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Authors

Pozzi, Alessandro
Tallarico, Marco
Moy, Peter K

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CLINICAL RESEARCH

Four-implant overdenture fully supported by a CAD/CAM titanium bar: A single-cohort prospective 1-year preliminary study

Alessandro Pozzi, DDS, PhD,^a Marco Tallarico, DDS, MSC,^b and Peter K. Moy, DMD^c

The rehabilitation of the completely edentulous jaw by combining 4 implants, 2 straight medially and 2 tilted distally, was developed to overcome the anatomic limitations related to bone loss, which would otherwise be difficult to treat without more complex augmentative techniques.^{1,2} In patients with an altered skeletal maxillomandibular relationship and horizontal/vertical bone resorption (Cawood and Howell³ class IV, V, and VI), a complete fixed dental prosthesis (FDP) supported by 4 implants may be a valuable treatment option for avoiding technique-sensitive augmentation surgery.⁴⁻⁶ In these patients, the treatment concept based on combining 4 implants, 2 straight medially and 2 tilted distally, seems to be a safe, effective, and efficient surgical and prosthetic protocol for both jaws.^{7,8} The posterior tilting of the 2 distal implants is advantageous in a region where bone height and nerve or sinus proximity do not allow the placement of axial implants. Nevertheless, the current evidence is limited by the quality of available studies and the paucity of data on long-term clinical outcomes of

ABSTRACT

Statement of problem. In patients with an altered skeletal maxillomandibular relationship and bone resorption, the rehabilitation of edentulous jaws by combining 4 implants, 2 straight medially and 2 tilted distally, may be preferred to avoid a bone augmentation procedure.

Purpose. The purpose of this single cohort 1-year prospective study was to evaluate the clinical performance of a 4-implant overdenture fully supported by a computer-aided designed/computer-aided manufactured (CAD/CAM) titanium bar.

Material and methods. This single cohort prospective study included edentulous participants rehabilitated with a 4-implant overdenture in 1 of the 2 jaws. The outcomes were implant and prosthetic survival and success rates, any biologic and technical complications, periimplant marginal bone loss, changes in the oral health impact profile (OHIP), bleeding on probing, and the plaque index.

Results. Eighteen participants received 72 implants. One year after implant placement, no implants or prosthesis had failed, and no biologic or technical complications had been observed. At the 1-year follow-up, the mean marginal bone loss was 0.29 ± 0.16 mm. The OHIP summary scores demonstrated a significant improvement in oral health-related quality of life. At the 1-year follow-up, positive bleeding was found in 2 participants (11.1%) around 3 implants (4.1%). Three participants (16.6%), accounting for 5 implants (6.9%), showed a slight amount of plaque.

Conclusions. A 4-implant overdenture supported by a CAD/CAM titanium bar may be a reliable option for the treatment of the edentulous mandible and maxilla over a 1-year period. Oral health-related quality of life significantly improved in all treated participants. (J Prosthet Dent 2016;■:■-■)

5 years or more.⁹⁻¹² Moreover, hygienic maintenance of the prosthesis can be challenging, particularly in patients classified as Cawood and Howell class V or VI,³ when extensive prosthetic flanges are needed.¹³ In these patients, an overdenture can be a reliable option, and the patient should be fully informed of the benefits and limitations of both fixed and removable prostheses.¹⁴⁻¹⁷ Therefore, patient demand, compliance, dexterity,

^aInterim Chair, Oral Surgery and Implant Dentistry, Marche Polytechnic University, Ancona, Italy.

^bLecturer, University of Sassari, Surgical, Micro-Surgical and Medical Science Department, Sassari, Italy.

^cChair and Director, Implant Dentistry and the Dental Implant Center at UCLA, University of California, Los Angeles, Calif.

