveolar ridges of the mandible, two in the anterior and two in the distal regions. The surgical preparation of the sites was performed accord-

Fig. 1
Ground section illustrating the results of healing after one month at a test site. 16× magnification. Alizarin red and Stevenel's blue stain.

Fig. 2
Ground section illustrating the results of healing after one month at a control site. 16× magnification. Alizarin red and Stevenel's blue stain.

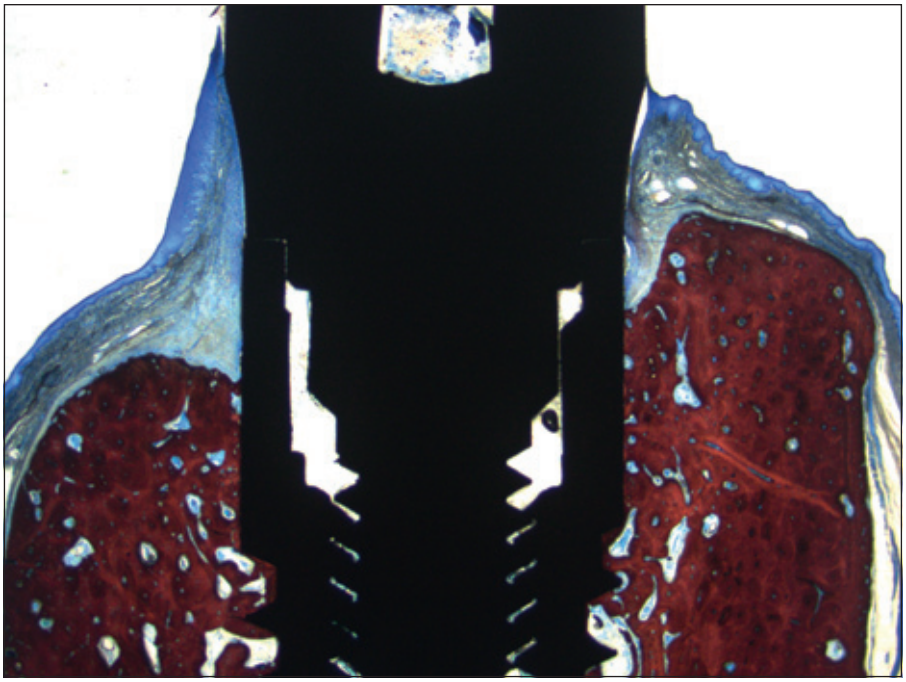
Fig. 1

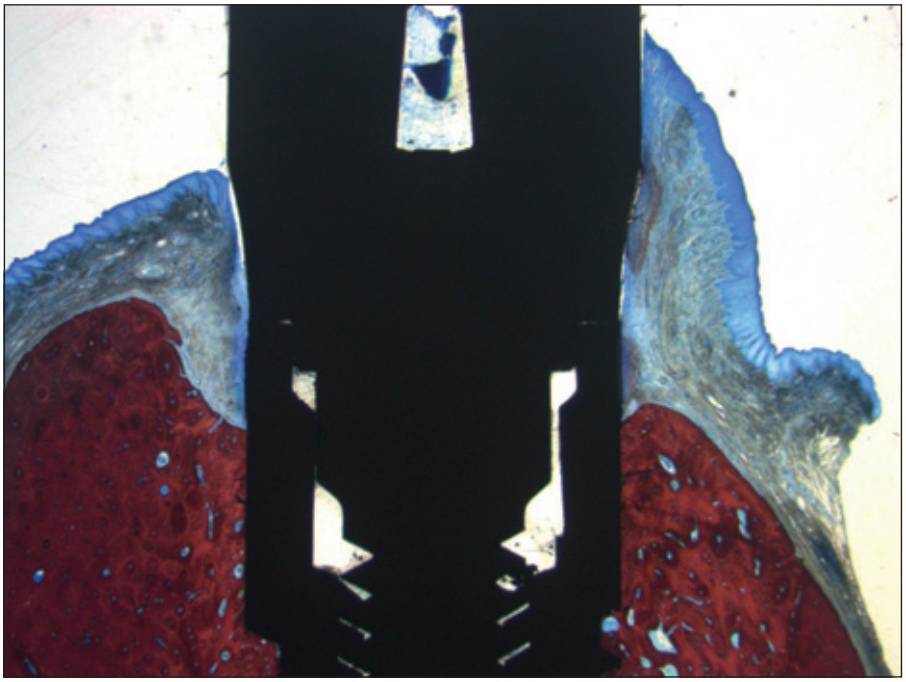
Fig. 2

ing to the manual of the implant system used. Twist drills were used to prepare each recipient site. Four implants (Premium, Sweden & Martina, Due Carrare, Italy), 7 mm long and 3.3 mm wide, were subsequently inserted. Before connection, two of the four abutments were detoxified (test group), while two were left untreated (control group). One abutment of each group was placed on to one of the two mesially and one of the two distally located implants, respectively, according to the randomization allocation. The flaps were sutured to allow nonsubmerged healing. After one month of healing, the surgical procedures were applied on the other side of the mandible, again following a randomization protocol.

After every surgery, the animals underwent antibiotic treatment for ten days (Stomorgyl 10, one tablet/10 kg daily; Merial Saúde Animal, Paulinia, Brazil) and received anti-inflammatory drugs for five days (Maxicam 2 mg, one

Fig. 3

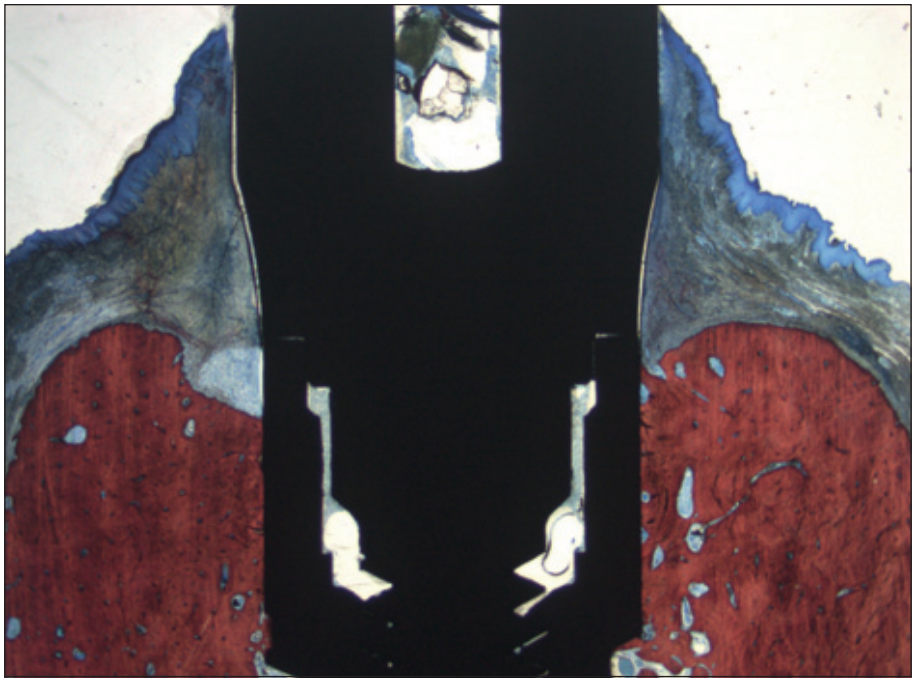

Fig. 3

Ground section illustrating the results of healing after two months at a test site. 16× magnification. Alizarin red and Stevenel's blue stain.

Fig. 4

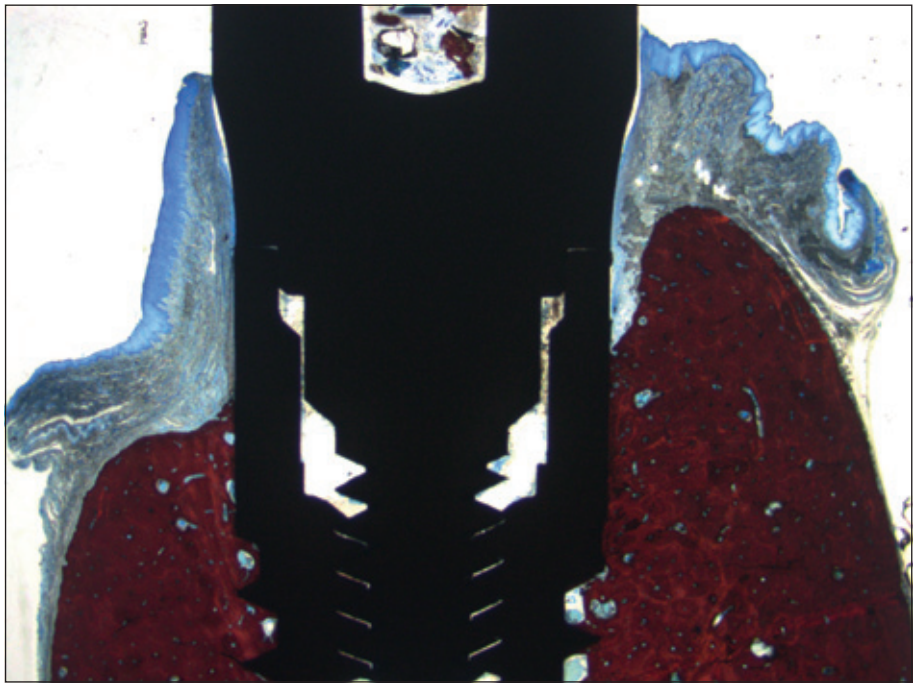

Fig. 4

Ground section illustrating the results of healing after two months at a control site. 16× magnification. Alizarin red and Stevenel's blue stain.

tablet/20 kg daily; Ourofino Saúde Animal, Cravinhos, Brazil) and an analgesic for three days (Tramal 50 mg, 4 mg/kg, subcutaneous; every 8 h; União Química Farmacêutica Nacional, Pouso Alegre, Brazil).

The animals were kept in kennels at the university's field laboratory with free access to water and feed of moistened balanced dogfood. Daily inspection of the wounds for clinical signs of complications and cleaning of the healing abutments were performed. The animals were euthanized one month after the last surgery by applying an overdose of thiopental (Cristália, Campinas, Brazil) and 25 meq of potassium chloride IV.

Abutment preparation

The control group abutments, after being milled and polished, were cleaned by steam for 30 s

(VAP 1; Zhermack, Cologne, Germany) before delivery. The test group abutments, after being milled, polished and cleaned for 30 s (VAP 1), underwent argon plasma treatment (75 W power and -10 MPa pressure for 12 min at room temperature) in a plasma reactor (Diener electronic, Jettingen, Germany) present in the same clinical facility, but in a different room.

Histological preparation

Individual bone blocks containing one implant each and the surrounding soft and hard tissue were fixed in a 4% formaldehyde solution. The blocks were dehydrated in a series of graded alcohol solutions and finally embedded in resin (LR White, hard grade; London Resin Company, Berkshire, U.K.). The blocks were cut in a buccolingual plane using a diamond band saw fitted in a precision slicing machine (EXAKT Apparatebau, Norderstedt, Germany) and then reduced to a thickness of about 50–60 µm using a cutting–grinding device (EXAKT Apparatebau). The histological slides were stained with alizarin red and Stevenel's blue and examined under a standard light microscope for histometric analysis.

Histological analysis

In a microscope at 100× magnification, the following landmarks were identified: the shoulder of the implant (IS), the most coronal bone-to-implant contact (B), the top of the adjacent bony

Table 1
Comparison between test and control groups one month after implant placement. Data are presented in mm as mean ± standard deviation (Median; IRQ 25th–75th mm).

Table 1

	n	IS-B	IS-C	PM-C	PM-AJE
Test	8	1.43 ± 0.99 (1.25; 0.89–1.93)	0.67 ± 0.53 0.51; 0.26–0.96	2.61 ± 0.37 2.54; 2.38–2.78	2.39 ± 0.33 2.36; 2.29–2.48
Control	8	1.61 ± 0.74 (1.53; 1.35–1.81)	0.50 ± 0.59 0.37; 0.22–0.81	2.59 ± 0.36 2.55; 2.33–3.75	2.59 ± 0.41 2.48; 2.32–2.82
***p* value**		0.711	0.562	0.960	0.342

Table 2
Comparison between test and control groups two months after implant placement. Data are presented in mm as mean ± standard deviation (Median; IRQ 25th–75th mm).

Table 2

	n	IS-B	IS-C	PM-C	PM-AJE
Test	8	1.72 ± 0.70 1.64; 1.28–2.29	0.50 ± 0.48 0.45; 0.23–0.66	2.59 ± 0.27 2.51; 2.45–2.70	2.78 ± 0.44 2.79; 2.55–3.05
Control	7	2.18 ± 0.71 1.98; 1.56–2.58	0.91 ± 0.64 0.64; 0.49–1.20	2.86 ± 0.84 2.59; 2.40–3.02	2.42 ± 0.64 2.69; 1.95–2.81
***p* value**		0.453	0.222	0.904	0.327

Table 3
Comparison between one and two months timepoints. Data are presented in mm.

Table 3

		n	IS-B	IS-C	PM-C	PM-AJE
Test	**1 month**	8	1.43 ± 0.99	0.67 ± 0.53	2.61 ± 0.37	2.39 ± 0.33
	2 months	8	1.72 ± 0.70	0.50 ± 0.48	2.59 ± 0.27	2.78 ± 0.44
***p* value**			0,385	0,131	0,879	0,042
Control	**1 month**	8	1.61 ± 0.74	0.50 ± 0.59	2.59 ± 0.36	2.59 ± 0.41
	2 months	7	2.18 ± 0.71	2.91 ± 0.64	2.86 ± 0.84	2.42 ± 0.64
***p* value**			0.360	0.274	0.342	0.520

crest (C), the top of the periimplant mucosa (PM) and the apical termination of the junctional epithelium (AJE). The following linear measurements were performed parallel to the long axis of the implant: the vertical distances between (*i*) IS and B (IS–B), (*ii*) IS and C (IS–C), (*iii*) PM and C (PM–C), and (*iv*) PM and AJE (PM–AJE).

Randomization procedure

The dogs randomly received implants in the right or left side of the mandible in the first surgery and in the other side in the next surgery. Immediately after implant placement, untreated (as they come from industry; control group) or detoxified abutments (argon plasma; test group) were randomly assigned to the implant sites. A balanced random permuted block approach was used to prepare the randomization tables to prevent an unequal balance between the two groups. A blinded statistician generated the allocation sequence and assigned abutments to sites. Assignment was performed using opaque envelopes containing the generated unique randomization code opened immediately after implant placement.

Statistical analysis

Mean values and standard deviations were calculated for each outcome variable. Measurements of the buccal and lingual aspects were performed, with an accuracy of 0.01 mm. Mean values between the buccal and lingual aspects were obtained.

Median and interquartile values were also calculated in order to give a better description of the data set (25th, 50th [median] and 75th percentiles). All measurements were rounded to the nearest decimal. Data were pooled for abutment treatment (cleaned or activated titanium implant abutments). The primary variables were IS–C and IS–B. Differences between the test and control sites were analyzed using the nonparametric Mann–Whitney *U* test. Comparisons between each time point were made by paired tests in order to detect any changes in marginal periimplant bone levels. All statistical comparisons were conducted at the 0.05 level of significance.

Results

In total, 64 implants were placed in eight beagle dogs. All of the animals remained in good health during the experimental period and no complications occurred during the healing period. An $n = 8$ was reached at the one-month period, while an $n = 7$ was reached at the two-month period because one dog lost implants in the control group.

After one month of healing **(Table 1)**, in the test group, at the buccal aspect, IS–B was 1.43 ± 0.99 mm, IS–C was 0.67 ± 0.53 mm, PM–C was 2.61 ± 0.37 mm and PM–AJE was 2.39 ± 0.33 mm. In the control group, IS–B was 1.61 ± 0.74 mm, IS–C was 0.50 ± 0.59 mm, PM–C was 2.59 ± 0.36 mm and PM–AJE was 2.59 ± 0.41 mm. No statistically significant differences were found between the groups ($p > 0.05$; **Table 1**). The median and interquartile values are reported in **Table 1**.

After two months of healing **(Table 2)**, in the test group, IS–B was 1.72 ± 0.70 mm, IS–C was 0.50 ± 0.48 mm, PM–C was 2.59 ± 0.27 mm and PM–AJE was 2.78 ± 0.44 mm. In the control group, IS–B was 2.18 ± 0.71 mm, IS–C was 0.91 ± 0.64 mm, PM–C was 2.86 ± 0.84 mm and PM–AJE was 2.42 ± 0.64 mm. No statistically significant differences were found between the groups ($p > 0.05$; **Table 2**). The median and interquartile values are reported in **Table 2**.

The results between the first and the second time points showed no statistically significant differences between the test and control groups, except for PM–AJE of the test group, with higher values observed two months after implant placement **(Table 3)**.

Discussion

Although cleaning procedures (cleansing with alcohol, soap or steam vapor) at the end of the laboratory phase should be carried out according to law in the U.S.,[21] Europe (EN ISO 17664:2004) and Australia (*ADA's Guidelines for Infection Control*, 2015), several microscopic impurities can be detected on the abutment surface even after these treatments. Microscopic impurities on the abutment surface due to industrial processes can often be detected also after industrial prepackaging procedures.[22] Additional metallic microparticles mixed with lubricant and oxide layers can be produced during the laboratory workflow and adsorbed contaminants can be accumulated during delivery.[17] Such pollution and oxide layers can directly and indirectly trigger a soft- and hard-tissue inflammatory response or at least alter the interaction with the soft- and hard-tissue environments.[15]

A very important area of research is the development of efficient high-vacuum technologies able to clean and functionalize surfaces to replace conventional methods of cleaning metallic or polymeric surfaces. In this context, cold plasma technology represents an efficient alternative and has been the subject of increasing attention.

Low-temperature plasma equipment works within a vacuum chamber in which atmospheric gases have been evacuated typically below 0.1 torr. This low pressure allows for a relatively long free path of accelerated electrons and ions. Since the ions and neutral particles are at or near ambient temperatures and the electrons, which are at high-temperature or electronvolt levels, have relatively few collisions with molecules at this pressure, the reaction remains at low temperature.With appropriate plasma parameters, argon plasma removes all chemical traces of previous treatments, in effect producing cleaner and better controlled surfaces than with conventional preparation methods.[23]

Furthermore, the advantages of plasma cleaning can be exploited to enhance the soft-tissue response during the prosthetic implant phase. Change in the surface wettability of commercial pure titanium, in fact, might determine the functional response of fibroblasts and is therefore a critical factor for the adhesion of soft tissue to the titanium abutment.

In the present study, no differences were found between the test and control groups for the first time point (one month of healing). However, at the second time point (two months), despite the absence of statistically significant differences, a trend showing slightly better marginal bone levels in the test group, compared with the control group, was observed. This may explain why a previously published study showed statistically significantly better radiographic bone level maintenance in humans after two- and five-year follow-up at the treated sites.[24] This may suggest that, in a longer follow-up, statistical significance could also be reached in experimental studies.

Although a recently published *in vitro* study presented no quantitative differences in terms of cell adhesion between plasma-cleaned or only sterilized titanium disks after 8 h, the same study reported qualitative differences in terms of cell spreading.[25] This may suggest that a shorter analysis time frame may only show differences at the microscopical level.

It can be speculated that the differences in terms of IS–B, IS–C and PM–C between the test and control groups, although they did not reach significant levels, could be the early expression of better organization of periimplant soft tissue due to a more "proactive" abutment. This speculation could be supported by the dissimilar outcomes reported by two studies with different time points. In fact, while Canullo et al. reported an absence of histological differences after one week,[26] Garcia et al. observed significantly better outcomes after two weeks in terms of connective cell adhesion and soft-tissue arrangement around abutments cleaned by plasma compared with sterile abutments.[27] For this reason, the outcomes of the present investigation should be taken with caution owing to the short follow-up that may have failed to disclose differences.

