KEY WORDS
dental implants, case series, cantilevered prosthesis, single implant

Case series

SINGLE IMPLANTS SUPPORTING A 3-UNIT CANTILEVERED MAXILLARY PROSTHESIS: A PROSPECTIVE CASE SERIES WITH 2-YEAR FOLLOW-UP

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OBJECTIVES. To evaluate the clinical outcome of a purpose-designed implant, placed in the upper premolar position of distally edentulous jaws, supporting a 3-unit cantilevered screw-retained prosthesis.

MATERIALS AND METHODS. Sixteen patients received, in the upper premolar area, a single implant specifically designed to support a 3-unit distally cantilevered screw-retained prosthesis. Implants were loaded after 3 to 5 months of submerged healing, depending on bone density. Eight prostheses were made of metal-composite and eight of fibre-reinforced composite at the discretion of the dentist. Outcome measures, evaluated by an independent assessor, were: prosthesis and implant failure, complications and peri-implant marginal bone level changes.

RESULTS. No patient dropped out. No implant or prosthesis failed. Three (19%) patients were affected by complications. After 2 years the mean marginal bone loss was 0.45 mm.

CONCLUSIONS. These short-term results suggest that a 3-unit distally cantilevered prostheses can be supported in the maxilla by a single, purpose-designed dental implant up to 2 years after loading. Proper studies with follow-ups of about 10 years are needed to ascertain the long-term prognosis of this treatment option.

CONFLICT OF INTEREST STATEMENT. This case series was completely self-financed, and no financial support was sought or obtained, not even in the form of free materials.

INTRODUCTION

The rehabilitation of edentulous atrophic jaws with fixed prostheses can be challenging since there may always be not sufficient bone to place conventional implants. In such cases, bone augmentation procedures or special types of dental implants (short, tilted, trans-sinus, pterygoid and zygomatic implants) must be considered. One of the most common and challenging conditions to treat is distal edentulism, in which molars, and sometimes premolars, have been lost. In this situation, often only small amounts of crestal bone are left due to the presence of large pneumatized sinuses or the mandibular canal.

The ideal treatment for distal edentulism in the presence bone volumes insufficient to place even a substantial number of implants as short as 4 mm would be a fixed implant-supported prosthesis, ideally without involving bone augmentation procedures (sinus lifts, bone block inlays or onlays). To this end, tilting implants have been proposed, but rehabilitation with these may be difficult and patients may find it difficult to maintain adequate oral hygiene. The use of zygomatic[1,2], nasal[3] or pterygoid implants, may be associated with serious complications and can be challenging to place. It would be preferable to be able to offer patients a

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functional fixed implant-supported prosthesis after minimal surgical intervention at reduced biological and economical cost and with good long-term success rates. In this context, it would be interesting to discover whether posterior edentulous maxillae with large pneumatized sinuses could be rehabilitated with a fixed 3-unit cantilevered prosthesis supported by a single implant placed in the premolar area, where sufficient bone volumes may still be available.

In some countries, cantilevers are seldom used because implant-supported prostheses with long cantilevers have been associated with higher complications and failures rates, as compared to prostheses with no or short cantilevers, especially in posterior areas[4,5]. That being said, no significant differences in bone loss are generally observed[5-7]. One of the possible reasons for the less successful outcomes with cantilevered prostheses is biomechanical, specifically that they rely on conventional implants and prostheses, which have not been specifically engineered to perform this task. Therefore, it would be interesting to investigate whether a purpose-designed implant supporting more robust prostheses could reduce the risks of such biomechanical complications, even in challenging cases.

Hence, the aim of this prospective case series was to evaluate the clinical outcomes of single purpose-designed implants placed in the premolar position of distally edentulous upper jaws and supporting a 3-unit screw-retained distally cantilevered prosthesis. This article is reported according to the **STrengthening the Reporting of OBservational studies in Epidemiology** (STROBE) guidelines (www.strobe-statement.org).

MATERIALS AND METHODS

This study was designed as an open prospective case series. Any patient with distal maxillary edentulism from the premolars and less than 3 mm of bone height below the maxillary sinus who was 18 or older and able to understand and sign informed consent was eligible for inclusion in this case series. Eligible patients needed to have sufficient bone volumes in the upper premolar region to allow the placement of one implant with a diameter of 5 mm and length at least 8.5 mm, as well as canine guide, effective contralateral dentition and sufficient intermaxillary space to host a prosthesis framework of at least 4 mm in height. Immediate post-extraction dental implants were allowed.