Conclusion

Within the limitations of the present study, although differences between the test and control groups failed to reach significance, a trend of better marginal bone levels was found at the test sites compared with the control sites. This might suggest that the use of argon plasma might improve the soft-tissue integration of titanium abutments.

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Competing interests

The authors declare that they have no competing interests.

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Dentin hypersensitivity: a state-of-the-art and novel approach with ozone therapy

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Abstract

Objective

The study evaluated the possibility of extending the use of ozone therapy in dentistry to the treatment of dentinal hypersensitivity.

Methods

The prospective study included 40 patients. All of the enrolled patients were randomized into two groups, allocating one patient to the ozone group and the subsequent one to the paint group. The patients' responses to air stimuli were recorded using a numeric rating scale (NRS), asking each patient to express the degree of pain experienced on a scale of 0 to 10 at baseline, after 14 days and monthly for six months, after the last ozone session. The evaluation was performed by recording the post-treatment hypersensitivity according to the NRS and by completion of a questionnaire.

Results

Evaluating the trend of NRS values at the various time points within the two individual groups using the Friedman test, a gradual improvement of the symptoms was registered in the paint group ($p < 0.024$) and in the ozone group ($p < 0.000$).

Conclusion

Both therapies proved to be effective. The paint demonstrated an immediate desensitizing action, which was not observed in the treatment with ozone. However, in the long term, the paint did not ensure a significant reduction in NRS values. Treatment with ozone proved to be more effective in the maintenance of long-term results.

Keywords

Ozone, dentinal hypersensitivity, desensitization.

Introduction

Dentinal hypersensitivity is defined as a "sensation of pain that appears in response to chemical, thermal, tactile or osmotic stimuli in contact with exposed dentin, which cannot be related with other alterations or dental pathologies."[1] Although dentinal hypersensitivity is a widespread condition, therapeutic strategies available today are not always effective or satisfactory.[2]

Today, there are three prevailing theories regarding the etiopathogenesis of dentinal hypersensitivity:

1. The direct innervation theory assumes that a direct stimulation of the nerve endings occurs in response to external events that excite the processes of the odontoblastic body.[3] This theory is not sufficiently supported: Few tests support the existence of nerve endings in the dentin surface, precisely where the dentin is more sensitive; moreover, the plexus of Raschkow does not become mature until complete eruption of the tooth.
2. The odontoblast receptor theory supposes, consequent to painful stresses, the release of neurotransmitter substances by odontoblasts is responsible for a reaction of the nerve endings present in the dentin that stimulates the pulp response. This theory assumes the ability of the odontoblasts to behave as nerve receptors and transmit signals to the nerves of the pulp. This theory has been discredited because the cellular matrix of the odontoblasts cannot be stimulated and produce nerve impulses; moreover, there are no synapses between the odontoblasts and nerves of the pulp.[4]
3. The hydrodynamic theory, proposed by Martin Brännström, is the most widely recognized and accredited for the pathophysiology of dentinal hypersensitivity.[5] This theory claims that dentinal hypersensitivity is the result of fluid movement within the tubules caused by thermal and physical changes or the presence of osmotic stimuli at the level of the exposed dentin. The fluid movement stimulates the baroreceptors and causes the nervous discharge.

From a clinical point of view, dentinal hypersensitivity is caused by:

– gingival recession;
– abrasion;
– erosion;
– abfraction;
– hypoplasia or abnormalities of enamel development.

Moreover, dentinal hypersensitivity may also have an iatrogenic origin: in conservative treatments, when dentin is exposed to an etching acid for too long or as a result of periodontal surgery (mucogingival, resective or regenerative).[1]

Therapy and classification of desensitizing agents

The desensitizing agents currently on the market essentially have two modes of action:

1. occlusion of the dentinal tubules, with consequent permeability reduction;
2. reduction of the dentinal nerve fiber activity and therefore of the transmission of the pain stimulus to nerve centers.

Professional treatments include application of paints, varnishes, resins and bonding agents to occlude the dentinal tubules. The materials most frequently used are fluoride, potassium nitrate, potassium oxalate and calcium phosphate, and these generate endodontic crystallizations with consequent reduction of the movement of fluid in the tubules.[6]

We report a complete list of all compounds, which could be used for desensitization:

1. Composite resins, glass ionomer cements, glass ionomer modified-resins and compomers: applied on the dentin-exposed surface, these ensure the occlusion of the tubules.[3]
2. Resin-based products with hydrophilic characteristics that contain hydroxyethyl methacrylate (HEMA), ammonium chloride, fluoride and glutaraldehyde: the last, used in different desensitizers, causes coagulation of the plasma and closing proteins in tubules, thus inhibiting the movement of dentinal fluid outward. The HEMA penetrates into the tubules and, after polymerization, occludes them, reducing permeability.
3. Portland cements based on silicate calcium, tricalcium silicate, tricalcium aluminate and tetra-calcium aluminoferrite: these have shown efficacy in reducing dentin permeability owing to the ability to produce hydroxyapatite in contact with body fluids containing phosphate.
4. Sealants: They contain microfillers, which occlude the tubules and create a barrier effect in the tooth.
5. Paints: These are generally based on synthetic resins, contain calcium fluoride and sodium fluoride, and exert a remineralizing, protective

and insulating effect on thermal and chemical stimuli.[6]

6. Varnishes: These have an obstructive and antibacterial action, contain fluorides and often chlorhexidine. They adhere to the dentin and gradually release the two active substances.
7. Fluorides: Fluoride acts on the hydroxyapatite crystals of enamel, transforming them into fluorapatite, with binding characteristics that are more stable and resistant to the action of an acidic pH and determine the precipitation of calcium phosphate into the tubules.
8. Pastes containing casein phosphopeptide and amorphous calcium phosphate: These substances favor the remineralization processes of the dental surfaces. The casein phosphopeptide maintains the calcium and phosphate in a noncrystalline amorphous state and acts as an adhesive, adhering to the hard and soft tissue of the oral cavity by slowly releasing calcium and phosphate ions, which penetrate into the enamel, forming apatite crystals.[3]

Ozone

Ozone (O_3) is a natural gaseous molecule defined as an allotropic form of oxygen. The idea of using ozone in medicine has developed slowly during the last century and was stimulated by the lack of antibiotics and the antiseptic properties of ozone. Its liquid form is able to penetrate into the tissue and mucous membranes. The effects of ozone in the organism depend on its chemico-physical characteristics, high reactivity and oxidative potential: antimicrobial, anti-inflammatory, analgesic, immunostimulant, anti-hypoxic and biosynthetic.[7] Owing to its high oxidative potential, ozone oxidizes the cellular components of bacterial cells, thereby modifying the intracellular components with consequent loss of function of organelles. When the cell membrane is damaged during this process, the cell is destroyed. In conclusion, ozone causes the lysis of the cell.

Ozone activities:

1. Antimicrobial:
   - Damage to the cytoplasmic membrane
   - Oxidation of intracellular components
2. Analgesic
3. Immunostimulant:
   - Activation of the humoral immune system
   - Immunoglobulin synthesis
4. Anti-hypoxic
5. Increased phagocyte activity
6. Activation of biological antioxidants:
   - Activation of the aerobic processes (Krebs cycle, glycolysis, beta-oxidation of fatty acids)
   - Increase of cellular metabolism (ribosomes and mitochondria)
7. Biostimulating:
   - Synthesis of interleukins, leukotrienes and prostaglandins
   - Immunoglobulin synthesis.

The main fields of application of ozone therapy in dentistry include

- conservative treatment of carious lesions;
- nonsurgical periodontal therapy;
- oral pathology (cheilitis, ulcers, osteonecrosis); and
- oral surgery.

Treatment of dentinal hypersensitivity with ozone therapy

Dentin consists of 76% minerals, 20% organic matrix and 10% water. The main component of the organic matrix is collagen.[4] Since ozone reacts quickly to compounds containing double bonds (such as C = C, C = N and N = N, bonds and organic amine bonds contained in the collagen),[7] dentin represents an ideal substrate for its action. The mechanism of oxidation of ozone is based on the direct and indirect effects of the reaction. Direct oxidation is a selective reaction during which ozone reacts rapidly with organic material containing double bonds, organic groups or amines. The indirect reaction leads instead to the production of hydroxyl radical groups, extremely unstable compounds that have an oxidative power even stronger than that of ozone. Hydroxyl radicals do not affect the inorganic tissue, but attack the organic components of the dentin.[8] These reactions, both direct and indirect, are responsible for the preferential attack of ozone on peritubular demineralized dentin, leading to an increase in the diameter of the dentinal tubules. Therefore, the use of ozone, not allowing the direct obstruction of the tubules, does not reduce the feeling of hypersensitivity; consequently, it is not expected that the use of ozone will reduce the pain sensation of dentinal hypersensitivity, at least not by means of the occlusion of the dentinal tubules. However, other studies have suggested that ozone increases the patency of the dentinal tubules,

thus facilitating the entry of minerals from the saliva and desensitizing agents containing fluoride.[9, 10]

Study aim

The aim of the present study was to assess the effectiveness of ozone in reducing dentinal hypersensitivity. The results obtained with ozone therapy were compared with those of an active control group, treated with a paint-on desensitizing agent.

Materials and methods

The prospective study was conducted at the Division of Oral Medicine and Pathology of the dental clinic of the Ospedale Maggiore (Trieste, Italy). All of the procedures performed were in accordance with the ethical standards of the institutional and national research committee and with the principles embodied in the Helsinki Declaration of 1975, as revised in 2013. The study included 40 patients between the ages of 21 and 85, selected according to the following criteria:

1. Inclusion criteria:
   - presence of dentinal hypersensitivity;
   - single or multiple dental elements;
   - dental elements affected by noncarious lesions of the enamel (abrasion, erosion, demineralization, white spot);
   - exposed root of a nonimplant prosthesis;
   - cooperative and able to define the pain experienced according to a numeric rating scale (NRS).

2. Exclusion criteria:
   - radiotherapy in the head neck region;
   - xerostomia;
   - carious lesions; and
   - Class V fillings.

All of the enrolled patients were randomized into two groups, allocating one patient to the ozone group and the subsequent one to the paint group, until the predetermined number was reached.

Study design

First, for all of the patients, a thorough clinical oral examination was performed in order to identify the elements affected by dentinal hypersensitivity. Then, through an objective examination, a dental hygienist recorded the presence of gingival recession and dental abrasion, performed periodontal screening and recording, and scored the patient according to the plaque index. All of the patients were asked to complete a questionnaire regarding their food and oral hygiene habits and the severity of their dentinal hypersensitivity symptoms (Appendix A).

The pain symptomatology was quantified, evoking the stimulus through the application of a jet of compressed air at the level of the affected element. A numeric rating scale (NRS) was used, asking each patient to express the degree of pain on a scale of 0 to 10, in which 0 represented the absence of pain and 10 the worst pain imaginable.

Treatment with ozone

The ozone group was treated with the medical ozone generator OZONE DTA (Sweden & Martina, Due Carrare, Italy), which produces ozone through the formation of an electromagnetic field. Treatment with ozone was planned for four sessions one week apart each (T1, T2, T3, T4), according to the following protocol:

1. evaluation and registration of the NRS (0–10) with a jet of compressed air;
2. cleansing of the affected element using a dental water brush mounted on a micromotor, without using an abrasive paste;
3. drying of the element with compressed air;
4. ignition and activation of the machinery, set to program No. 6;
5. application of the tip of the probe without contact with the dental element, but in a perpendicular position with respect to the area of the tooth concerned, with continuous movement on the whole area for a total duration of 1 min;
6. evaluation and registration of the NRS (0–10) with a jet of compressed air.

The patients were reassessed after 14 days (FU1) and monthly for six months (FU2, FU3, FU4, FU5, FU6, FU7) after the last ozone session. The evaluation was performed by recording the post-treatment hypersensitivity according to the NRS and by completion of the questionnaire. An example of a clinical case is provided in **Figure 1**.

Treatment with paint

For the paint group, the VivaSens desensitizing varnish (IvoclarVivadent, Schaan, Liechtenstein)


Fig. 1

Fig. 1
Ozone application at tooth #13 (affected by a vestibular recession of 3 mm).

was used. It contains ethanol, water, hydroxypropyl cellulose, potassium fluoride, polyethylene glycol dimethacrylate and other methacrylates. Treatment with VivaSens was performed in a single session, according to the following protocol:

1. evaluation and registration of the NRS (0–10) with a jet of compressed air;
2. cleansing of the affected element using a dental water brush mounted on a micromotor, without using an abrasive paste;
3. drying of the element with compressed air;
4. application of three drops of VivaSens using a microbrush over the entire surface of the element for 1 min;
5. drying of the element with compressed air for 30 s;
6. evaluation and registration of the NRS (0–10) with a jet of compressed air.

Once the desensitizing agent had been applied, each patient was recommended not to rinse, drink or eat for the following 30 min, as indicated by the manufacturer. The patients were re-assessed, recording NRS score, after 14 days (FU1) and monthly for six months (FU2, FU3, FU4, FU5, FU6, FU7) after the last paint application.

Statistical analysis

Statistical analysis was performed using SPSS for Windows (Version 16.0; SPSS, Chicago, Ill., U.S.). A p-value of less than 0.05 was considered the cut-off of significance in the contrast of the null hypothesis. The t-test for equality of the median was used to assess the equality of the age distribution and the chi-squared test to evaluate the homogeneity of sexes in both groups. The Mann–Whitney test was used to evaluate the significance of differences between groups in NRS values at baseline (T0) and in the course of the follow-up. The Fisher two-tailed exact test was used to evaluate the homogeneity of distribution between groups regarding the following parameters: presence of recession; presence of plaque; presence of abrasion; presence of periodontal pocket depths of > 3.5 mm; pain in response to cold, hot, mechanical or osmotic stimuli; pain evoked by forced inhalation through gritted teeth; using an electric toothbrush; previous dental whitening; previous periodontal surgery; and frequent intake of acidic foods or beverages. The Friedman test was used to evaluate the variation of VAS (Visual Analog Scale) within the paint group and ozone group, respectively. The Wilcoxon test was used to assess the differences in VAS values between times within the two groups and between T0 and T1, between T0 and FU6, and between T0 and FU7 in the paint group and between T0 and T4, between T0 and FU6, and between T0 and FU7 in the ozone group, respectively. Bonferroni's corrections were applied, where necessary, in multiple comparisons.

Results

The 40 patients, 34 females and 6 males, respectively, were distributed in two groups with

Table 1

Parameter	Groups								
NRS	Paints				Ozone				DIFF. (Mann Whitney)
	Median	IQR 25	IQR 75	Number	Median	IQR 25	IQR 75	Number	
T0	7.0	7.0	8.0	N = 20	7.5	5.3	8.8	N = 20	NS
T1	2.0	.0	4.5	N = 20	6.5	5.0	8.0	N = 20	$p < 0.000$
T2	.	.	.	N = 0	5.0	3.0	7.0	N = 20	NS
T3	.	.	.	N = 0	4.0	2.0	6.0	N = 20	NS
T4	.	.	.	N = 0	3.0	1.0	5.8	N = 20	NS
FU 15 days	2.0	.0	5.0	N = 20	2.5	1.3	4.8	N = 20	NS
FU 1 month	2.0	.0	5.8	N = 20	2.0	1.0	4.0	N = 20	NS
FU 2 month	.5	.0	3.0	N = 20	2.5	.3	4.0	N = 20	NS
FU 3 month	.5	.0	4.5	N = 20	2.0	.0	4.0	N = 20	NS
FU 4 month	2.5	.0	5.8	N = 20	1.5	.0	4.0	N = 20	NS
FU 5 month	2.0	.0	5.8	N = 16	1.0	.0	4.0	N = 19	NS
FU 6 month	.0	.0	4.0	N = 5	.0	.0	1.0	N = 7	NS
DIFF.	$\acute{I}p < 0.024$				$p < 0.000$				

IQR = Interquartile ranges; Number = Number of patients evaluated for time; DIFF = Differences between groups (Mann Whitney); NS = Statistically not significant.

an average age of 49.0 ± 17.5 (range: 22.0–85.0):
– Varnish group: 20 patients, with an average age of 50.7 ± 15.2 (range 22.0-73.0);
– Ozone group: 20 patients, with an average age of 47.3 ± 19.8 (range 22.0-85.0).

The *t*-test for equality of the median demonstrated that age was uniformly distributed in both groups ($p < 0.547$).

We report the descriptive analysis with respect to the clinical examination and the questionnaire answers:
–Twenty-three patients (57.5%) had at least one gingival recession of > 3 mm in the area of reported hypersensitivity.
– Twelve patients (30%) had bacterial plaque in the area of reported hypersensitivity.
– Twelve patients (30%) had abrasion in the area of reported hypersensitivity.
– Ten patients (25%) had periodontal pocket depths of > 3.5 mm at the level of the hypersensitive tooth.
– Thirty-eight patients (95%) reported pain due to cold stimuli.
– Five patients (12.5%) reported pain due to hot stimuli.
– Twenty-one patients (52.5%) reported pain due to mechanical stimuli.
– Ten patients (25%) reported pain as a result of forced inhalation through gritted teeth.
– Eight patients (20%) reported pain due to osmotic stimuli.
– Eleven patients (27.5%) reported using an electric toothbrush.
– Two patients (5%) reported having undergone a dental whitening treatment.
– Three patients (7.5%) reported having undergone periodontal surgery.
– Nine patients (22.5%) reported consuming acidic foods or beverages frequently.

The severity of the dentinal hypersensitivity reported by patients was evaluated according the NRS at the following times: T0, T1, T2, T3, T4 and FU1, FU2, FU3, FU4, FU5, FU6, FU7. Ozone group patients were seen once a week for four consecutive weeks (T1, T2, T3, T4) and later for controls at FU1, FU2, FU3, FU4, FU5, FU6, and FU7. At T0, the NRS in the ozone group was 7.0 (7.0–8.0) and 7.5 (5.3–8.8) in the paint group. Therefore, both groups started at a high degree of pain and were comparable in dentinal hypersensitivity at baseline. Evaluating the trend of NRS values at the various time points within the individual groups using the Friedman test, a gradual improvement of the symptoms was registered in the paint group ($p < 0.024$) and in the ozone group ($p < 0.000$). Considering the variation in NRS values within groups before and after the specific treatment, the following results were registered, as reported in **Table 1**.

Table 1
Trend of NRS values within the two groups at the various time points.

In the paint group, a significant reduction in NRS values was observed ($p < 0.000$ between T0 and T1) before treatment (T0) and immediately after the application (T1). A significant reduction in NRS values was not observed prior to treatment and at the end of the follow-up for all of the patients ($p < 0.003$ between T0 and FU6).

In the ozone group, a significant reduction in NRS values was observed before treatment and after the fourth session of ozone therapy ($p < 0.000$ between T0 and T4). A significant reduction in NRS values was registered prior to treatment and at the end of follow-up for all of the patients ($p < 0.000$ between T0 and FU6). Concerning the six-month follow-up, a significant difference in NRS values ($p < 0.05$ between T0 and FU7) was observed.

A significant decrease in NRS values was registered ($p < 0.000$ according to the Mann–Whitney test) in the paint group. The raw data revealed a progressive decrease in NRS values in patients treated with ozone. Moreover, the follow-ups revealed a further maintenance of the results regarding NRS values at six months.