Patients were not accepted into this case series if any of the following exclusion criteria applied: 1) general contraindications to implant surgery (at the discretion of the surgeon); 2) uncontrolled diabetes; 3) pregnancy or lactation; 4) addiction to alcohol or drugs; 5) psychiatric problems; 6) unrealistic expectations; 7) irradiation to the head and/or neck; 8) previous or ongoing treatment with intravenous aminobisphosphonates; 9) poor oral hygiene and motivation; 10) untreated periodontitis; 11) active infection or severe inflammation in the area intended for implant placement; 12) need for bone-augmentation procedures at the implant site; 13) participation in other trials; 14) lack of opposing occluding dentition/prosthesis/dentures.

Patients were categorised on the basis of their declaration into non-smokers, moderate smokers (up to 10 cigarettes per day) or heavy smokers (more than 10 cigarettes per day). Patients were also grouped according to the type of dentition occluding against the fixed prosthesis under investigation (natural dentition/fixed prosthesis *versus* removable prosthesis).

All patients received through explanation and were informed about alternative treatment options before signing informed written consent and being enrolled in the trial. Patients were recruited and treated in one private practice in Pavia, Italy. One dentist (Dr. Cannizzaro) performed all surgeries, and another dentist (Dr. Sorce) did all the prosthetic interventions.

Preliminary screening was performed on cone-bean CT scans. All patients received professio-

nal oral hygiene treatment prior to the operation, and prophylactic antibiotics (2 g of amoxicillin orally) one hour prior to the intervention. Patients allergic to penicillin were given 600 mg of clindamycin 1 hour prior to the intervention. Patients rinsed with a 0.2% chlorhexidine mouthwash for 1 minute immediately prior to the intervention. Local anaesthesia was administered using articaine with epinephrine 1:100,000. Flaps were raised after crestal incision, but implants could also be placed flapless and free-hand.

A tapered titanium implant (Syra Magnum, Sweden & Martina, Due Carrare, Italy) with 1.5-mm-high external hexagon and zirconia-blasted acid-treated surface was specially designed. All implants had a diameter of 5 mm, but the operator was free to choose the implant length (8.5 and 10 mm) according to clinical indications.

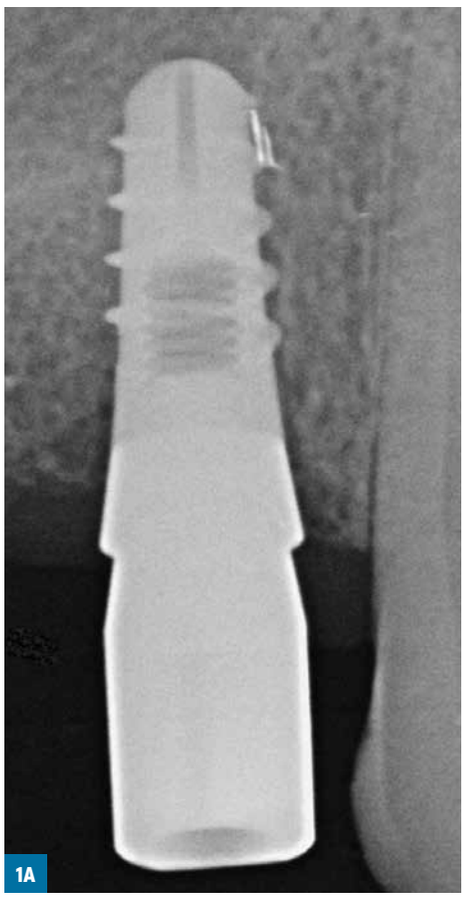
Bone quality was subjectively quantified by tactile perception at drilling, and classed as either soft, medium or hard. In soft bone, the last drill was two sizes less than the implant diameter; in medium bone quality, the last drill was one size less than the implant diameter; and in hard bone, the final drill had the diameter corresponding to that of the implant. Implants were positioned 2 mm subcrestally, and the insertion torque was measured using the motor (W&H Elcomed SA-310, Dentalwerk Buermoos, Buermoos, Salzburg, Austria) set at a torque of 80 Newton/cm. Healing screws were placed and implants submerged, and flaps were sutured when necessary.

After surgery, patients were instructed to avoid brushing at the surgical sites and to rinse twice a day with 0.12% chlorhexidine for 2 weeks. A cold soft diet was recommended for 7 days. Analgesics (ibuprofen 400 mg) were provided to be taken twice a day with meals, as required by the patient. Where present, sutures were removed after about 10 days. The duration of the healing period was decided according to bone quality: implants placed in hard bone were left to heal unloaded for three months, those in medium bone quality for four months, and those inserted in soft bone were left to heal unloaded for 5 months. No removable maxillary dentures were allowed during the healing period.

At the end of the healing period, in the presence of a substantial amount of keratinised mucosa, access to the healing screw was made using a diamond bur. In the presence of limited keratinised mucosa, a small flap was raised after crestal incision. Titanium or chrome-cobalt abutments with purpose-made anti-rotation slots were fitted (**FIG. 1A**) and thermoplastic caps placed on them (**FIG. 1B**). Impressions were taken with standard trays using a polyether material (Impregum, F Espe Dental, Seefeld, Germany). A plaster model was then cast (**FIG. 1C**). A small titanium bar was soldered to the titanium abutments (**FIG. 1D**), and a diagnostic model in wax was made and functionally tested in the patient's mouth (**FIGS. 1E, F**). A precise silicon master was then prepared from this functional model.

Two types of fixed definitive screw-retained prostheses were fabricated on titanium abutments: a metal-composite one for eight patients and a fibre-reinforced composite for the remaining eight patients, according to the clinician's preference. For the metal frameworks, two grade 5 titanium bars measuring 4 x 2 mm were soldered to the implant abutments using an argon welder (PUK D2, Lampert Werktechnik GmbH, Werneck, Germany) and grade 2 titanium as a filler, to compensate for the heat-induced metal retraction and thereby minimise framework tension and distortion (**FIG. 1G**). Fibre-reinforced-composite (FRC) prostheses were made using Trilor Arch (Bioloren, Saronno, Italy), a technopolymer consisting of thermo-hardening resin and multidirectional fibreglass reinforcement. The framework was hand-milled from a preformed arch, and cemented with a dual-cured, self-adhesive resin cement (TheraCem, Bisco, Schaumburg, Illinois, USA) onto the titanium abutment, which had been customised according to specific needs and equipped with anti-rotation properties (**FIGS. 1H-K**). Finally, mono-block composite teeth were prepared in the same way for both