Discussion

The present study takes into consideration the possibility of extending the use of ozone therapy in the dental field to the treatment of dentinal hypersensitivity. The purpose of the research was to evaluate the effectiveness of ozone in the reduction of pain due to hypersensitivity. From the results obtained, the desensitizing treatment with paint was proven effective in terms of immediate results, attributable to the paint's ability to form a protective layer, a mechanical barrier on the affected surface. The provisional barrier seals the dentinal tubules, preventing the flow of the dentinal fluid and therefore interrupting nerve stimulation and the consequent perception of pain. The six-month follow-up, however, did not find significant maintenance of the results. This may be due to the inability of adhesive agents to withstand the stress of the oral environment and their undergoing a progressive dissolution that causes the restoration of the initial sensitivity values, as observed by Jain et al.[11]

In the present study, no significant difference was reported after six months from the first application, but this was probably due to the insufficient sample sizes of patients. Therefore, the use of paint-on desensitizers, whose effectiveness is well established and well documented in the literature, may not be a definitive treatment and may require repeated applications throughout the patient's life. Duke et al. observed that the action of paint can still be effective up to five months.[12]

In the ozone group, a progressive reduction in NRS values was observed; this can be attributed to the beneficial action of the ozone itself on the tooth surface. In contrast to what was observed by Azarpazooh et al.,[13] one application of ozone was not sufficient to resolve the pain symptoms linked to dentinal hypersensitivity; the results appeared more evident from the second application on, instead. As observed by Bocci et al., the increase in patency of the tubules caused by the application of ozone on the dental surface may facilitate the entry of minerals in the saliva and desensitizing agents.[10] In this way, the sealing of the dentinal tubules would be continuous owing to the mineral salts contained in the saliva (mainly calcium and fluoride). According to this theory, it can be assumed that the action of ozone causes a sort of repair of the dentin by modifying its internal structure and therefore leading to long-term effects. The long-term maintenance of the beneficial effect of ozone therapy, as well as the reduction of pain, seems more evident if compared with the use of paint, despite the small numeric sample. Considering that ozone does not occlude the dentinal tubules, its action could be enhanced by the concomitant use of fluoride-based products or amorphous calcium phosphate to create a smear plug in the tubules. In fact, as noted by another study,[14] there is a synergy between ozone and fluoride that does not occur with other desensitizers, such as oxalates. For this reason, ozone therapy could be associated with fluoride products in both professional application and at-home care.

Conclusion

Both therapies proved to be effective. The paint demonstrated an immediate desensitizing action, which was not observed in the treatment with ozone. However, in the longer term, the paint did not ensure a significant reduction in NRS values. Treatment with ozone proved to be more effective in the maintenance of long-term results. It can therefore be said that ozone therapy in the management of dentinal hypersensitivity represents an innovative and effective technique, with good maintenance of long-term results.

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Competing interests

None of the authors have any conflict of interest to disclose.

Appendix A

Dentinal hypersensitivity: questionnaire for the patient
Name:
Surname:
Number:
1- What's your pain sensation on a 0-to-10 scale?
2- Do you feel pain when taking hot/cold food/beverages?
3- Do you feel pain when you brush your teeth?
4- Do you feel pain when breathing with gritted teeth?
5- Do you feel pain when eating some types of food? (chocolate, candies, sweet food...)
6- Have you ever been subdued to dental treatment such as dental bleaching or periodontal surgery?
7- Do you frequently eat: fruit-juices, sugar-rich beverages (coca cola, fanta...)
8- Do you use some of the following dental hygiene devices? Hard toothbrush: Electric toothbrush: Whitening toothpaste:
Objective examination:
Tooth
Recession (mm) Abrasion
Gingivitis
Periodontitis disease (probing depth > 3,5mm)

Appendix A
Questionnaire at first visit

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Success, survival and failure rates of dental implants: a cross-sectional study

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Abstract

Objective

The purpose of the present study was to evaluate the success, survival and failure rates of dental implants placed in the Implantology Clinic at the School of Dentistry of Ribeirão Preto of the University of São Paulo, Ribeirão Preto, Brazil.

Materials and methods

The cross-sectional study included only patients who had undergone prosthetic rehabilitation. The following criteria were evaluated by interview and dental record analysis: age, sex, presence of systemic disease, history of smoking, area in which the implant was placed, implant diameter and height, and type of prosthesis seated on the implant. The following parameters were clinically analyzed: pain, mobility, probing depth, bleeding on probing, and presence or absence of exudate. The amount of bone loss was assessed radiographically. The study included 35 implants placed in 19 patients.

Results

There was a success rate of 74% after definitive prosthetic rehabilitation, while six implants showed bone loss of between 2 and 4 mm, being classified as satisfactory survival. There was no relationship between the success and/or survival rate and any of the parameters evaluated. Four implants presented with periimplant mucositis, while periimplantitis was observed in two implants. Regarding the definitive restorations, 17 prostheses were classified as successful, while there were complications in eight prostheses.

Conclusion

Success and survival rates of 74% and 100%, respectively, were observed. Within the limitations of this cross-sectional study, the data suggest that the implant success rate does not seem to be related to factors like age, sex, habits, systemic disease, macroscopic characteristics or area in which the implant was placed.

Keywords

Dental implants, periodontics, periimplantitis.

Introduction

The use of dental implants is considered a revolution in modern dentistry.[1] However, there are differences between professional and patient objectives.[1] While the patient is usually concerned with esthetics and function, dental professionals expect success regarding biological and mechanical stability and the facilitation of oral hygiene.[2]

There is consensus among authors that the success of dental implant treatment depends on the presence and maintenance of surrounding bone, mainly in the bone crest area. However, one of the major challenges encountered in implantology is the process of bone resorption around the implant after insertion or during its use. In the literature, bone resorption of approximately 1.2 mm in height during the first year of function is reported, with 0.1 mm more resorption for every subsequent year.[3] This loss with a V or U shape has been called saucerization.[4]

In 1986, Albrektsson et al. established the following criteria for implant success:[5] The implant should have no mobility and demonstrate no radiolucent areas radiographically, annual vertical bone loss after the first year should be less than 0.2 mm, and there should be no persistent and/or irreversible symptoms. The most common parameter used in clinical reports is the survival rate, indicating whether the dental implant is physically in the mouth or has been removed.[6] However, with this method, implants that should be removed owing to pain or illness may be retained and erroneously considered successful.

In 1993, an implant quality of health scale was created by James and developed by Misch.[7,8] This scale was later modified at the International Congress of Oral Implantologists' Pisa Consensus Conference in 2007, presenting four clinical categories that contain conditions of success, survival and failure of the implant. Survival can be divided into two categories: satisfactory survival, which describes implants with less than ideal conditions, but for which there is no need for clinical intervention; and compromised survival, which includes implants with less than ideal conditions requiring clinical treatment to reduce the risk of implant failure. Implant failure is the term used for implants that require removal or that have been lost. Implant success is a term used to describe clinical conditions and must include at least a 12-month period for implants serving as prosthetic abutments. Early success is suggested for implants that are retained for a period of one to three years, intermediate success for three to seven years and long-term success for a period longer than seven years. In this new approach, pain, mobility, radiographic bone loss, probing depth and periimplant disease are evaluated.[9]

Regarding periimplant disease, since the bone loss caused by stress or bacteria leads to the deepening of the sulcular gap and decreases oxygen tension, anaerobic bacteria become the primary promoter of continuous bone loss.[9] Exudate or an abscess around an implant indicates exacerbation of periimplant disease and possibly accelerated bone loss. Exudate persisting for more than one or two weeks normally requires surgical intervention in the periimplant area to eliminate the etiological factors.[9] The reduced bone height after the exudate episode exposes the implant to secondary occlusal trauma. The dentist should re-evaluate and reduce the stress factors for the new bone condition to improve the performance in the long term.[9]

Considering the importance of maintenance of the crestal bone around dental implants, the aim of this study was to evaluate the success, survival and failure rates of implants placed over three years based on the implant quality of health scale of the Pisa Consensus Conference.

Materials and methods

This study included 19 patients who received implants and prostheses on implants in the Implantology Clinic at the School of Dentistry of Ribeirão Preto of the University of São Paulo, Ribeirão Preto, Brazil, between 2007 and 2013. The patients were recalled for clinical and radiographic examinations from three to six years after implant placement.

The following criteria were evaluated by interview and dental record analysis: age, sex, presence of systemic disease, history of smoking, area in which the implant was placed, implant diameter and height, and type of prosthesis seated. For the analysis of implant diameter, the following classification was used: narrow when the diameter was less than 3.5 mm, regular when the diameter was 4.0–4.8 mm, and wide when the diameter was greater than 5.0 mm. Regarding height, implants were classified as short when they were less than 10 mm, regular when 10–12 mm, and long when greater than 12 mm.

Table 1
Prevalence of hypertension, diabetes mellitus and tobacco use.

Table 1

Variable	*n* (%)
Hypertension	3 (15.8)
Diabetes mellitus	2 (10.5)
Smoking habit	5 (26.3)
None	9 (47.4)
Total	19 (100.0)

Table 2
Dental implant placement area.

Table 2

Region	Mandible *n* (%)	Maxilla *n* (%)
Anterior	13 (37.15)	5 (14.30)
Posterior	13 (37.15)	4 (11.40)
Total	26 (74.30)	9 (25.70)

The success and survival rates of the implants were analyzed based on the criteria of the Pisa Consensus Conference, according to the following clinical parameters: pain (absent, absent in function, sensitivity in function, pain in function), mobility (present or absent), probing depth (PD), bleeding on probing (BOP), exudate (absent, with exudate history, with uncontrolled exudate) and radiographic bone loss. The PD and BOP measurements were taken at four aspects of each implant: mesial (M), distal (D), buccal (B) and lingual/palatal (L/P).

For the assessment of radiographic bone loss, a periapical radiograph using the bisecting angle technique was performed at the time of patient recall. The radiographs were digitalized and analyzed using the Image Tool software (Trophy-Radiologie, Vincennes, France) to verify and determine the resulting linear distance between the implant shoulder and bone crest. The average values for the M and D aspects were used as a single measurement for each implant. From this analysis, the implants were divided into the following categories: bone loss of less than 2 mm; bone loss of between 2 and 4 mm; bone loss of more than 4 mm, but less than half of the implant body; and bone loss greater than half of the length of the implant. According to these criteria, the implants were classified as successful, having satisfactory survival, having impaired survival or failed.

Biological and prosthetic complications, such as periimplant mucositis, periimplantitis, abscesses or fistulas, or any mechanical and prosthetic complications, such as fracture of the implant and/or of any prosthetic component, were also evaluated. Patients with BOP or positive suppuration, a PD of greater than 5 mm and radiographic bone loss were diagnosed as having periimplantitis.[10]

Results

The study included 35 implants placed in 19 patients, six men and 13 women, with the following age distribution: two patients aged between 30 and 39, six patients between 40 and 49, seven patients between 50 and 59, three patients between 60 and 69, and one patient between 70 and 79. The prevalence of systemic disease and a smoking habit was assessed by interview and the results are presented in **Table 1**.

Table 3

Diameter	Height		
	Short (< 10)	Regular (10–12)	Long (> 12)
	n (%)	*n* (%)	*n* (%)
Narrow (< 4.0)	3 (8.6)	15 (42.9)	10 (28.6)
Regular (4.0–4.8)	2 (5.7)	4 (11.4)	1 (2.8)
Total	5 (14.3)	19 (54.3)	11 (31.4)

Table 4

	Pain	Exudate	Mobility
Variable	***n***	***n***	***n***
Absent	34	33	35
Varying	1	0	0
Presence	0	2	0

The implants were classified according to the placement area: mandible and maxilla and anterior and posterior **(Table 2)**. Three patients were rehabilitated with full-arch fixed prostheses supported by osseointegrated implants, 20 received single prostheses and two received an overdenture.

Concerning the implant diameter, 80% of the implants were classified as narrow and 20% as regular **(Table 3)**. Regarding the implant height, 14.28% of the implants were classified as short, 54.28% as regular and 31.46% as long **(Table 3)**. A higher frequency of implants of 11 mm in height and less than 4 mm in diameter was observed.

Regarding the presence of clinical signs associated with the implants, such as pain, exudate and mobility, 18 patients (who received 34 implants) reported no pain. The presence of pain in function occurred in only one implant and the presence of exudate in two implants **(Table 4)**.

In general, PDs of less than 4 mm were observed in most cases. Only one implant showed a PD of 5 mm at the M aspect, while a PD of 6 mm and BP were observed at one implant at the L/P aspect and at three implants at the D and B aspects. BOP was present at five implants at the M, B and L/P aspects, and at three implants at the D aspect **(Table 5)**. Four implants could not be evaluated owing to the presence of a protocol-type prosthesis.

Twenty-six of the 35 implants were evaluated in periapical radiographs by measuring the linear distance between the implant shoulder and bone crest. Only 17.1% of the implants showed bone loss of between 2 and 4 mm, while the remaining implants presented with less than 2 mm **(Table 6)**.

Analyzing all of the parameters established a success rate of 74% (20 implants), while 26% of the implants (six implants) were classified as having impaired survival **(Fig. 1)**. The implants that had impaired survival showed different characteristics regarding location, size and PD. Regarding the height of these implants, three were longer than 12 mm, two were 10–12 mm in height and one less than 10 mm in height. Concerning the diameter, four of these implants were narrow and two were regular. Around the six implants classified as having impaired survival, a PD of greater than 4 mm was observed. Of all of the implants evaluated, four presented with periimplant mucositis (11.4%) and two with periimplantitis (5.7%), diagnosed by the pres-

Table 3
Implant distribution according to diameter and height (mm).

Table 4
Presence of clinical signs during follow-up.

Table 5

	Aspect			
	M	*D*	*B*	*L/P*
Variable	*n* (%)	*n* (%)	*n* (%)	*n* (%)
PD				
≤ 4 mm	30 (96.8)	28 (90.3)	28 (90.3)	30 (96.8)
> 4–< 6 mm	1 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)
≥ 6 mm	0 (0.0)	3 (9.7)	3 (9.7)	1 (3.2)
Total	31 (100.0)	31 (100.0)	31 (100.0)	31 (100.0)
BOP				
Present	5 (16.1)	3 (9.7)	5 (16.1)	5 (16.1)
Absent	26 (83.9)	28 (90.3)	26 (83.9)	26 (83.9)
Total	31(100.0)	31(100.0)	31(100.0)	31 (100.0)

PD = Probing depth; BOP = Bleeding on probing; M = Mesial; D = Distal; B = Buccal; L/P = Lingual/palatal.

Table 5
Probing depth and bleeding according to aspect during follow-up.

Table 6

Quantity	*n* (%)
< 2 mm	20 (76.9)
2–4 mm	6 (23.1)
> 4 mm	0 (0.0)
> ½ of implant length	0 (0.0)
Total	26 (100.0)

Table 6
Quantity (mm) of bone loss on radiograph during follow-up.

ence of BOP or suppuration and radiographic bone loss.

Regarding the definitive rehabilitation, 17 prostheses were classified as successful, while prosthetic complications were observed in eight implants (splinter or porcelain fracture, fracture of the prosthetic components, failure of the cement or screw loosing), resulting in a 68% success rate and a 32% survival rate of the prosthetic restorations **(Fig. 2)**.

Discussion

This study aimed to evaluate the success, survival and failure rates of implants based on the implant quality of health scale developed at the Pisa Consensus Conference. The success category describes optimal conditions; the survival category describes functional implants, but not in an ideal condition, and is divided into satisfactory and impaired survival; and the failure category includes implants that should or could be removed.

In this study, one patient reported pain on function and implant mobility was observed in a second one. In both cases, the factor that caused such impairment was the presence of an unsatisfactory prosthesis. Misch et al. state that pain should not be associated with the implant after healing, and when it is observed, it is associated with an improper prosthetic component or with pressure on the tissue owing to seating of the prosthesis, suggesting that the prosthetic component can contribute to the instability of the implant.[9]

Fig. 1

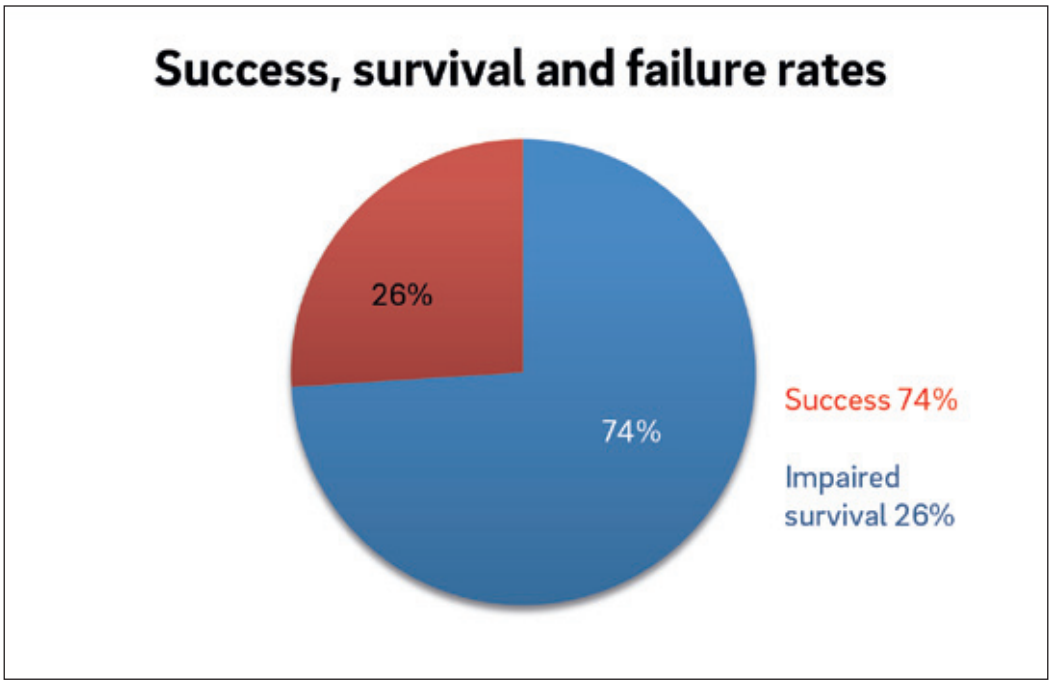

Fig. 1
Distribution of the implants according to the scale of implant health.[9]

Fig. 2

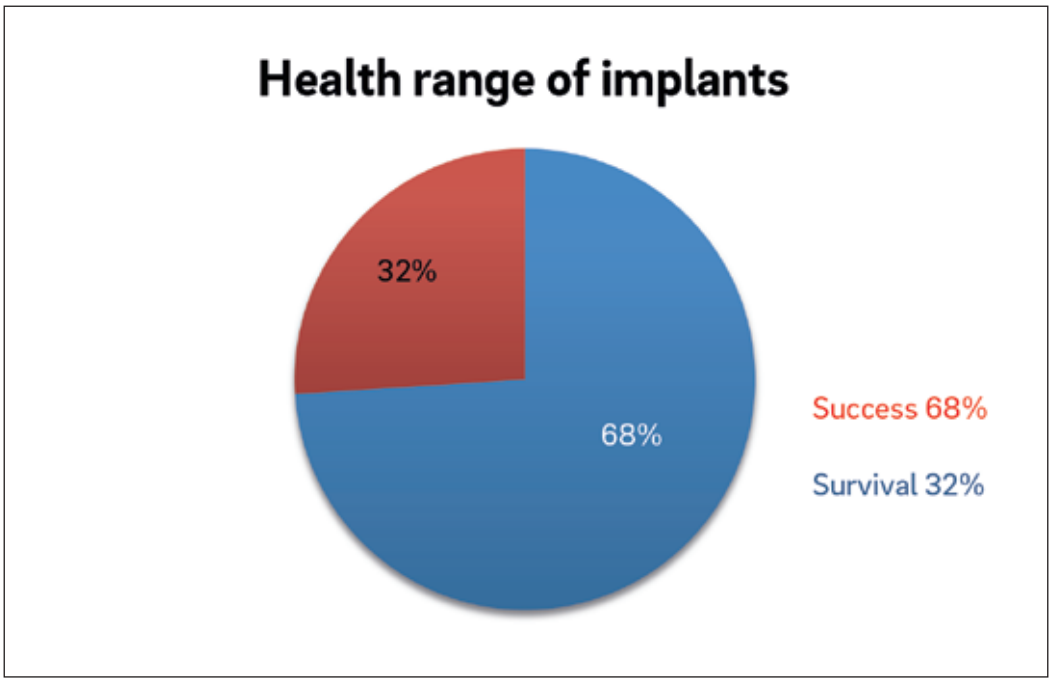

Fig. 2
Distribution of the prosthetic rehabilitation according to the quality.