types of frameworks (**FIGS. 1L, M**). Using the transparent silicon master, a **light-curing micro hybrid composite** (Ceramage Shofu, San Marcos, Ca, USA) was light-polymerised in a single block, replicating the model that was tried and functionalised in the mouth of the patient.
The cantilever length was between 10 to 12 mm, premolars being about 5 mm long and molars about 7 mm long in the mesiodistal direction (**FIG. 1N**). Prostheses were screwed onto the implants using standard torque of 35 Ncm (**FIGS. 1O, P**). Each patient's occlusion was adjusted so that there was minimal occlusal contact on the cantilever.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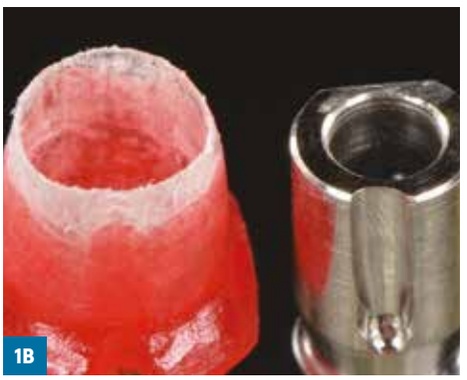
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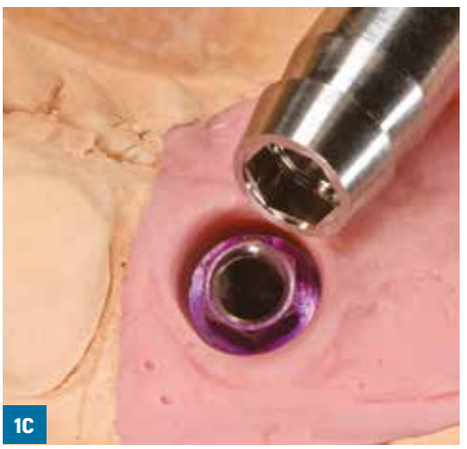
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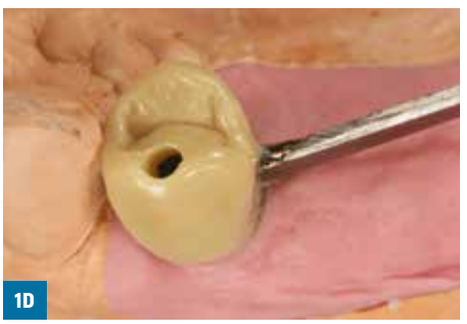
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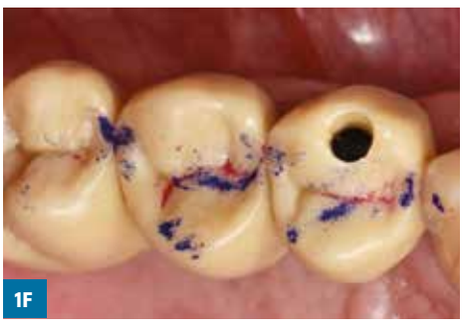
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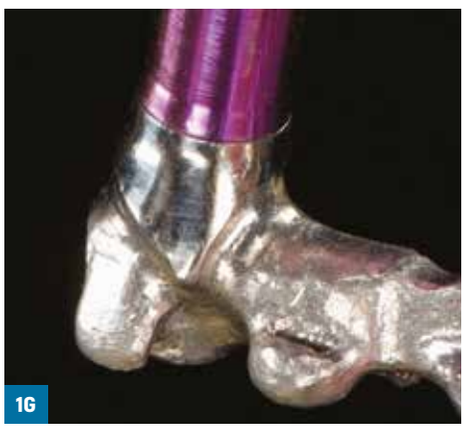
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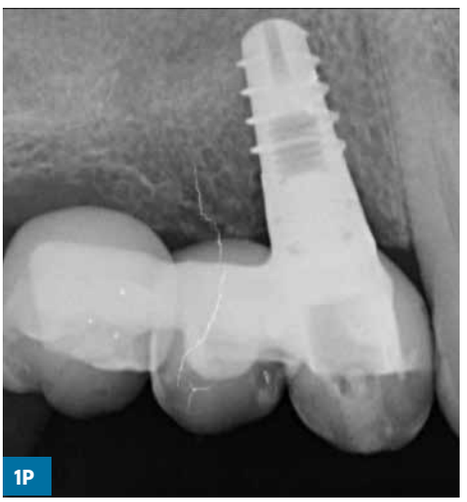

FIGS. 1A-P: *Periapical radiograph at abutment connection: the impression was taken with a chrome-cobalt abutment, but all definitive abutments were made of titanium (A); thermoplastic caps and abutments with slots made for impression-taking (B); laboratory model (C); provisional titanium bar soldered to the abutment (D); functionalisation of the wax mock-up, note the canine guidance (E); decreased contacts in the mesiodistal direction (F); titanium bar soldered to the titanium abutment (G); pristine titanium abutment to be connected to a fibre-reinforced-composite framework (H); titanium abutment after customisation, note the anti-rotation shape (I); abutment after surface-blasting to facilitate cementation (J); fibre-reinforced composite framework cemented onto the abutment (K); preparation of the mono-block composite layer (L, M); a definitive screw-retained titanium-composite 3-unit cantilevered prosthesis before delivery (N); clinical (O) and radiographic (P) views of metal-composite prosthesis in situ.*

Patients were recalled for maintenance every six months, checking for implant stability and occlusion; maintenance procedures were performed as needed.

The outcome measures evaluated in the present study were the following.

- Prosthesis failure: a definitive prosthesis lost due to implant failure(s) or that had to be remade for any reason.
- Implant failure: the presence of any mobility of the individual implant and/or any infection dictating implant removal, and/or fracture of the implants rendering the implant unusable. Individual implant stability was measured at abutment connection, and thereafter every 6 months.
- Any biological or prosthetic complications.
- Peri-implant marginal bone level changes: assessed on periapical digital radiographs taken with the paralleling technique at implant placement, initial loading, and 1 and 2 years after loading. In case of indiscernible bone levels, the radiographs were re-taken. Radiographs were stored on a personal computer in TIFF format with 600-dpi resolution. Peri-implant marginal bone levels were measured using Scion Image software (Scion Cor-

poration, Frederick, MD, USA), calibrated for each single image using the known implant length. Measurements of the mesial and distal bone crest levels adjacent to each implant were made to the nearest 0.01 mm. Reference points for the linear measurements were: the coronal margin of the implant collar and the most coronal point of bone-to-implant contact. Mesial and distal measurements were averaged for each implant and for each group.