BOP was found in eight implants and increased PD (> 4 mm) in five implants. The occurrence of BOP after insertion of a probe with light pressure reveals the presence of an inflammatory lesion in the gingiva around the tooth. With respect to the mucosa around the implant, the accuracy of the diagnostic role of BOP seems to be greater than around natural teeth.[11] In the present study, 58% of the periimplant tissue was considered healthy.

In addition to these criteria, other factors may be related to the rate of success or failure of the implant, such as age, sex, systemic disease, smoking, area of implant placement, implant diameter and height, additional surgery and bone resorption. In the present study, the success and survival rates were similar among the age groups, corroborating with the findings in the literature that the age of the patient is not related to the implant success rate.[12–14] Five patients with systemic disease and five with a smoking habit were included in the study. Regarding systemic disease, studies have shown

that there is no obvious difference in the quality of periimplant tissue,[15] and this was observed in our study too, since implants in patients with diabetes were successful. However, in smoking patients, there is evidence that the habit has an important influence on the periimplant tissue, regarding both the healing after implant placement and the implants' long-term prognosis.[16–19] There is a higher risk of inflammation and periimplant bone loss in smokers compared with nonsmokers.[16–19] In our study, the implants placed in smokers did not fail, but 60% of them had bone loss of 2–4 mm, which can be seen as a dubious or even unfavorable prognosis, considering the follow-up period after implant placement.

The literature shows a lower success rate of implants placed in the maxilla compared with the mandible,[20] a fact that is related to the lower density of the maxillary bone. The residual bone height becomes insufficient owing to the loss of alveolar bone. However, the molar area in both the maxilla and mandible displays substantial bone deficiency owing to increased occlusal forces, increasing the failure rate of implants in this area.[20] In Type IV bone, the cortical bone is very thin, and the lack of dense bone makes it difficult to achieve adequate stability. The mandibular retromolar area and the maxillary molar region are formed by low-quality bone, while implants placed in the anterior mandible area have high success rates owing to increased cortical bone. In this study, there was no difference between implants placed in different regions of the jaws regarding their success or survival, corroborating the findings of Kim et al.[21] It is necessary to consider that the study was conducted with a small number of patients and that probably in a larger sample these differences would be evident.

In our study, various implant systems were analyzed without differences in the success rate or acceptable survival rate, corroborating the findings of Ferrigno et al.[22] and Telleman et al.,[23] who found similar results for the survival of different types of implant designs. In a literature review, Opperman et al. also concluded that, regarding implant survival, there are no types, surfaces or implant systems that present clear advantages over others.[24]

In summary, in the present study, 74% of the implants examined were classified as successful, with excellent prognoses, while 26% of the implants were classified as having impaired survival. Therefore, success and survival rates of 74% and 100%, respectively, were observed. It is important to highlight that only patients who had undergone definitive prosthetic rehabilitation were evaluated and maybe that is why no failure was observed, since Jeong et al. reported that failure usually occurs before seating of the definitive prosthesis.[25]

Conclusion

Within the limitations of this cross-sectional study, the data suggest that the implant success rate does not seem to be related to factors like age, sex, habits, systemic disease, macroscopic characteristics or area in which the implant was placed. This study can be considered preliminary and provides the basis for the design of further studies.

Author contributions

ABA, UDR and LPM made substantial contributions to conception and design, acquisition of data, and analysis and interpretation of data, and wrote substantial parts of the manuscript. ABA, LPM and UDR were involved in drafting the manuscript, participated in the data analysis and interpretation of the results, and revised critically for important intellectual content.

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Implant rehabilitation of extremely atrophic mandibles (Cawood and Howell Class VI) with a fixed-removable solution supported by four implants: one-year results from a preliminary prospective case series study

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Abstract

Objective

The objective of this study was to report one-year preliminary data on Cawood and Howell Class VI patients rehabilitated with a fixed-removable solution.

Materials and methods

Completely edentulous patients, aged 18 years or older, presenting with severely atrophic mandibles (Class VI according to Cawood and Howell) were enrolled and treated using four implants, a CAD/CAM titanium bar and a low-profile attachment system to support an implant-supported overdenture. Outcome measures were success rates of the implants and prosthesis, complications, marginal bone level changes, bleeding index, plaque index and patient satisfaction (Oral Health Impact Profile).

Results

A total of 16 Osstem TSIII implants were placed in four consecutive edentulous participants. All of the treated patients were female with an average age of 71.5 (range: 64–82). Patients were followed up for a mean period of 13.8 months (range: 12–16) after loading. No participants dropped out, and no deviation from the original protocol occurred. At the one-year follow-up, no implants or prosthesis had failed and no biological or technical complications had occurred. At the one-year follow-up, the mean marginal bone loss was 0.23 ± 0.07 mm. The Oral Health Impact Profile summary scores demonstrated a significant decrease throughout the study, from 66.5 ± 3.7 to 19.3 ± 2.8. At the one-year follow-up, the bleeding index was 1.6% and the plaque index was 4.7%.

Conclusion

Within the limitations of this study, an overdenture fully supported by four implants and a CAD/CAM titanium bar with a low-profile attachment system, can be considered an effective and predictable option for patients with Cawood and Howell Class VI atrophic mandibles. Minimum marginal bone remodeling, good periodontal parameters and patient satisfaction can be expected.

Keywords

Implant, atrophic mandible, CAD/CAM titanium bar, overdenture.

Introduction

Prosthetic rehabilitation on implants in severely atrophic patients is a challenge. In a Cawood and Howell Class VI case, the mandible presents with a depressed ridge form, inadequate in height and width, evident basilar bone loss, and alveolar nerve exposure.[1] A mandibular implant overdenture is a viable treatment option for edentulous mandibles, improving overall patient satisfaction compared with a removable complete denture.[2] These studies document successful treatment outcomes and better oral health-related quality of life as compared with wearing of complete dentures.[3] The number of implants to be placed and the type of retention have been controversially discussed.[4–6] The implant survival rate of mandibular overdentures is high regardless of the number of implants.[7] Therefore, two single standing implants with ball attachments have sometimes been considered a risk and some investigators suggest using four implants with a splinting bar.[6, 8–10]

In patients with an alternated skeletal maxillomandibular relationship, a fixed-removable solution may be a viable option for soft- and hard-tissue reconstruction and for the All-on-4 concept for the rehabilitation of patients presenting with extremely atrophic mandibles (Cawood and Howell Class VI).[1, 11] A fixed-removable solution may be a feasible option to overcome the technical complications of other treatment options.[4, 12] Moreover, hygienic maintenance of the prosthesis can be challenging when extensive prosthetic flanges are needed to provide adequate lip and check support to overcome esthetic problems typical of aging.[13]

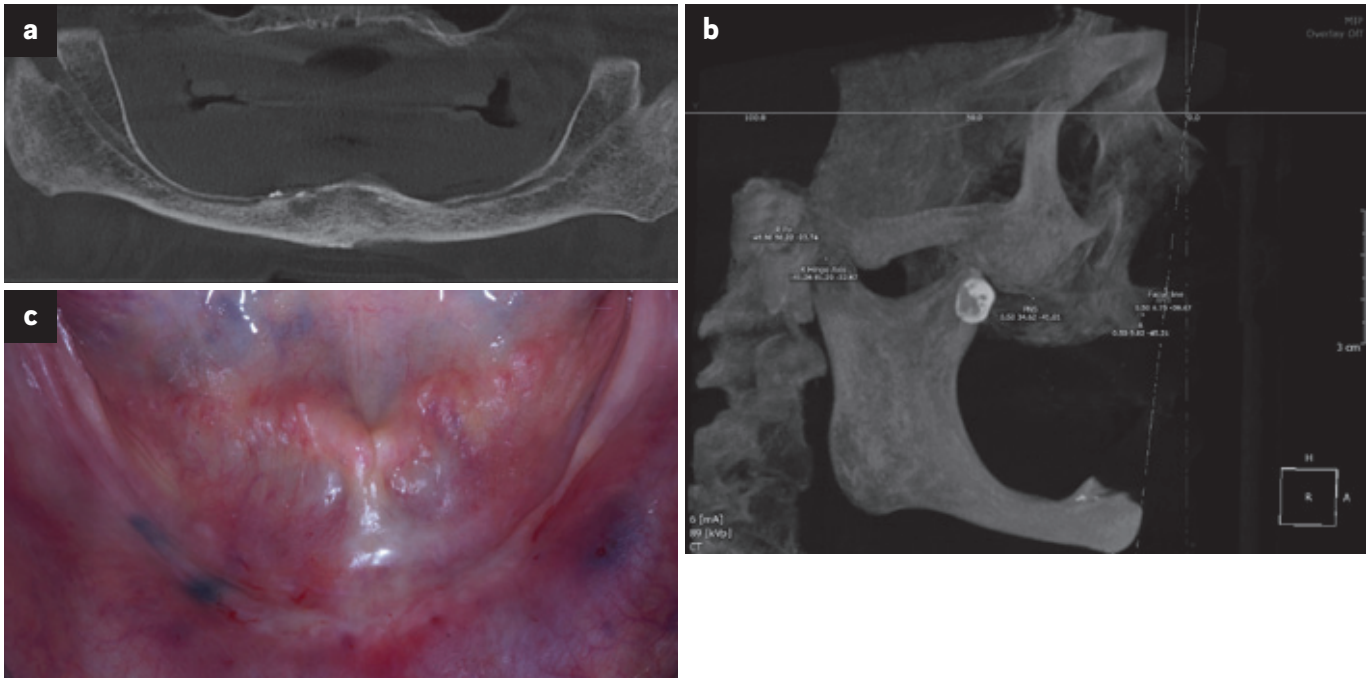
The purpose of this preliminary case series study was to report one-year preliminary data on Cawood and Howell Class VI patients rehabilitated with a fixed-removable solution. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines.[14]

Materials and methods

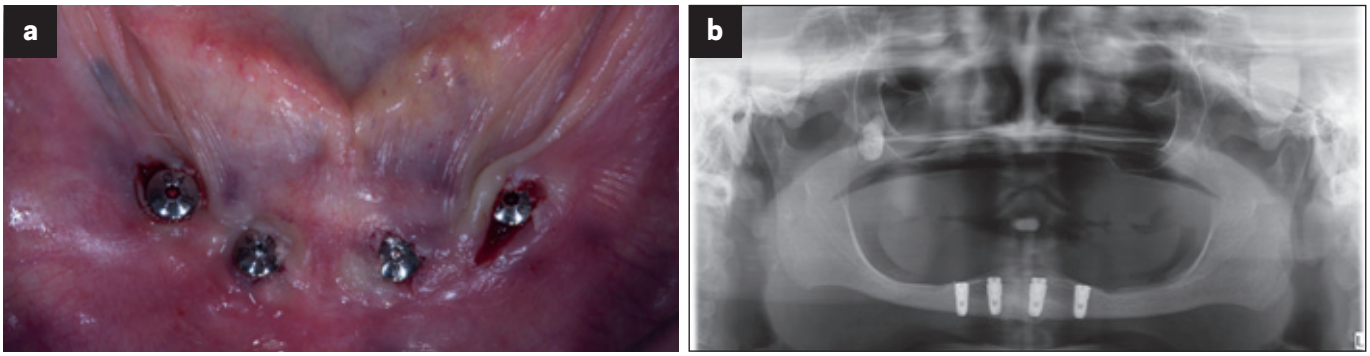
This preliminary investigation was designed as a prospective study conducted according to the principles embodied in the Helsinki Declaration of 1975, as revised in 2008. Completely edentulous patients, aged 18 years or older, presenting with severely atrophic mandibles (Class VI according to Cawood and Howell)[1] were enrolled and treated in consecutive order after being informed about the nature of the study and providing their written informed consent. All of the surgical and prosthetic procedures were performed in a private center in Rome, Italy, by a certified implantologist (MT) between September 2015 and February 2016. Exclusion criteria were general contraindications to oral surgery, pregnancy or nursing, intravenous bisphosphonate therapy, alcohol or drug abuse, heavy smoking (≥ 10 cigarettes/day), radiation therapy to the head or neck region within the last five years, parafunctional activity, untreated periodontitis, full-mouth bleeding on probing, and a full-mouth plaque index of ≤ 25%, and allergy or adverse reactions to the restorative materials.

Preoperative photographs, radiographs **(Figs. 1a–c)** and model casts were produced for initial screening and case evaluation. A radiographic guide was made by duplicating the relined pre-existent removable complete mandibular denture, if judged viable from an esthetic and functional perspective; otherwise, a new radiographic guide was made according to the functional and esthetic requirements. A cone beam computed tomography (CBCT) scan (CRANEX 3Dx, SOREDEX, Tuusula, Finland) was taken of each enrolled patient wearing the radiographic guide and a bite index in centric occlusion with an extraoral volume transfer element (Evobite, 3DIEMME, Cantù, Italy), fixed using a dedicated silicone material (3DIEMME). Then, the radiographic guide and the bite index were repositioned in the master cast and optical scanning was performed. Radiographic and prosthetic data were imported into a dedicated diagnostic and medical imaging software (3Diagnosys 4.2, 3DIEMME). The digitalized model and radiographic guide were accurately superimposed over the reconstructed bone volume by CBCT, based on the volumetric elements, present in both the CBCT volume and the optical scan (Evobite). Four implants per patient were planned in the anterior area of the mandible, according to the prosthetic setup. After careful functional and esthetic evaluation and final verification, the prosthetic-driven plan was approved, and a stereolithographic surgical template was fabricated with a newer rapid prototyping technology (New Ancorvis, Bargellino, Italy).

One hour before implant placement, patients received a single dose of an antibiotic (2 g of amoxicillin or 600 mg of clindamycin if allergic to penicillin) and professional hygiene therapy. Prior to the start of surgery, the patients rinsed



Figs. 1a–c



Figs. 2a & b

Fig. 3

Figs. 1a–c

Preoperative radiographs (a & b) and intraoral photograph (c).

Figs. 2a & b

Clinical view (a) after placement of the four implants (Osstem TSIII, 4.5 × 10 mm) according to a one-stage protocol. Radiograph after implant placement (b).

Fig. 3

Definitive impression taken using plaster as both splinting and impression material.

with 0.2% chlorhexidine for 1 min. The surgical template (New Ancorvis) was fitted in the patient's mouth, then local anesthesia was administered with a 4% articaine solution with 1:100,000 epinephrine (Ubistein, 3M ESPE, Milan, Italy). The implants were placed in the planned anatomical sites according to a one-stage approach **(Figs. 2a & b)**[15] using the surgical template. Each patient received four Osstem TSIII bone level implants (Osstem TSIII, Osstem, Seoul, South Korea), placed either without a flap or with a minimally invasive flap, according to the drilling protocol recommended by the manufacturer (OsstemGuide Kit). After surgery, the existing removable complete denture was relined chairside (Sofreliner Tough Soft, Tokuyama Dental, Montecchio Precalcino, Vicenza, Italy) to accommodate the healing of the hard and soft tissue, thereby ensuring no pressure on the healing abutments. Occlusion was checked during osseointegration of the implants.

After implant placement, all of the patients received oral and written recommendations on medication, oral hygiene maintenance and diet. Analgesics (500 mg of paracetamol plus 30 mg of codeine, or 600 mg of ibuprofen) were administered as needed. Eight weeks later, a definitive impression was taken using plaster (Snow White Plaster No. 2, Kerr, Orange, Calif. U.S.) as both splinting and impression material **(Fig. 3)**.[16] A complete mounting technique was used to articulate the opposite arch cast (KaVo PROTARevo 7, KaVo Dental, Biberach, Germany). Then, esthetics and function of the final occlusal vertical dimension, tooth position and interocclusal record were verified and approved by both the clinician and the patient at the try-in appointment. Afterward, the master cast and the try-in were digitalized with an optical scanner (Identica T500, Medit, Seoul, South Korea).

A CAD/CAM titanium bar was virtually designed **(Figs. 4a & b)** according to the ridge and prosthetic contours and implant position in order to enhance a vertical path of insertion of between 4 and 6°. Then, a one-piece titanium bar was manufactured **(Fig. 5)** from a homogenous solid block of a medical titanium alloy (Ti6Al4V, New Ancorvis). Four to five threadable OT Equator attachments (Rhein 83, Bologna, Italy) were placed along the implant bar. The fit of the implant bar was clinically and radiographically tested in the patient's mouth according to a previously published protocol.[17, 18] A cast cobalt–chromium alloy metal framework (Vitallium, DENTSPLY International, York, Pa., U.S.)

Figs. 4a & b

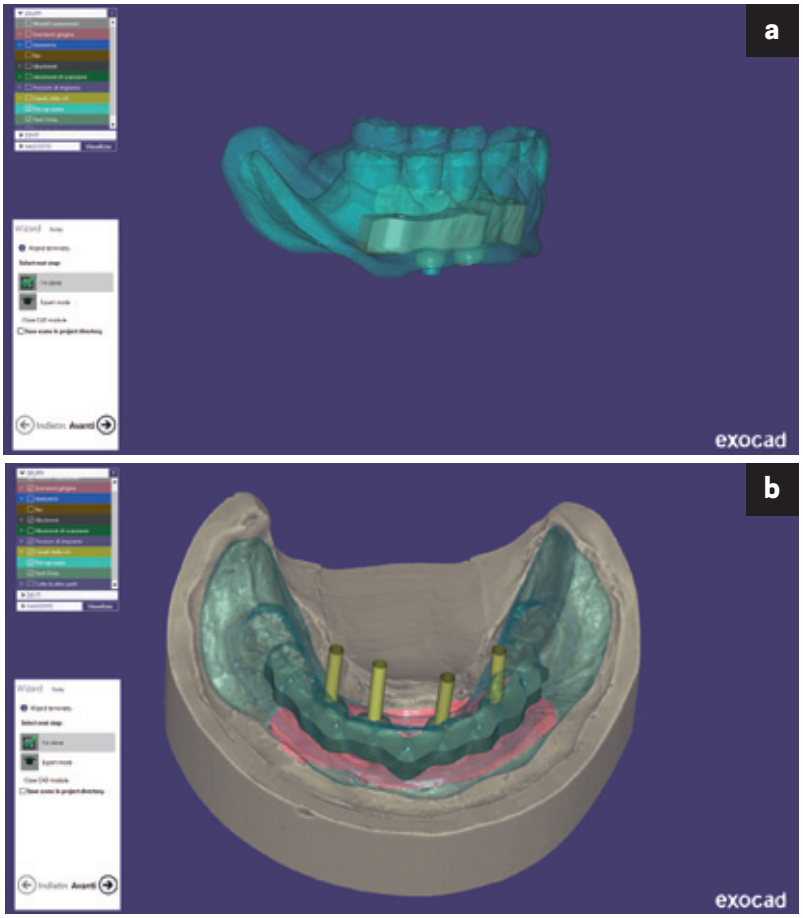
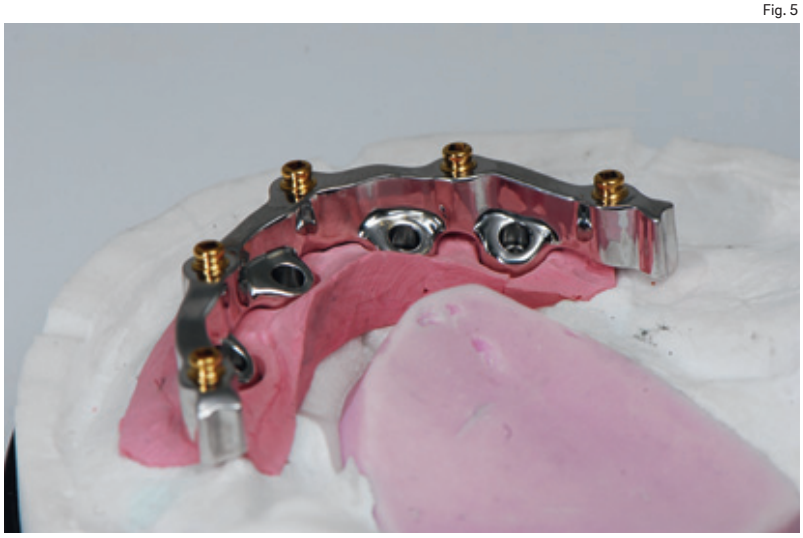


Fig. 5



Figs. 4a & b
CAD/CAM images showing the titanium bar project, according to the prosthetic volume of the overdenture (a) and the relationship between the titanium bar and implants placed (b).

Fig. 5
CAD/CAM titanium bar.

Fig. 6
Metallic counterpart of the overdenture.

was conventionally fabricated on to the CAD/CAM titanium bar as a counterpart **(Fig. 6)**. Finally, the overdenture was finished, sealing the borders to minimize food impaction and saliva and air leakage. The titanium bar was screwed at the abutment level according to the manufacturer's instructions, and the fixed-removable solution was delivered **(Figs. 7a–c)**. All of the patients were then enrolled in a standard implant recall program. Oral hygiene maintenance was checked and radiographs were taken early after final prosthesis delivery. Occlusion was checked at every appointment **(Figs. 8a & b)**.

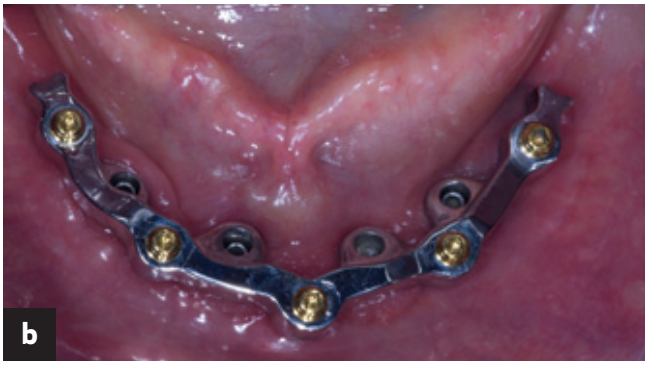
Outcome measures

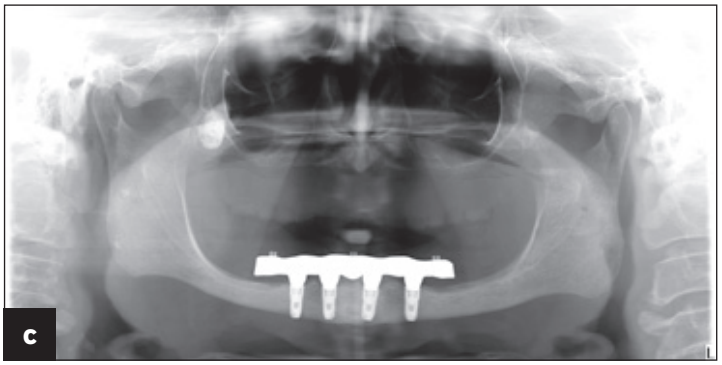
The primary outcome measures were the following:

- Success rates of the implants and prosthesis: An implant was considered a failure if it presented with any mobility, assessed by tapping or rocking the implant head with the metallic handles of two instruments, progressive marginal bone loss or infection, and any mechanical complications rendering the implant unusable, although still mechanically stable in the bone. A prosthesis was considered a failure if it needed to be replaced with another prosthesis.
- Complications: Any biological (pain, swelling, suppuration, etc.) and/or mechanical (screw loosening, fracture of the framework and/or the veneering material, etc.) complications were evaluated.
- Marginal bone levels: The levels were assessed using intraoral digital periapical radiographs (Digora Optime, SOREDEX; photostimulable phosphor imaging plate, size 2, pixel size of 30 µm, resolution of 17 lp/mm) at implant placement (baseline) and one year after loading. Intraoral radiographs were taken with the paralleling technique by means of a periapical radiograph with a commercially available film holder (Rinn XCP, Dentsply Rinn, Elgin, Ill., U.S.). The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. All readable radiographs were uploaded to an image analysis software package (DfW 2.8, SOREDEX) that was calibrated using the known length or diameter of the dental implants and displayed on a 24 in. LCD screen (iMac, Apple, Calif., U.S.) and evaluated under standardized conditions (ISO 12646:2004). The marginal bone levels were determined from linear measurements performed by an independent calibrated examiner on each periapical radiograph, from the mesial and distal margin of the implant neck to the most coronal point where the bone appeared to be in contact with the implant.
- Patient satisfaction with function and esthetics was assessed using a scale of 1–10, where

Fig. 7a

Figs. 7b & c

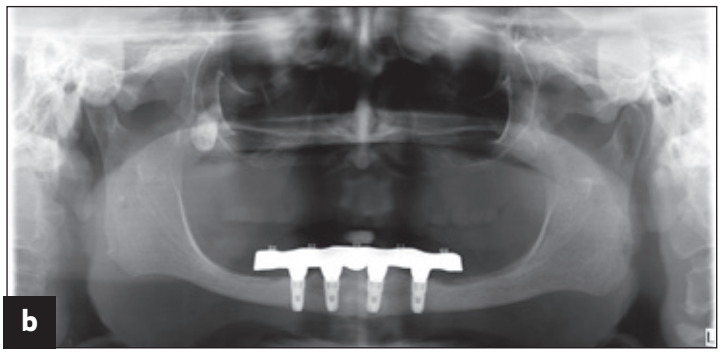




Figs. 7a–c

Clinical view of the overdenture at the time of prosthesis delivery (a & b) and radiographic view early after final prosthesis delivery (c).

Figs. 8a & b



Figs. 8a & b

One-year follow-up of a mandibular CAD/CAM titanium bar screwed on to implants (a). Dental panoramic tomogram taken one year after loading, showing the perfect fit of the bar on the implants (b).

10 = fully satisfied, 5 = satisfied and 1 = not satisfied. Quality of life was assessed by the Oral Health Impact Profile (OHIP-21) questionnaire, which was completed by the participants. The questionnaire consists of seven subscales (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap) with two to four questions each. Participants chose from five possible responses for each question as follows: never, hardly ever, occasionally, fairly often and very often. Items were scored on a five-point ordinal scale ranging from 1 (never) to 5 (very often). Lower OHIP total scores are suggestive of improvement in oral health-related quality of life. The questionnaire was administered before treatment and one year after definitive prosthesis delivery.

– Bleeding index and plaque index were evaluated at four sites around each implant–abutment interface at the one-year examination with a periodontal probe (PCPUNC156, Hu-Friedy, Milan, Italy).

An independent dentist (EX) evaluated the implant and prosthetic survival and success rates and administered the patient satisfaction and OHIP questionnaires. Complications were assessed and treated by the treating clinician (MT), who was nonblinded. Marginal bone level changes were evaluated by an independent radiologist. An independent blinded dental hygienist who was otherwise not involved in the study performed all of the periodontal measurements.

All data analysis was carried out according to a pre-established analysis plan using software (IBM SPSS Statistics for Macintosh, Version 22.0, IBM, Armonk, N.Y., U.S.). Descriptive analysis was performed using means, standard deviations and a 95% confidence interval. Comparison of the means for marginal bone level changes, patient satisfaction and OHIP scores between the baseline and one-year follow-up examinations was performed by paired tests. A biostatistician with expertise in dentistry analyzed the data.

Results

A total of 16 Osstem TSIII implants (14 regular platform and two mini platform) were placed in four consecutive edentulous participants. All of the participants were followed up for a minimum of one year (mean: 13.8 months; range: 12–16) after definitive loading. All of the treated patients were female with an average age of 71.5 (range: 64–82). The main patient and implant characteristics are shown in **Table 1**. No participants dropped out, and no deviation from the original protocol occurred. At the one-year follow-up, no implants or prosthesis had failed, resulting in cumulative implant and prosthetic survival rates of 100%. No biological or technical complications occurred during the follow-up, resulting in cumulative implant and prosthetic success rates of 100%. At the one-year follow-up, the mean marginal bone loss was 0.23 ± 0.07 mm. The OHIP summary scores demonstrated a significant decrease (P = 0.0002) throughout the study, from 66.5 ± 3.7 to 19.3 ± 2.8. At the one-year follow-up, the bleeding index was 1.6% and the plaque index was 4.7%. All of the data are summarized in **Table 1**.

Discussion

This prospective study was designed to evaluate the one-year clinical and radiographic outcomes and patient satisfaction of Cawood and Howell Class VI patients treated with a fixed-removable overdenture supported by four implants, placed using guided surgery, and a CAD/CAM titanium bar. Because it was designed as a single-cohort, proof-of-concept study, the main limitations were the lack of a control group and a small sample size. Hence, this investigation should be considered as a pilot for future multicenter randomized clinical trials with control group comparison.

The results of the present one-year preliminary prospective case series study reported implant and prosthetic survival and success rates of 100% and greater patient satisfaction, indicating that patients with extremely atrophic mandibles (Cawood and Howell Class VI) may be rehabilitated using this fixed-removable solution.

Complete maxillary and mandibular dentures have been the conventional standard of care for edentulous patients. However, most patients report significant problems adapting to their mandibular dentures owing to a lack of comfort, retention and stability and to the inability to chew and eat properly, resulting in pain and discomfort. Recent evidence from studies carried out over the past decade has determined that the two-implant overdenture is considered

Table 1

	Age (years)	Sex	Smoking	Implants	Implants 7 mm length	Implants 8.5 mm length	Implants 10 mm length	Implants 3.5 mm wide	Implants ≥ 4 mm wide	Failed implant	Failed prosthesis	MBL (mm)	OHIP T0	OHIP T1	BI	PI
Patient 1	64	F	0	4	0	0	4	0	4	0	0	0.16	71.0	22.0	0/16	1/16
Patient 2	82	F	0	4	2	2	0	2	2	0	0	0.26	63.0	21.0	1/16	0/16
Patient 3	68	F	0	4	0	2	2	0	4	0	0	0.19	68.0	16.0	0/16	2/16
Patient 4	72	F	0	4	0	0	4	0	4	0	0	0.32	64.0	18.0	0/16	0/16
Total		4F/0M	0	16	2	4	10	2	14	0	0				1/64 (1.6%)	3/64 (4.7%)
Mean ± SD	71.5 ± 7.7											0.23 ± 0.07	66.5 ± 3.7	19.3 ± 2.8		

MBL = Marginal bone loss; OHIP = Oral health impact profile; T0 = Baseline; T1 = One year after definitive prosthesis delivery; BI = Bleeding index; PI = Plaque index; SD = Standard deviation.

Table 1
Characteristics and results of included patients/implants.

the first alternative treatment for the completely edentulous mandible.[19, 20] Nevertheless, the placement of at least four implants of standard length may allow the delivery of an overdenture supported by a CAD/CAM titanium bar and a low-profile attachment system,[21] avoiding any bearing area on the soft tissue and reducing the denture base extension.[22] The OT Equator for bars exists in two types, castable and prefabricated (threadable). In the present study, the prefabricated shape was used. This type of attachment is initially of higher cost, but it is highly wear resistant, its surface being of titanium nitride. Furthermore, it is easy to replace, if needed.

A fixed dental prosthesis on four implants may be a possible alternative to a mandibular overdenture on four implants and supported by a CAD/CAM titanium bar with a low-profile attachment system. Nevertheless, it is associated with higher marginal bone loss, high frequency of complications and poor plaque control, particularly in extremely atrophic patients.[23–26] In the present study, a trend of minimum marginal bone loss and good periodontal parameters was observed within the one-year follow-up, demonstrating that a good level of hygiene can be expected using this fixed-removable solution. Similar to with a fixed dental prosthesis, patient satisfaction significantly improves owing to an improvement in esthetics and masticatory function. Moreover, the prosthetic flanges of a fixed-removable solution allow for full lip and cheek support.

Conclusion

Within the limitations of this study, a mandibular overdenture on four implants and supported by a CAD/CAM titanium bar with a low-profile attachment system can be considered an effective and predictable option for patients with Cawood and Howell Class VI atrophic mandibles. Minimum marginal bone remodeling, good periodontal parameters and patient satisfaction can be expected.

Competing interests

MT is the Research Project Manager at Osstem AIC, Italy. However, this study was self-supported. Hence, the authors declare no conflicts of interest.

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Kinesiographic evaluation of patients under orthodontic treatment with or without tooth extraction

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Abstract

Objective

In orthodontic practice, it is always required to decide whether to extract a tooth or to close the gap in the case of edentia. There are no scientific reports on changes to the temporomandibular joint and muscle system after orthodontic treatment including dentition size and shape reduction. The objective of this study was to improve diagnostic methods using computed diagnostic equipment.

Materials and methods

After undergoing orthodontic treatment with dentition size and shape reduction, 127 patients aged between 16 and 32 were examined. Patients with physiological occlusion and without any functional problems were included in the control group. Morpho-functional investigation of mandibular movement was conducted via a kinesiograph.

Results

All of the patients showed some functional problems on the frontal and lateral planes.

Conclusion

Improvements were seen with the regain and restoration of the edentulous spaces.

Keywords

Temporomandibular joint, TMJ, temporomandibular disorder, TMD, occlusal plane, muscular function.

Figs. 1a–c

Figs. 2a–c

Introduction

In order to determine a correct, comprehensive diagnosis of the maxillofacial system and the muscle chains, different methods of diagnosis are used, such as clinical examination, facial profile and photometry, anthropometric diagnostics of the dentition and occlusion, radiographic diagnostics (dental panoramic tomogram, lateral cephalogram, CT, MRI, etc.) and functional diagnosis (kinesiography, electromyography, myostimulation, posotonic state identification, etc.). All these methods have been extensively investigated and applied in the orthodontic department of the Moscow State University of Medicine and Dentistry, Moscow, Russia. Owing to these kinds of diagnostic equipment, a correlation between orthodontic treatment with dentition size and shape reduction (owing to tooth extraction **[Figs. 1a–c]** or partial primary or secondary tooth edentia **[Figs. 2a–c]**) and temporomandibular disorder (TMD) has been observed.

In orthodontic practice, it is required to decide between extracting a tooth and closing the gap in the case of edentia. It is necessary to state that these border cases arise rather rapidly. It was decided to assess this issue from the perspective of different orthodontic approaches. The study was based on several scientific articles.[1–20]

All of the structures of our body are phylogenetically connected. There is obvious continuity from vertebral column to cranium. All cranial bones are generated from the first three vertebrae during the evolutionary process. There are also two subsystems that unite the entire body: the craniosacral and craniomandibular ones, joining together in the central nervous system. They are divided into musculoaponeurotic chains, starting from the cranial bones.[21, 22] In light of this, it is necessary to know that all body systems are able to change during orthodontic treatment. Occlusal changes also influence the connection of cranial bones and as a result they can lead to TMD. By reorganizing the systems, we can improve stability and quality of treatment.

Therefore, while different authors' conclusions about extraction or nonextraction treatment are based on clinical, radiographic, CT or MRI examination, there are insufficient data on muscle adaptation to decide on the treatment in this case. There are no scientific reports on changes to the temporomandibular joint (TMJ) and muscle system after orthodontic treatment with dentition size and shape reduction (owing to tooth extraction or partial primary or secondary tooth edentia). This makes it difficult to evaluate the treatment choices properly in relation to the effect on the muscles and TMJ. These parameters are known as being essential for patients' health. Consequently, the aim of this study was to improve diagnostic methods after orthodontic treatment with dentition size and shape reduction using computed diagnostic equipment.

Figs. 1a–c
The patient after orthodontic treatment (several years ago) with the second premolar extraction.

Figs. 2a–c
The patient after orthodontic treatment with space closure (primary edentia of tooth #22).

Fig. 3

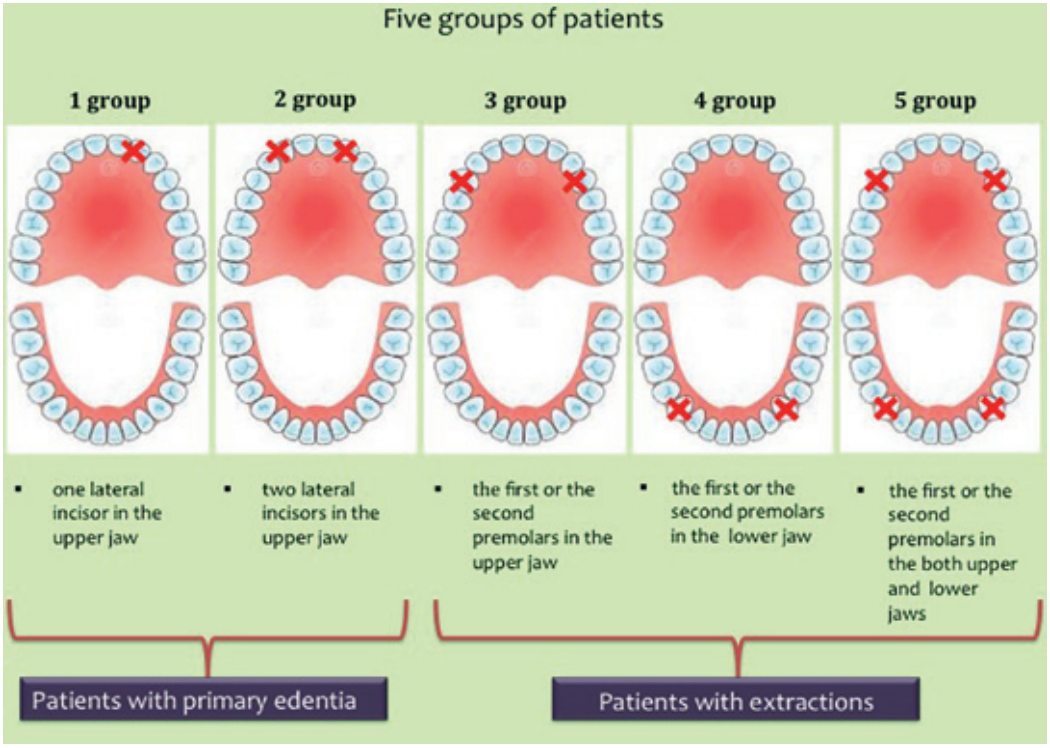


Fig. 3
Five groups of patients were selected according to the area of the absent teeth.

Fig. 4
The BioKeyNet kinesiograph and the patient wearing the kinesiograph mask.

Fig. 5
Kinesiographic interpretation in graphic and digital forms.