The final follow-up was conducted 2 years after implant loading. All maintenance procedures, implant stability and radiographic evaluations were performed by one independent dentist (Dr. Lazzarini), who was not aware of the nature of the study. Complications were dealt with and reported directly by Dr. Cannizzaro.

The patient was the statistical unit of the analyses. Descriptive statistics were prepared. Paired t-tests were applied to compare marginal bone levels at baseline and at 12 and 24 months after loading. All statistical comparisons were conducted at the 0.05 level of significance.

RESULTS

Thirty-one patients were originally consecutively screened, but 15 patients were not treated because they did not feel confident that a single implant would be able to support a 3-unit cantilevered fixed prosthesis, and instead chose alternative treatment solutions or no treatment at all (6 patients). Sixteen patients were consecutively recruited and treated from September 2017 to February 2018. No drop-out or protocol deviations occurred during the 2-year post-loading period investigated. Data from all patients were evaluated in the statistical analyses. The main baseline characteristics of the patients, site and treatment are presented in **TABLE 1**. Nine patients with various pre-existing medical conditions and pathologies were included.

No prosthesis or implant failure occurred.

In total, three complications occurred in three patients. In two patients the prosthesis connecting screw loosened two months after prosthesis delivery, due to insertion with a torque lower than 35 Ncm, and was screwed back in using the proper torque. One patient did not attend check-up appointments for over a year, and presented 16 months after loading with local pain and purulent exudate (peri-implantitis). A bony crater was present around the implant. The area was surgically debrided and osteoplasty was performed to reduce the depth of the bony crater.

Mean peri-implant marginal bone levels are reported in **TABLE 1**. At implant placement the mean value was 0.12 mm (SD 0.11), and two years after loading it was 0.57 mm (SD 0.44); the difference, of 0.45 mm (CI 95% from 0.22 to 0.69), was statistically significant (P = 0.0009).

DISCUSSION

The prospective case series presented here aimed to evaluate whether a single implant, purpose-designed to avoid more complicated procedures such as sinus lifts, pterygoid or zygomatic implants, would be able to support a 3-unit distally cantilevered fixed prosthesis in the posterior maxilla. Although pertaining to a limited case series, the findings are encouraging, since no implant failed as of 2 years after loading, and the complications that did arise were manageable. Furthermore, our findings are in general agreement with a previous pilot RCT[8] that also suggested good short-term outcomes with an identical single implant supporting a cross-arch fixed prostheses of 8 to 10 mandibular teeth, and other studies evaluating single implants supporting mandibular overdentures[9,10]. Interestingly, a recent systematic review[11] comparing mandibular overdentures supported by one *versus* two implants did not find

TABLE 1 PATIENT AND INTERVENTION CHARACTERISTICS (16 PATIENTS AND 16 IMPLANTS)

Females	11 (69%)
Mean age at implant insertion (range)	62.8 years (44 to 76)
Non-smokers	11 (69%)
Smoking up to 10 cigarettes/day	5 (31%)
Smoking more than 10 cigarettes/day	0 (0%)
Patients with ongoing or past medical conditions*	9 (56%)
Patients wearing removable prosthesis in the mandible	5 (31%)
Implants inserted in fresh extraction sockets	2 (12.5%)
Implant inserted flapless	7 (44%)
Mean insertion torque (range)	57.3 (18 to 80)
Implants placed in soft bone quality	2 (12.5%)
Implants placed in medium bone quality	12 (75%)
Implants placed in hard bone quality	2 (12.5%)
Implants of length 8.5 mm	8 (50%)
Implants of length 10 mm	8 (50%)
Implants positioned in the first premolar site	11 (69%)
Implants positioned in the second premolar site	5 (31%)
Mean marginal bone levels at implant placement (SD)	0.12 mm (0.11)
Mean marginal bone levels at implant loading (SD)	0.18 mm (0.10)
Mean marginal bone levels at 1 year after loading (SD)	0.38 mm (0.20)
Mean marginal bone levels at 2 years after loading (SD)	0.57 mm (0.44)