Fig. 4

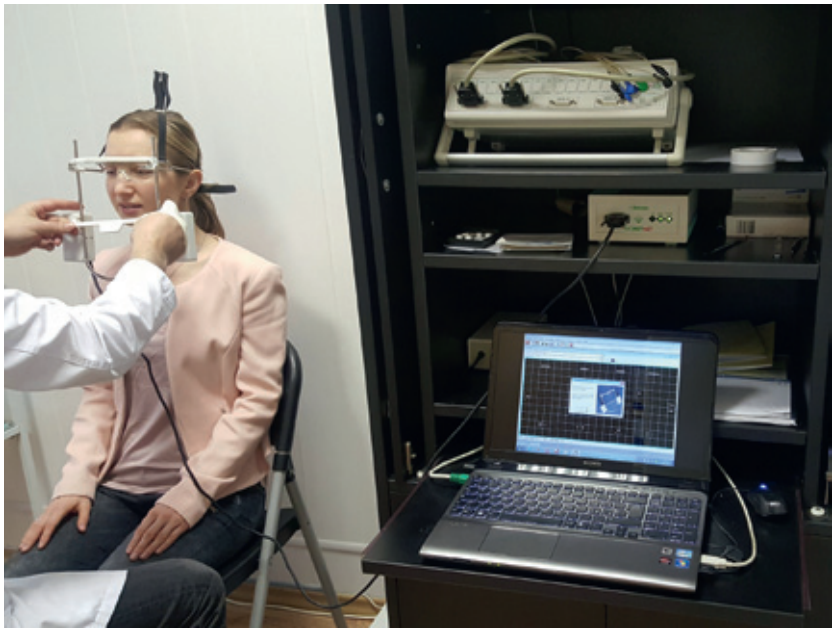
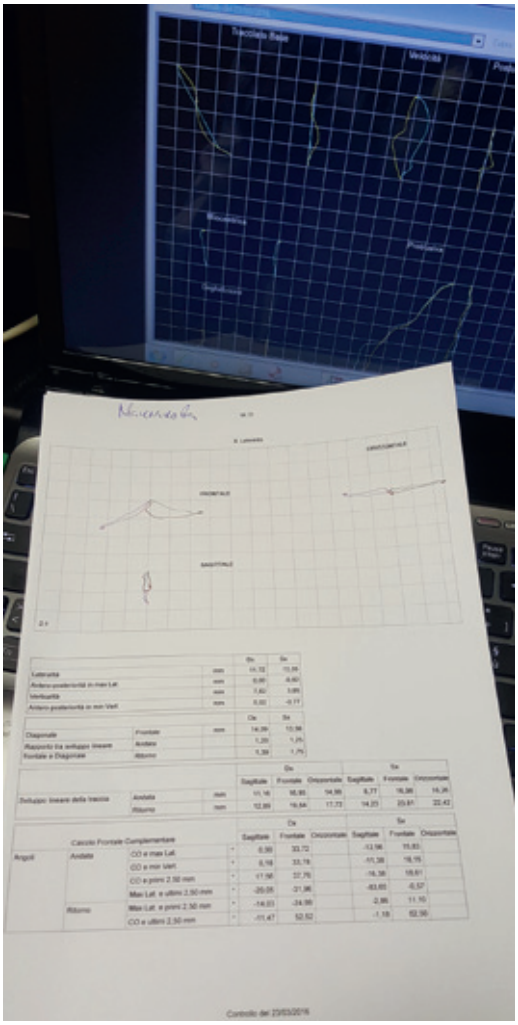


Fig. 5



Materials and methods

This cross-sectional observational study included 127 patients aged between 16 and 32 during a period of two years. The patients were examined after orthodontic treatment that included dentition size and shape reduction for partial primary or secondary tooth edentia. Five groups of patients were selected according to the area of the absent teeth **(Fig. 3)**:

1) absence of one lateral incisor in the upper jaw; composed of 21 patients;
2) absence of two lateral incisors in the upper jaw; composed of 16 patients;
3) absence of the first or the second premolar in the upper jaw; composed of 24 patients;
4) absence of the first or the second premolar in the lower jaw; composed of 19 patients; and
5) absence of the first or the second premolar in both the upper and lower jaws, composed of 22 patients.

Moreover, a control group was formed of 25 patients with physiological occlusion and without any functional problems. Morpho-functional investigation of mandibular movement was conducted using a kinesiograph (BioKeyNet, Bioket, San Benedetto del Tronto, Italy; **Fig. 4**). Kinesiography is the precise registration of the various movements of the mandible in three planes—sagittal, frontal and horizontal—including muscle contraction speed with complex performance in graphic and digital forms **(Fig. 5)**.[23, 24]

In order to assess the current morpho-functional condition of the entire dentoalveolar system, the following functional tests and their further modification were set in various planes:

1. maximum mandibular lowering and lifting;
2. maximum mandibular lowering and lifting with regular and maximum movement speed;
3. maximum mandibular extension (a movement path was studied, including an individual angle of mandibular lowering and the trajectory of mandibular protrusion and its deviation);
4. maximum lateral mandibular movement (investigation was conducted on the trajectory of a mandibular movement and its individual angle, turning to the right and to the left);
5. mandibular movement from its regular physiological rest position to its common teeth joining myocentric index (an individual angle was tested to perform a mandibular anterior or posterior movement).[24]

Results

The first group showed well-defined restrictions. While the mandible was lowered and lifted in the frontal plane, a simultaneous decrease in muscle contraction speed was seen in 80% of these patients, particularly in the vertical index (**Fig. 6**; **Table 1)**. In the mandibular movement in the sagittal plane, a frontal block was observed. This block was also registered in all patients in the remaining groups **(Table 2)**.

In the second group, the mandibular lowering and lifting led to its deviation and to the decreasing of the muscle contraction speed (**Fig. 7**; **Table 1**). This occurrence was even more marked compared with that seen in the first group, owing to the more distal position of the mandible **(Table 3)**. The protrusive movement according to angle showed a significant frontal block and difficulty during mandibular movement (**Fig. 8**; **Table 2**). This group was also characterized by blocked mandible lateral movement to both the right and the left sides, with trajectories simultaneously shortening **(Tables 4 & 5)**. TMD was seen in 60% of patients, while 40% of patients exhibited full blocking of lateral and protrusive movement.

The third group was divided into two subgroups according to the type of mandibular movement. The first subgroup (40% of the patients) was characterized by a severe decrease (flat angles) of lateral and protrusive angles (**Tables 2, 4 & 5**; **Figs. 8 & 9**). In contrast, the second subgroup (60% of the patients) showed an obvious increase (deep angles) of the lateral and protrusive angles (**Tables 2, 4 & 5**; **Figs. 8 & 9**). These outcomes showed an impairment of the essential lateral and frontal mandibular movements. Furthermore, the second subgroup was characterized by a distal position of the mandible **(Table 3)**, restriction of movement during its lowering and lifting, and TMD **(Table 1)**.

In the fourth group, all of the patients without exception (100%) showed considerable restriction of mandibular lowering with its deviation **(Fig. 10)**, restriction of the muscle contraction speed **(Table 1)**, and a decrease of the lateral and the protrusive angles **(Tables 2, 4 & 5)**.

In the fifth group, restriction of mandibular lowering and lifting (36.85 mm) and its deviation during protrusion (2.62 mm) were observed **(Table 2)**. The mandibular movement restriction to the left side (2.40 mm) showed values double that of the right side (1.56 mm; **Tables 4 & 5**;

Table 1
Mandibular movement during the lowering–lifting test.

Table 2
Mandibular movement during the protrusion test.

Table 3
Mandibular movement during the myocentric test in the frontal and sagittal planes.

Table 1

Index / Group	Mandibular lowering–lifting in frontal plane (mm)		Working angle (individual mandibular movement angle) in sagittal plane (°)	Mandibular movement speed (mm/s)	
	Vertical	Mandibular deviation during lowering (mm): to right (+); to left (-)		Lowering	Lifting
1st group	36.05	1.10	42.08	16.50	20.75
2nd group	30.00	2.26	41.19	9.60	13.20
3rd (1st sub-group) group	38.12	-0.80	40.21	16.60	21.33
3rd (2nd sub-group) group	28.69	-1.31	38.46	17.80	32.60
4th group	33.00	2.86	45.42	18.00	26.75
5th group	36.85	1.72	40.78	16.57	33.00
Norm (N)	43.72 ± 1.30	1.84 ± 0.28	38.89 ± 1.10	19.78 ± 1.35	31.94 ± 3.73

Table 2

Index / Group	Mandibular movement in vertical plane (mm)	Mandibular deviation during protrusion in vertical plane (mm): to right (+); to left (-)	Mandibular movement in sagittal plane (mm)	Centric occlusion angle (°)—maximum protrusion Only for 3rd group	Angle (°) 2.5 mm from start of mandibular movement Only for 3rd group	Diagonal (mm) Only for 3rd group
1st group	5.47	1.68	7.09			
2nd group	3.00	-1.09	5.21			
3rd (1st sub-group) group	2.84	1.12	8.71	19.40	19.79	8.27
3rd (2nd sub-group) group	6.36	0.67	7.00	41.90	61.16	9.50
4th group	3.75	1.21	8.60			
5th group	5.00	2.62	8.99			
Norm (N)	3.62 ± 0.21	1.08 ± 0.19	9.28 ± 0.53	28.20 ± 2.68		9.77 ± 0.53

Table 3

Index / Group	Myocentric, frontal plane (mm)	Individual angle, sagittal plane (°)
1st group	0.10	36.42
2nd group	0.19	31.86
3rd (1st sub-group) group	-0.08	28.79
3rd (2nd sub-group) group	-0.10	25.33
4th group	0.09	33.58
5th group	-0.12	33.11
Norm (N)	1.78 ± 0.17	26.89 ± 1.76

Table 4

Index / Group	Angle (°) 2.5 mm from start of mandibular Movement Only for 3rd group		Mandibular movement (mm)		Centric occlusion angle (°) —maximum lateral movement Only for 3rd group	
	Right	Left	Right	Left	Right	Left
1st group			0.79	1.75		
2nd group			1.40	1.05		
3rd (1st sub-group) group	29.13	-12.89	3.61	1.89	70.56	33.00
3rd (2nd sub-group) group	-11.85	-17.60	1.57	0.37	24.51	4.93
4th group			2.66	1.63		
5th group			2.45	1.56		
Norm (N)			13.34 ± 0.98	11.88 ± 0.95	33.81 ± 4.53	23.91 ± 6.20

Table 5

Index / Group	Angle (°) 2.5 mm from start of mandibular movement Only for 3rd group		Mandibular movement (mm)		Centric occlusion angle (°) —maximum lateral movement Only for 3rd group	
	Right	Left	Right	Left	Right	Left
1st group			10.44	10.64		
2nd group			5.00	6.10		
3rd (1st sub-group) group	21.03	23.20	10.00	10.37	5.74	16.97
3rd (2nd sub-group) group	44.05	47.43	7.68	8.68	30.68	28.60
4th group			8.23	9.22		
5th group			9.61	9.00		
Norm (N)			9.14 ± 0.40	9.24 ± 0.44	22.12 ± 2.35	22.56 ± 2.13

Fig. 11). This group exhibited a distal position of the mandible **(Table 3)** and TMD.

Clinical case

A patient came to our clinic after a previous treatment performed in another private clinic. She complained of great discomfort in the TMJ area. The previous treatment had included the extraction of the second premolars of the lower jaw. The following diagnostic scheme was carried out in our clinic, according to the protocol for patients with TMD:

1) anthropometric studies of digital jaw models (3-D scanning);
2) radiographic diagnosis; and
3) morpho-functional diagnosis using a kinesiograph **(Figs. 12 & 13)**, which showed a significant frontal block, a distal position of the mandible, TMD and a rotation of the occlusal plane.

During the one-year treatment in our department, the second premolar regions were regained and prepared for implant placement **(Figs. 14a–c)**. After the treatment, the kinesiographic data showed significant improvements. The myocentric graph indicated a change of the mandibular movement direction, the laterotrusion graph revealed normalization of the occlusal plane and the protrusion graph showed elimination of the frontal block **(Fig. 13)**.

Table 4
Mandibular movement during the laterotrusion test in the sagittal plane.

Table 5
Mandibular movement during the laterotrusion test in the frontal plane.

Fig. 6
Muscle contraction speed decreased during mandibular lowering and lifting in patients in the first and second groups.

Fig. 7
Protrusive movement with a significant frontal block and difficulty during mandibular movement in patients in the second group.

Fig. 8
Lateral mandibular movements in patients in the third group (the first and second subgroups).

Fig. 9
Protrusive mandibular movements in patients in the third group (the first and second subgroups).

Fig. 6

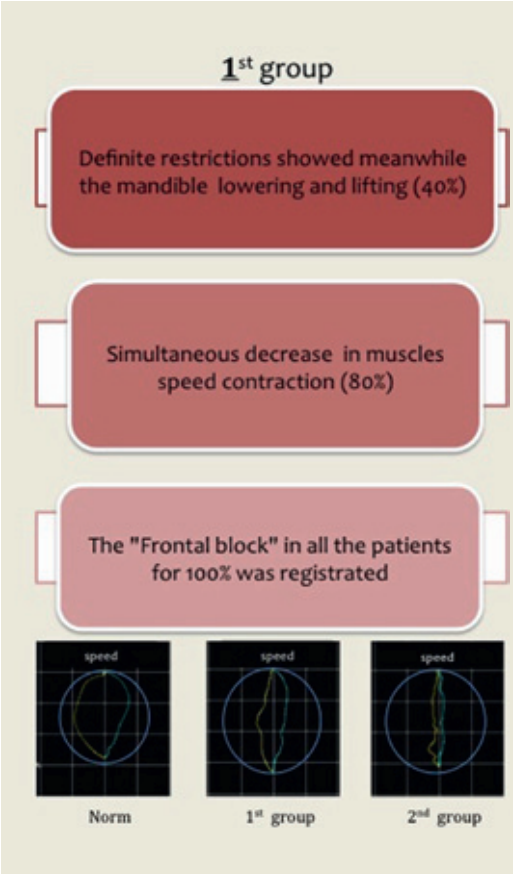


Fig. 7

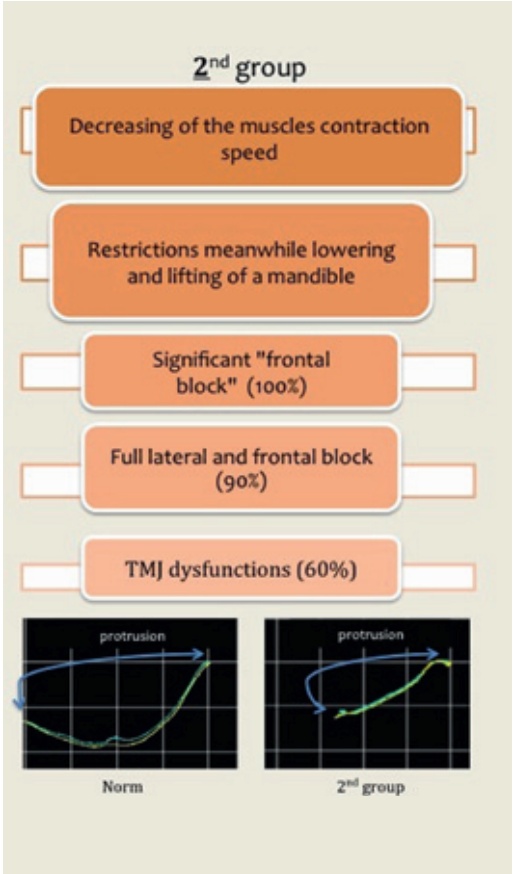


Fig. 8

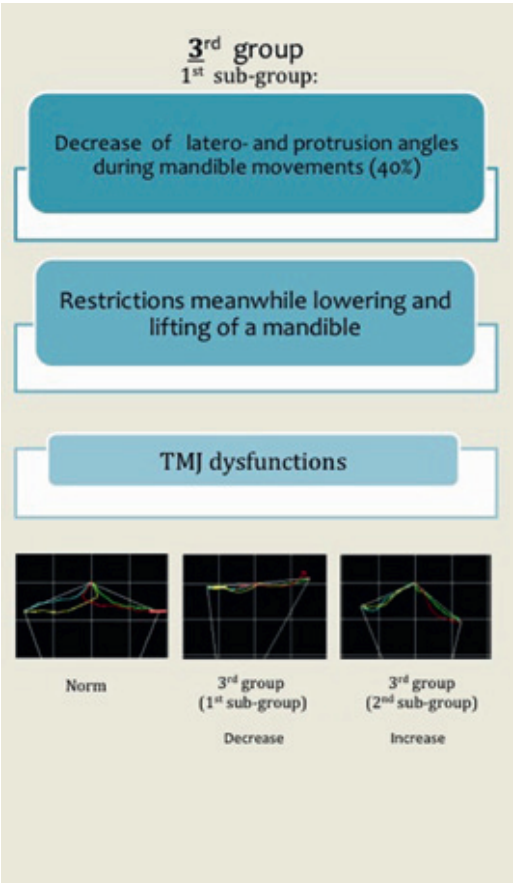


Fig. 9

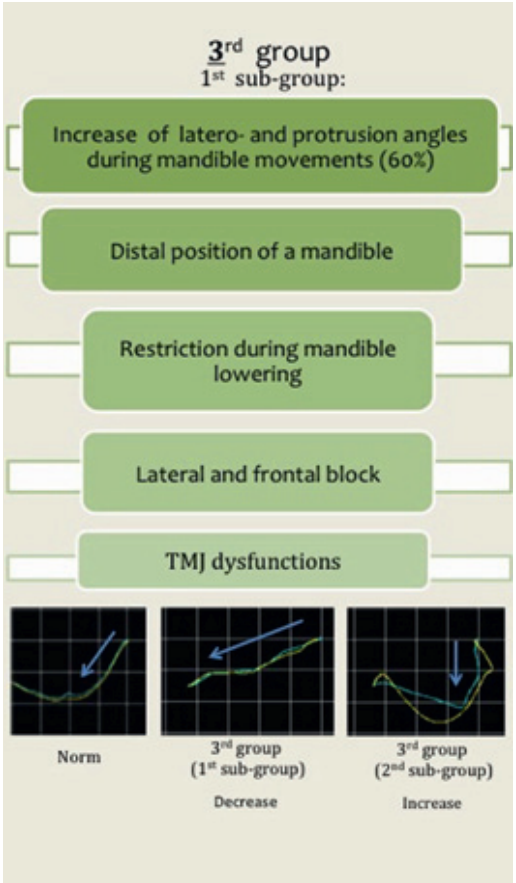


Fig. 10

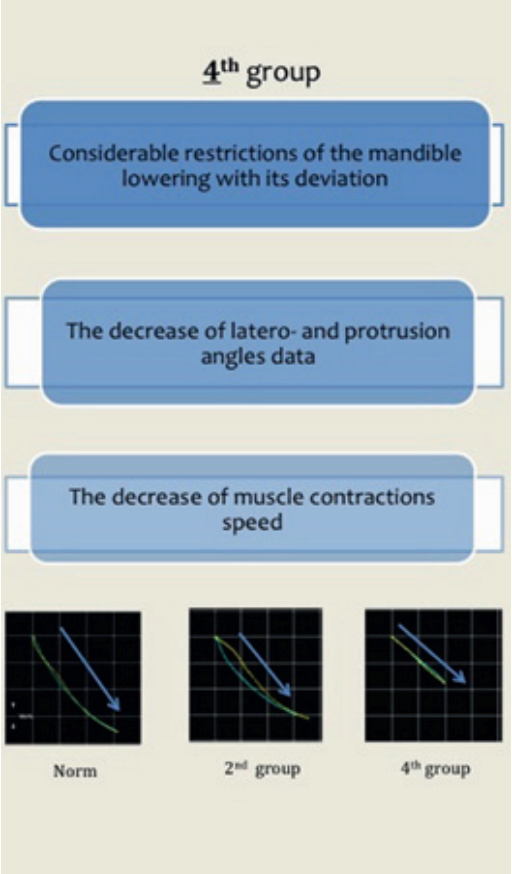


Fig. 11

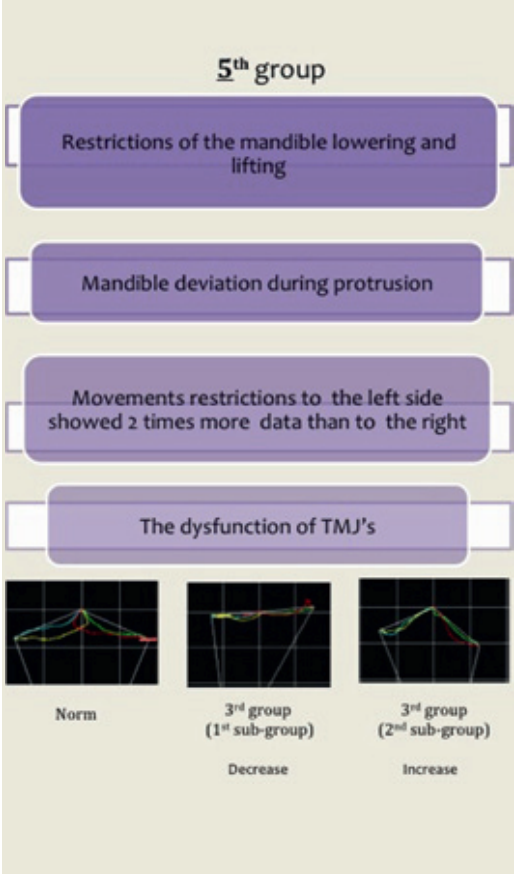


Fig. 10
Restriction of mandibular lowering in patients in the fourth group.