**One patient treated with oral bisphosphonates and under renal dialysis; one with anticoagulants for previous heart attack and hypertension; one with cardiac bypass and anticoagulants; one with hypertension and hepatitis C; one with non-insulin-dependent diabetes and hypertension; one with hormone therapy after prostate carcinoma; one with chronic bronchitis and hypertension; one with Parkinson's disease; and one with depression.*

that overdentures supported by two implants were superior. That being said, the review included only three RCTs with limited follow-up and a high risk of bias. Nonetheless, if long-term trials confirm the success of the treatment option reported here, it could be a valid alternative or replacement for more invasive or risky strategies for rehabilitating atrophic jaws.

The major limitations of the present study are the lack of a control group, the small number of patients included, and the short duration of follow-up, which may obscure latent biomechanical problems that become apparent later on. Indeed, though case series or single cohort studies can help clinicians evaluate the prognosis of a given treatment, they are not sufficient grounds on which to base clinical decisions. The fact that patients in the present study were treated by a single operator may also limit the generalisation of the present findings to other settings.

Hence, we cannot at this stage recommend loading single maxillary implant with a 3-unit cantilevered prosthesis; at present the approach is purely experimental and will require validation via longer-term multicentric prospective trials aimed at evaluating the prognosis of this treatment as compared to the available alternatives.

CONCLUSIONS

The present short-term results suggest that a 3-unit distally cantilevered prosthesis can be supported by a single, purpose-designed maxillary dental implant for 2 years after loading. Proper trials with follow-ups of about 10 years are, however, required to evaluate the prognosis of this experimental treatment.

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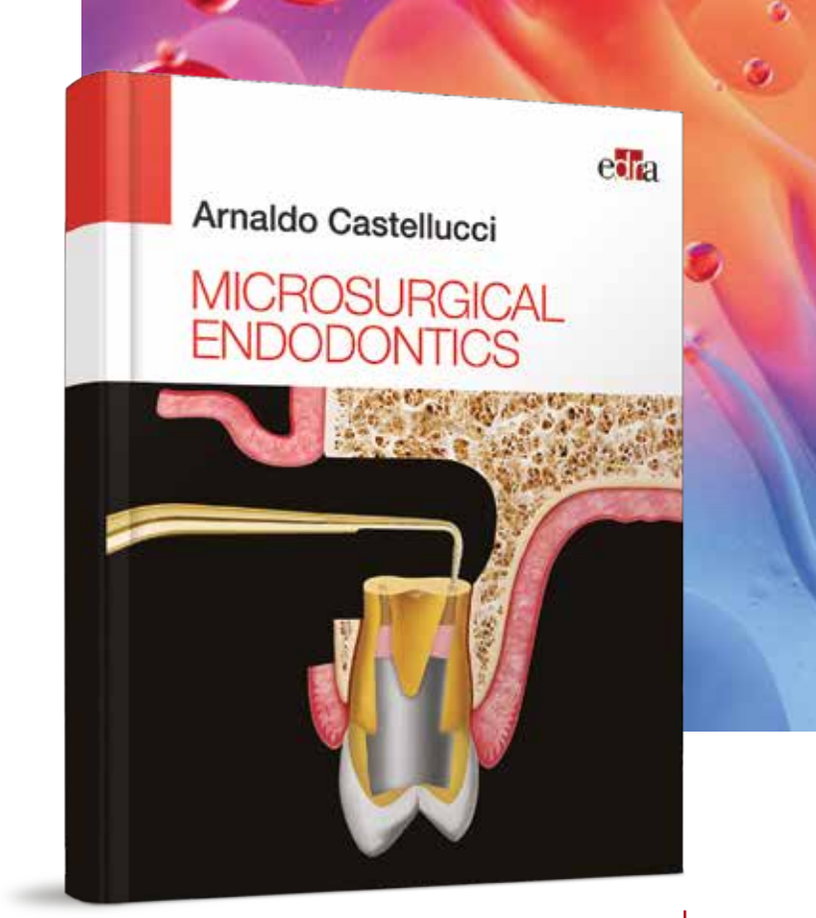

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