Fig. 11
Lateral mandibular movements in patients in the third group (the first and second subgroups) and the fifth group.

Fig. 12
Morpho-functional diagnostics using kinesiography.

Fig. 12

Discussion

A number of authors have carried out particular assessment in order to compare two approaches to patient treatment: extraction or nonextraction.[25–27] Various combinations of tooth extraction have been examined, and most of these cases were located in the area of the premolars (from one to four teeth). The requisite data were gained from models and radiographs before, during and after the treatment. Also, authors compared changes in extraction versus nonextraction orthodontic treatment using pre- and post-treatment lateral cephalograms, comparing the skeletal, dental and soft-tissue profile changes, but no functional diagnostics or TMJ condition study was performed. For example, an investigation was carried out at the University of California, San Francisco Graduate Orthodontic Clinic on treatment for correction of a Class I or II malocclusion. There were 148 patients examined. With regard to the primary decision as to whether extraction or nonextraction treatment was to be preferred, agreement among clinicians was higher than had been anticipated, but how did the clinicians make their decision on whether to extract? Crowding was cited as the first reason in 49% of decisions to extract, followed by incisor protrusion (14%). Clinicians focused heavily on appearance-related factors that are qualitatively determinable by physical examination of the surface structures of the face and teeth, but no functional tests were conducted.[28, 29]

Fig. 13a–c

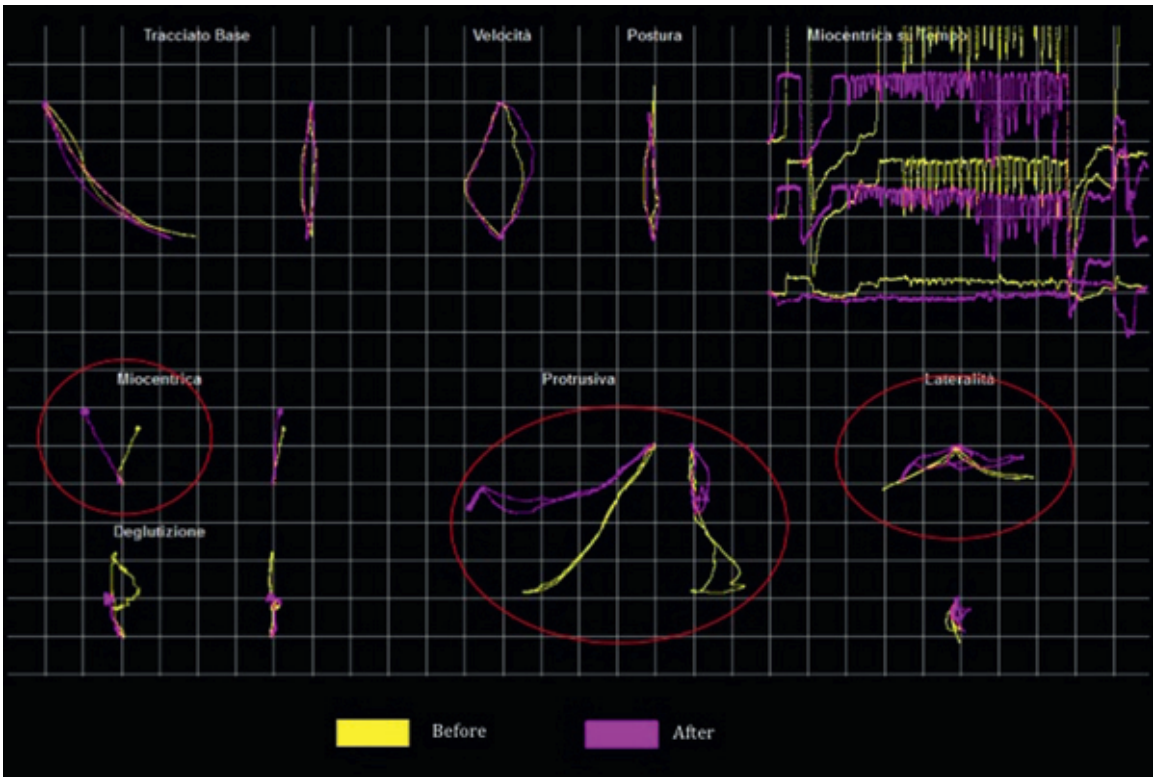


Fig. 14

Figs. 13a–c

The patient before and after treatment. Prepared spaces for the implants.
(a) Before treatment.
(b) Implant placement.
(c) After treatment.

Fig. 14

Example of the kinesiogram before (yellow) and after (violet) the patient's treatment.

Nevertheless, there is no one common approach to the decision on whether it is necessary to extract teeth as long as such clinical situations continue to arise.[4] In most cases, authors insist that tooth extractions are significant only for surgical patients. Furthermore, it is known that it is better not to perform tooth extractions with border cases in order to avoid further complications.[9]

We highly agree with authors who suggest provision of nonextraction orthodontic treatment by using finishing wires of a particular material, size and arch form. The main determinants of final arch form and dimension appear to be the original muscular and occlusally related arch form and dimension and the amount of crowding to be relieved.[30] Evident changes in soft tissue and dentoalveolar characteristics appear with tooth extraction than is the case with dental arch expansion and tooth movement. Also, several studies have been conducted to estimate the effect of dental arch length reduction (owing to dental extractions, dental agenesis and dental malpositions) during orthodontic treatment on the upper airway development.[31]

To our regret, there are no scientific reports on changes to the TMJ, muscle system and mandibular movements after orthodontic treatment with extraction. However, in our opinion, these indicators are more important than esthetic indicators. Esthetic indicators will be harmonious only when both morphological and functional indicators are taken into account.

All the methods for orthodontic research can be considered as a background for making a decision on further treatment and precise consequence assessment. The more initial scientific planning is carried out, the more effective the

treatment scheme formed and accomplished will be. Overall, orthodontic treatment planning, with or without extraction, is supposed to take into account not only morphological parameters but also parameters vital for function. Functional investigation of patients should be extensive and applied in current orthodontic practice.

Conclusion

In all of the groups examined after orthodontic treatment that included dentition size and shape reduction for partial primary or secondary tooth edentia, problems were registered during mandibular movements. These problems were mainly related to the restriction of mandibular movement during lowering and lifting, of lateral movement and of muscle contraction speed. Moreover, TMD was reported. Improvements were seen with the regain and restoration of the edentulous spaces.

Competing interests

The present study was self-funded. All of the authors declare no conflict of interests.

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Two implants supporting a mandibular overdenture to rehabilitate Cawood and Howell Class V and VI patients: a proof-of-concept study

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Abstract

Objective

The objective of this study was to present the preliminary results one year after loading for a single cohort of Cawood and Howell Class V and VI patients rehabilitated with a mandibular overdenture supported by two implants using a novel low-profile retention system.

Materials and methods

Completely edentulous individuals, aged 18 years or older at the time of implant placement, presenting as Class V or VI according to Cawood and Howell were enrolled and treated with two implants, low-profile direct implant overdenture attachments and a removable complete mandibular denture. Outcome measures were success rates of the implants and prosthesis, complications, marginal bone levels, bleeding index, plaque index and patient satisfaction (Oral Health Impact Profile).

Results

A total of 18 Osstem TSIII implants (diameter: nine regular and nine mini) were placed in nine consecutive edentulous patients (seven female and two male) presenting with Cawood and Howell Class V ($n = 6$) or VI ($n = 3$) mandibular atrophy. The average age of the patients was 68 (range: 53–77). The participants were followed up for a minimum of one year (mean: 18.2 months; range: 12–22) after definitive loading. No participants dropped out, and no deviation from the original protocol occurred. At the one-year follow-up, no implants or prosthesis had failed, resulting in cumulative implant and prosthetic survival rates of 100%. No biological or technical complications occurred during the follow-up, resulting in cumulative implant and prosthetic success rates of 100%. At the one-year follow-up, the mean marginal bone loss was 0.39 ± 0.15 mm. The Oral Health Impact Profile summary scores demonstrated a significant decrease one month after prosthesis delivery ($p = 0.0000$) and between the one-month and one-year follow-ups ($p = 0.0005$), after retention system replacement. At the one-year follow-up, the bleeding index was 8.3% and the plaque index was 9.7%.

Conclusion

Within the limitations of this study, a mandibular overdenture supported by two implants can be considered an effective and predictable option

for successful treatment of patients presenting with Cawood and Howell Class V or VI mandibular atrophy. After a short period of accommodation, it is recommended to replace the conventional retention caps with stronger ones to improve overdenture stability and thus patient satisfaction.

Keywords

Dental implant, overdenture, retention system, atrophic mandible, edentulous.

Introduction

Edentulism can lead to significant functional impairment and unfavorable esthetic and psychological changes in patients. Problems include restrictions in diet, speech impairment, loss of soft-tissue support and decreased vertical dimension.[1] The conventional method for treating edentulism is to provide complete dentures. However, progressive and irreversible loss of basal bone may lead to incrementally increasing difficulties for the denture patient, especially in relation to the mandible, creating problems like loss of retention and stability, hyperplasia and ulceration of the underlying mucosa, discomfort and pain, and impaired psychosocial functioning.[2] A removable implant-supported prosthetic design offers better retention and improves oral function and patient satisfaction compared with a conventional complete denture.[3,4] Furthermore, in the mandible, it is possible to load implants immediately without increasing the risk of implant failure.[5-7] Implant overdentures have been the subject of several clinical trials and systematic reviews, which have demonstrated them to be an effective and clinically predictable approach to obtaining improved retention and hence masticatory function and patient satisfaction.[8,9]

Implant overdentures can be divided into two subcategories:[1] implant-retained, mucosa-supported overdentures (retained by different abutment or bar designs); and overdentures fully supported by implants.[10,11] In contrast to a mucosa-supported overdenture, an overdenture that is rigidly anchored to a milled bar supported by four interforaminal implants prevents rotational movement of the prosthesis, reducing possible jaw resorption and consequently possibly also the incidence of prosthodontic maintenance.[10] In patients with an altered skeletal maxillomandibular relationship and severe bone atrophy (Cawood and Howell Class V and VI),[12] an overdenture fully supported by four implants has been shown to be a predictable method for long-term treatment of edentulous patients.[10] Nevertheless, limitations such as financial restrictions sometimes prevent the placement of a sufficient number of implants to accommodate a fixed dental prosthesis and therefore an alternative for edentulous patients with compromised oral function is required.

The purpose of this proof-of-concept study was to present the preliminary results one year after loading for a single cohort of Cawood and Howell Class V and VI[1] patients rehabilitated with a mandibular overdenture supported by two implants using a novel low-profile retention system. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines.[13]

Materials and methods

This prospective case series study was carried out in accordance with the Declaration of Helsinki of 1975, as revised in 2008. All of the participants were consecutively enrolled and treated in two private centers after being informed about the nature of the study and providing their written consent. Any healthy edentulous individual aged 18 years or older at the time of implant placement with Class V or VI mandibular atrophy according to Cawood and Howell,[1] assessed by a cone beam computed tomography scan **(Fig. 1)**, was considered eligible for the study. Exclusion criteria were general contraindications to oral surgery, pregnancy or nursing, intravenous bisphosphonate therapy, alcohol or drug abuse, heavy smoking (≥ 20 cigarettes/day), radiation therapy to the head or neck region within the last five years, parafunctional activity, untreated periodontitis, and allergy or adverse reactions to the restorative materials.

All of the patients received a new conventional removable denture before implant place-

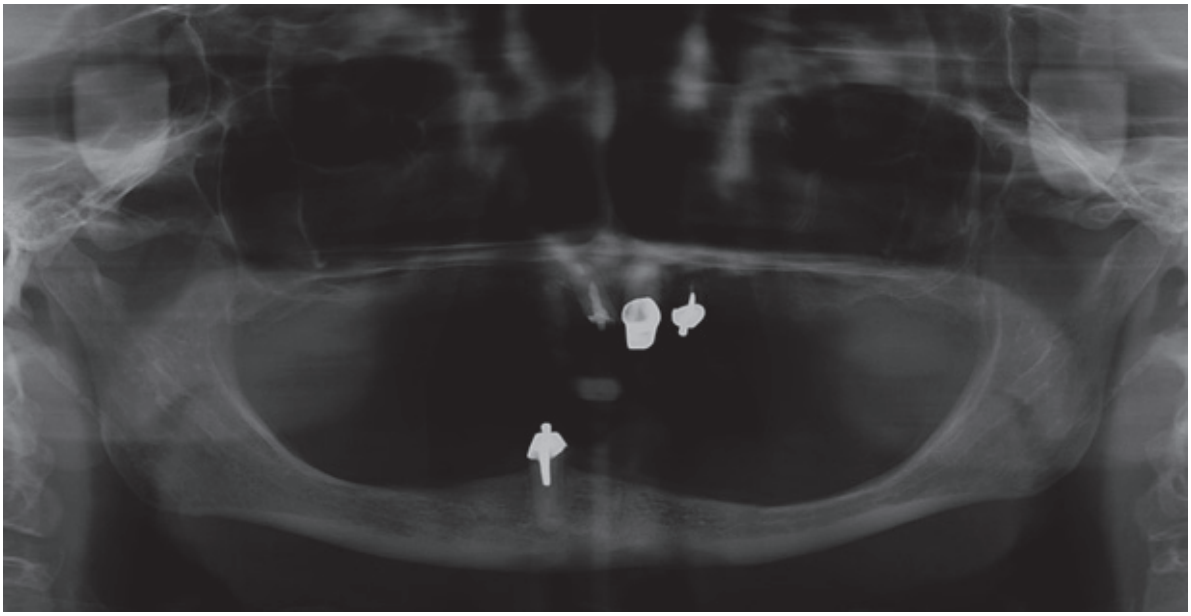
Fig. 1

Fig. 1
Preoperative radiograph.

ment, according to the respective functional and esthetic requirements. Impressions were taken, a master cast was poured, occlusal registrations were taken, and a wax-up was prepared and tried in. The conventional removable denture was delivered one week before the surgery and used as a guide for the implant placement. On the day of the surgery, a single dose of an antibiotic (2 g of amoxicillin or 600 mg of clindamycin if allergic to penicillin) was administered 1 h before implant placement and continued for six days after surgery. Immediately before surgery, the participants rinsed with a 0.2% chlorhexidine mouthwash for 1 min. Local anesthesia was administered with a 4% articaine solution with 1:100,000 epinephrine (Ubistein, 3M ESPSE, Seefeld, Germany). Minimally invasive mucoperiosteal flaps, without releasing incisions, were elevated. Then, the implants were placed in the interforaminal region of the mandible according to a one-stage approach.[14] Each participant received two implants (Osstem TSIII, Osstem, Seoul, South Korea), placed according to a previously published surgical protocol, recommended by the manufacturer, in order to achieve an insertion torque of at least 35 N cm.[15] After surgery, the patients were instructed to avoid brushing and trauma at the surgical site. A cold and soft diet was recommended for ten days. Smokers were recommended to avoid smoking for three days postoperatively, and oral hygiene instructions were given. Analgesics (600 mg of ibuprofen) were prescribed as needed. Sutures (if present) were removed after ten days.

The prosthetic procedures were begun eight weeks after implant placement. The healing abutments were unscrewed, the implant connections were cleaned and the newest low-profile direct implant overdenture attachments (OT Equator, Rhein83, Bologna, Italy; **Fig. 2**) were screwed on to the implants, using the OT Equator square screwdriver (Rhein83), with a torque range of 22–25 N cm. The cuff heights ranged from 0.5 to 7.0 mm, depending on the height of the transition zone of each implant, easily measured using the color-coded millimeter Cuff Height Measurer Gauge (Rhein83) after healing abutment removal. Afterward, spaces to accept the female housing steel cage were prepared in the fitting surface of the new removable complete mandibular denture. Silicone protective discs (Rhein83) were placed over the OT Equator attachments **(Fig. 3)**. Extra-soft (yellow, 600 g) or soft (pink, 1,200 g) retentive caps were placed in to the female steel housing, attached to the OT Equator and finally fixed to the denture using self-cured acrylic resin while the patient held the dentures in centric occlusion, chairside. After complete polymerization, the denture was picked up and silicone discs removed. Acrylic excess was trimmed and the denture was refined and polished **(Fig. 4)**. One month after prosthesis delivery, the retentive caps were replaced with a stronger type (violet, 2,700 g; **Fig. 5**). The occlusion was developed to deliver a lingualized occlusion in centric relation with balanced contacts during function, avoiding any premature contacts **(Figs. 6a & b)**.

Fig. 2

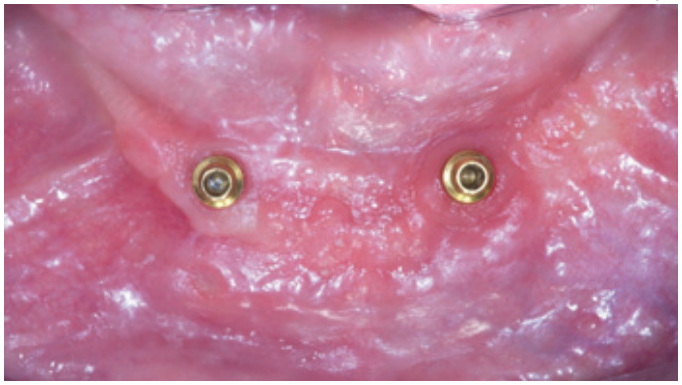

Fig. 3

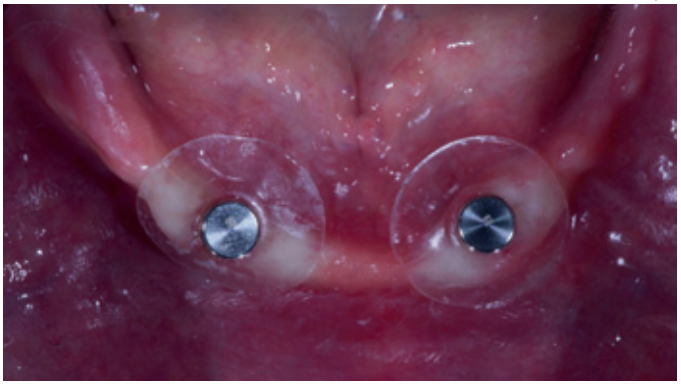

Fig. 4

Fig. 5

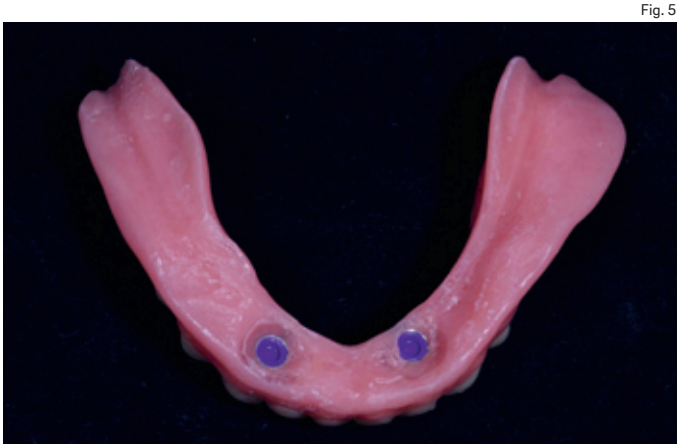

Fig. 6a

Fig. 6b

Nevertheless, when the opposing arch was a removable complete denture, the over-jet was left purposely broad, from 2 to 5 mm in order to avoid interferences during function. Instructions were given to the patients, and recall visits were scheduled for occlusal adjustments and oral hygiene quality control every six months and for retentive cap replacement every year **(Figs. 7 & 8)**.

Outcome measures

The primary outcome measures were the following:

– Success rates of the implants and prosthesis: An implant was considered a failure if it presented with any mobility, assessed by tapping or rocking the implant head with the metallic handles of two instruments, progressive marginal bone loss or infection, and any mechanical complications rendering the implant unusable, although still mechanically stable in the bone. A prosthesis was considered a failure if it needed to be replaced with another prosthesis.

– Complications: Any biological (pain, swelling, suppuration, etc.) and/or mechanical (screw loosening, fracture of the framework and/or the veneering material, etc.) complications were evaluated.

Fig. 2
Clinical view after placement of the two implants (Osstem TSIII) according to a one-stage protocol.

Fig. 3
Silicone protective discs before denture rebase.

Fig. 4
Soft retentive caps in the female steel housing.

Fig. 5
Stronger retentive caps.

Figs. 6a & b
View of the definitive prosthesis.

Table 1
Patients and implant outcomes.

	Age (years)	Sex	Smoking	Implants	Implants 8.5 mm length	Implants 10 mm length	Implants 3.5 mm wide	
Patient 1	67	F	0	2	0	2	0	
Patient 2	74	F	0	2	0	2	2	
Patient 3	77	F	0	2	0	2	2	
Patient 4	71	F	0	2	0	2	0	
Patient 5	66	F	0	2	0	2	0	
Patient 6	64	M	0	2	0	2	0	
Patient 7	53	F	0	2	0	2	2	
Patient 8	72	M	0	2	2	0	2	
Patient 9	68	F	0	2	0	2	1	
Total		7F/2M		18	2	16	9	
Mean ± SD	68 ± 7							

MBL = Marginal bone loss; OHIP = Oral health impact profile; T0 = Baseline; T1 = One month after definitive prosthesis delivery; T2 = One year after definitive prosthesis delivery; BI = Bleeding index; PI = Plaque index; SD = Standard deviation.

Fig. 7
Close-up view of the low-profile attachments (OT Equator).

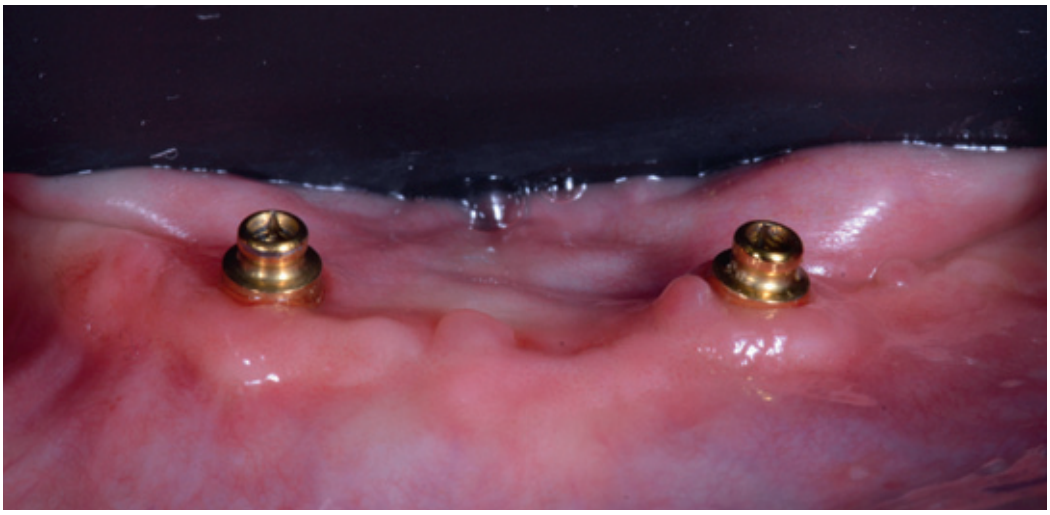

Fig. 7

– Marginal bone levels: The levels were assessed using intraoral digital periapical radiographs (Digora Optime, SOREDEX, Tuusula, Finland; photostimulable phosphor imaging plate, size 2, pixel size of 30 µm, resolution of 17 lp/mm) at implant placement (baseline) and one year after loading. Intraoral radiographs were taken with the paralleling technique by means of a periapical radiograph with a commercially available film holder (Rinn XCP, Dentsply Rinn, Elgin, Ill., U.S.). The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. All readable radiographs were uploaded to an image analysis software package (DfW 2.8, SOREDEX) that was calibrated using the known length or diameter of the dental implants and displayed on a 24 in. LCD screen (iMac, Apple, Calif., U.S.) and evaluated under standardized conditions (ISO 12646:2004). The marginal bone levels were determined from linear measurements performed by an independent calibrated examiner on each periapical radiograph, from the mesial and distal margin of the implant neck to the most coronal point where the bone appeared to be in contact with the implant.
– Patient satisfaction with function and esthetics was assessed using a scale of 1–10, where 10 = fully satisfied, 5 = satisfied and 1 = not satisfied. Quality of life was assessed by the Oral Health Impact Profile (OHIP-21) questionnaire, which was completed by the participants. The questionnaire consists of seven subscales (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disabil-

Table 1

	Implants ≥ 4 mm wide	Failed implant	Failed prosthesis	MBL mm)	OHIP T0	OHIP T1	OHIP T2	BI	PI
	2	0	0	0.20	69	38	26	1	0
	0	0	0	0.30	78	35	21	2	2
	0	0	0	0.30	83	29	21	0	0
	2	0	0	0.50	68	30	16	0	1
	2	0	0	0.30	65	22	22	0	0
	2	0	0	0.70	80	28	24	3	4
	0	0	0	0.30	74	34	22	0	0
	0	0	0	0.40	72	29	18	0	0
	1	0	0	0.50	76	24	18	0	0
	9	0	0					8.3%	9.7%
				0.39 ± 0.15	74 ± 6	30 ± 5	21 ± 3		

ity, and handicap) with two to four questions each. Participants chose from five possible responses for each question as follows: never, hardly ever, occasionally, fairly often and very often. Items were scored on a five-point ordinal scale ranging from 1 (never) to 5 (very often). Lower OHIP total scores are suggestive of improvement in oral health-related quality of life. The questionnaire was administered before treatment and one month and one year after definitive prosthesis delivery.

– Bleeding index and plaque index were evaluated at four sites around each implant-abutment interface at the one-year examination with a periodontal probe (PCPUNC156, Hu-Friedy, Milan, Italy).

An independent dentist evaluated the implant and prosthetic survival and success rates and administered the patient satisfaction and OHIP questionnaires. Complications were assessed and treated by the treating clinician, who was nonblinded. Marginal bone level changes were evaluated by an independent radiologist. An independent blinded dental hygienist who was otherwise not involved in the study performed all of the periodontal measurements.

All data analysis was carried out according to a pre-established analysis plan using software (IBM SPSS Statistics for Macintosh, Version 22.0, IBM, Armonk, N.Y., U.S.). Descriptive analysis was performed using means, standard deviations and a 95% confidence interval. Comparison of the means for marginal bone level changes, patient satisfaction and OHIP scores between the baseline and one-year follow-up examinations was performed by paired tests. A biostatistician with expertise in dentistry analyzed the data.

Results

A total of 18 Osstem TSIII implants of 8.5 mm (n = 2) or 10 mm (n = 16) in length and a regular diameter (n = 9) or mini diameter (n = 9) were placed in nine consecutive edentulous participants (seven female and two male) presenting with Cawood and Howell Class V (n = 6) or VI (n = 3) mandibular atrophy. The participants were followed up for a minimum of one year (mean: 18.2 months; range: 12–22) after definitive loading. The average age of the patients was 68 (range: 53–77). The main patient and implant characteristics are shown in **Table 1**. No participants dropped out, and no deviation from the original protocol occurred. At the one-year follow-up, no implants or prosthesis had failed, resulting in cumulative implant and prosthetic survival rates of 100%. No biological or technical complications occurred during the follow-up, resulting in cumulative implant and prosthetic success rates of 100%. At the one-year follow-up, the mean marginal bone loss was 0.39 ± 0.15 mm. The OHIP summary scores demonstrated a significant decrease between the pre-treatment scenario and the one-month after prosthesis delivery (p = 0.0000) and between the one-month and one-year follow-ups (p = 0.0005), after retention system replacement. At the one-year follow-up, the bleeding index was 8.3% and the plaque index was 9.7%. All of the data are summarized in **Table 1**.

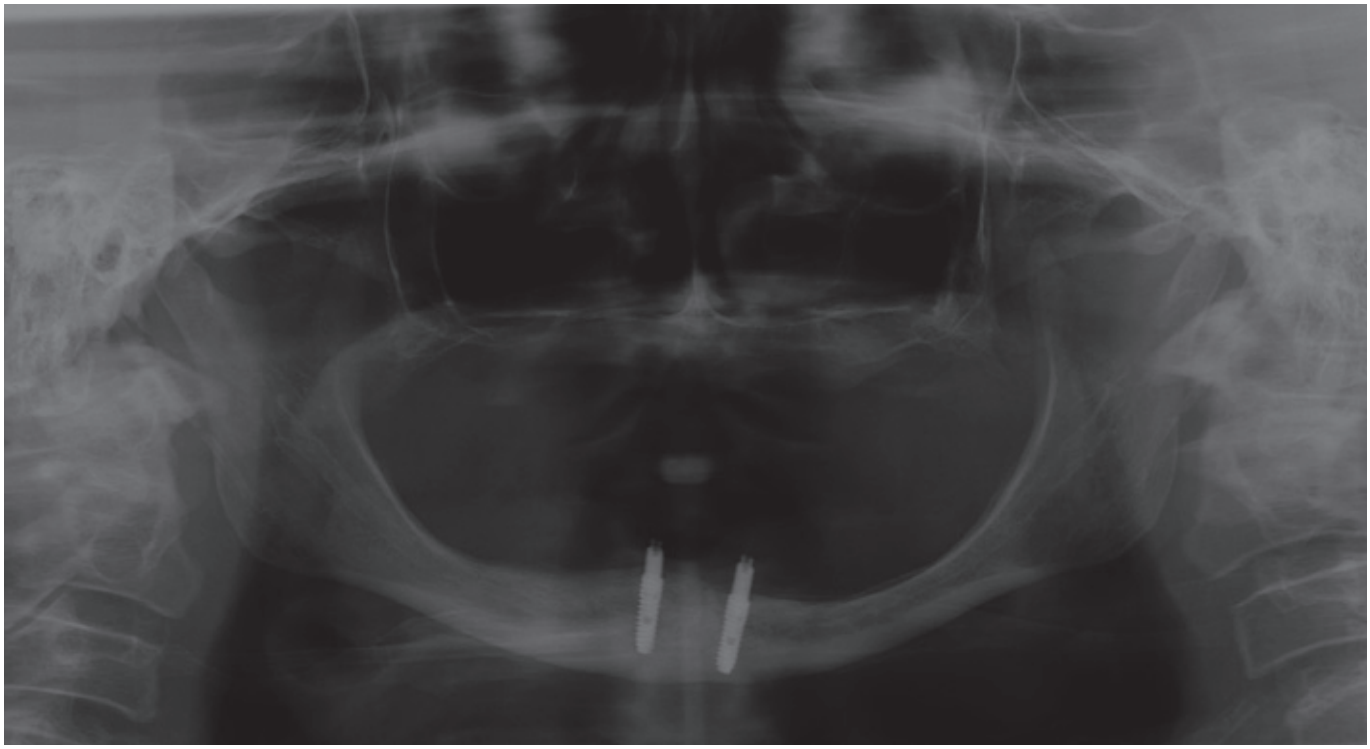

Fig. 8

Fig. 8
Postoperative radiograph.

Discussion

This prospective case series study was designed to evaluate the one-year clinical and radiographic outcomes and patient satisfaction of Cawood and Howell Class V and VI patients treated with a mandibular overdenture supported by two implants using a novel low-profile retention system. Because it was designed as a single-cohort study without sample size calculation, the main limitations were the lack of a control group and a small sample size. Hence, this investigation should be considered as a proof of concept for future multicenter randomized clinical trials with control group comparison.

The results of the present one-year preliminary prospective case series study reported implant and prosthetic survival and success rates of 100% and greater patient satisfaction, indicating that patients with extremely atrophic mandibles (Cawood and Howell Class V and VI) may be rehabilitated using fixed-removable solution.

Owing to increased life expectancy, the treatment of elderly patients is advancing in medicine. With the alveolar bone resorbed and the vertical dimension of the mandible reduced, an altered relationship to the maxilla; poor, variable bone for implant restoration; and loss of cheek and lip support result. According to the literature, implant-retained mandibular overdentures can be an effective treatment option for patients who have persistent problems with conventional dentures.[4] Various attachment systems have been successfully utilized to connect these overdentures to the implants including bar, ball, magnetic and resilient telescopic attachments.[16] A relatively recent attachment that has become increasingly popular is the OT Equator low-profile direct implant overdenture attachment **(Fig. 7)**. It is a resilient and self-aligning attachment system with stable retention. Owing to its low profile, it can be used with limited interarch distance. In addition, in the present study, the low-profile OT Equator attachments were used to rehabilitate severely atrophic patients, reducing the risk of denture base fracture over time. In addition, OT Equator attachments allow for angle compensation of up to 30°, which may be helpful in severely atrophic patients with different severities of mandibular atrophy and lingual concavities that may compromise the ability to place axial implants without bone reconstruction. Furthermore, the new Smart Box allows passive insertion under extreme conditions, also up to 50° divergence **(Fig. 8)**.

The findings of this study support the established evidence base for improvement in edentulous patients' satisfaction with their prostheses when two implants are used to retain their

complete mandibular dentures, even in severely atrophic patients. In the present study, extra-soft or soft retentive caps were used during the first month after loading in order to allow for easy management by patients. The stronger retentive caps were used to improve the balance between mucosal support and implant retention, also increasing patient satisfaction.

A mandibular overdenture supported by two implants is a well-proven treatment option for severely atrophic patients when a conventional removable denture is not sufficient to ensure function and esthetics. In this historic time, in which the average age of patients has increased, it is important to have a minimally invasive, safe and predictable treatment option that can greatly improve quality of life of patients.

Conclusion

Within the limitations of this study, a mandibular overdenture supported by two implants can be considered an effective and predictable option for successful treatment of patients presenting with Cawood and Howell Class V or VI mandibular atrophy. After a short period of accommodation, it is recommended to replace the conventional retention caps with stronger ones to improve overden-ture stability and thus patient satisfaction.

Competing interests

All authors declare no conflicts of interest.

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Patients have a right to privacy that should not be violated without informed consent. Identifying information, including patients' names, initials or hospital numbers, should not be provided in the manuscript or visual material unless the information is essential for scientific purposes and the patient (or parent or guardian) has given written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication. Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, authors should provide assurance that alterations do not distort scientific meaning. **When informed consent has been obtained, it should be indicated in the manuscript.**

Human and animal rights

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Declaration of Helsinki of 1975, as revised in 2013 (www.wma.net/en/30publications/ 10policies/b3/index.html). If doubt exists whether the research was conducted in accordance with the Declaration of Helsinki, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should indicate whether institutional and national standards for the care and use of laboratory animals were followed. Further guidance on animal research ethics is available from the International Association of Veterinary Editors' Consensus Author Guidelines on Animal Ethics and Welfare (www.veteditors.org/consensus-author-guidelines-onanimal-ethics-and-welfare-for-editors).

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Authors are required to declare any competing financial or other interests regarding the article submitted. Such competing interests are to be stated at the end of manuscript before the references. If no competing interests are declared, the following will be stated: "The authors declare that they have no competing interests."

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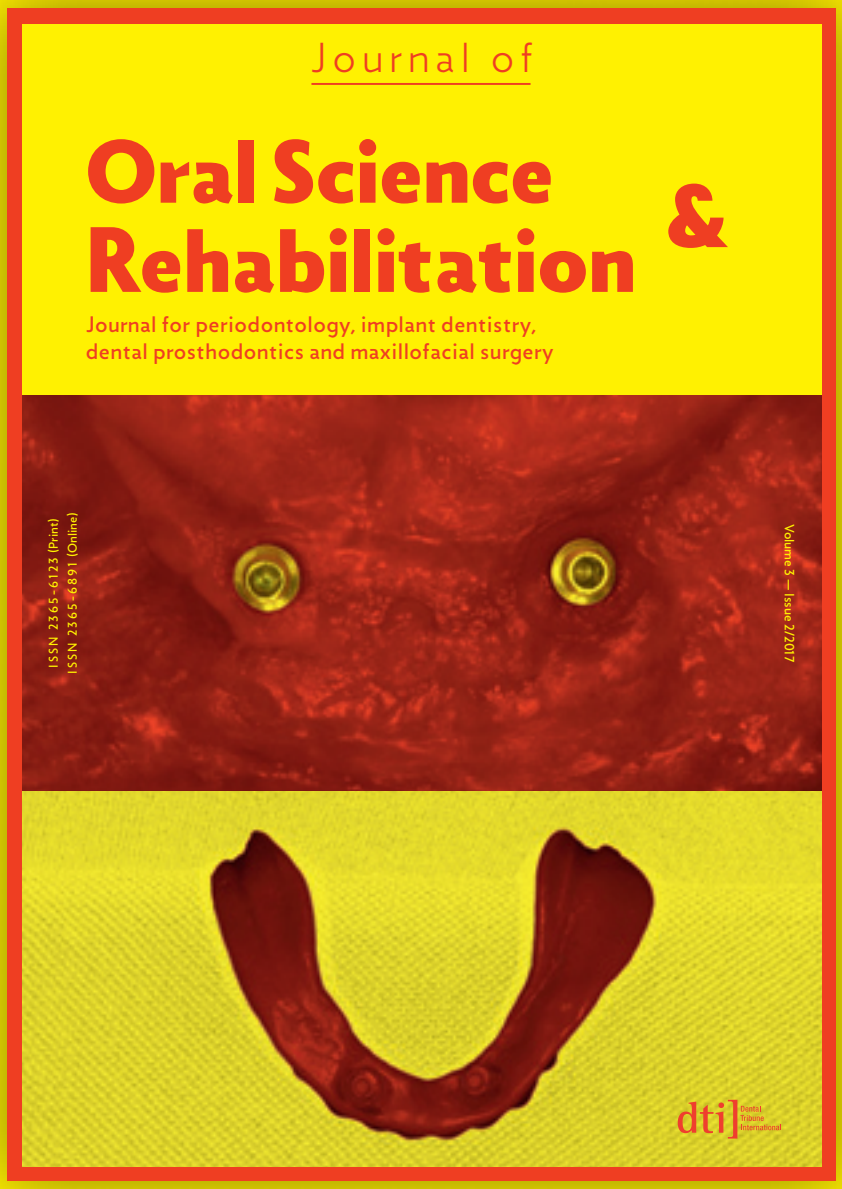

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