Clinical Implications

For the rehabilitation of edentulous patients, proper lip and cheek support, good treatment outcomes, and adequate levels of daily hygienic maintenance can be obtained with a 4-implant overdenture supported by a CAD/CAM titanium bar.

financial capability, skeletal maxillomandibular relationship, and residual bone anatomy must be considered in determining the appropriate implant number, implant position, and prostheses.¹⁸⁻²¹

The purpose of this report was to present the 1-year preliminary data from a single cohort prospective study of implant and prosthetic survival rates, patient satisfaction, and periimplant bone loss of a 4-implant overdenture (4IO) for the rehabilitation of the edentulous maxilla and mandible based on a complete removable dental prosthesis supported by a computer-aided designed/computer-aided manufactured (CAD/CAM) titanium bar screwed on 4 implants. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.²²

MATERIAL AND METHODS

This investigation was designed as single cohort prospective study, approved by the Institutional Review Board of the University of Rome, Tor Vergata, and conducted according to the principles embodied in the Helsinki Declaration of 2008. All participants were enrolled and treated in the study in consecutive order 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 IV, V, or VI according to Cawood and Howell³ as assessed by a cone beam computed tomography (CBCT) scan were considered eligible for this study. Exclusion criteria are listed in Table 1.

The patient's complete removable denture prosthesis (RDP) was relined at chairside to fit the denture-bearing area. Then, 6 to 8 spherical radiopaque gutta-percha markers (Hygienic Temporary Dental Stopping; Coltène/Whaledent) were placed in the lingual and palatal flanges. A centric occlusion rigid polyvinyl siloxane index (Exabite II NDS; GC America) was made to stabilize the patient's complete RDP against the opposing dentition during the CBCT scan. Two separate CT scans were made according to the double-scan protocol.²³ The first scan was made with the denture in place in the patient's mouth, and the second scan was of the denture only. The Digital Imaging and Communication in Medicine (DICOM) data of the 2 sets of scans were transferred to a 3-dimensional (3D) software planning

Table 1. Exclusion criteria

General Contraindications
Pregnancy or nursing
Intravenous bisphosphonate therapy
Alcohol or drug abuse
Heavy smoking (>10 cigarettes/day)
Radiation therapy to head or neck region within 5 years
Parafunctional activity
Untreated periodontitis
Full-mouth bleeding on probing and full-mouth plaque index $\geq 25\%$
Allergy or adverse reactions to the restorative materials

program (NobelClinician; Nobel Biocare) and matched to each other. Four implants were planned according to the All-on-4 protocol.^{1,2} After inspection and final verification, the virtual plan was approved and sent to a milling center (NobelProcera; Nobel Biocare), where stereolithographic surgical templates with hollow metallic cylinders were fabricated.

Before surgery, a definitive cast was poured from the stereolithographic surgical templates. A surgical occlusion index was made to seat the template before surgery. A single dose of antibiotic (2 g amoxicillin and clavulanic acid or clindamycin 600 mg if allergic to penicillin) was administered 1 hour before surgery and continued for 6 days after surgery. Before surgery, the participants rinsed with chlorhexidine 0.2% mouthwash for 1 minute. Local anesthesia was provided with a 4% articaine solution with epinephrine 1:100 000 (Ubistein; 3M Espe). The implants were placed in the planned anatomic sites according to a 1-stage approach using the surgical template with a flapless or a flap surgery and without tissue grafting (Fig. 1). Each participant received 4 implants (NobelReplace Conical Connection; Nobel Biocare) placed according to the surgical protocols recommended by the manufacturer.^{1,2} The implant recipient sites were customized according to the bone density²⁴ to achieve an insertion torque of at least 35 Ncm.²⁵

Differently to the original All-on-4 protocol,^{1,2} the implants were left to heal without loading. The existing complete removable denture was relined at chairside with a polyvinyl siloxane soft lining material (Sofreliner Tough Soft; Tokuyama Dental Corp) to accommodate the change of the ridge shape and vestibule, thereby ensuring no pressure on the implant healing abutments. All participants received oral and written instructions regarding medication, oral hygiene maintenance, and diet. Ibuprofen 600 mg was administered as needed. Six to eight weeks later, the definitive impression was made with either plaster (Snow White Plaster no. 2; Kerr Corp) or polyvinyl siloxane material (Flexitime dynamic Putty and Flexitime Light Flow; Heraeus Kulzer GmbH), according to a previously published protocol.²⁶ Esthetics, phonetics, occlusal vertical dimension, and centric relation were verified and approved by both the clinician and

Figure 1. Implants placed using surgical template derived from virtual plan.

Figure 2. CAD/CAM image showing relationship between titanium bar, locator attachments, prosthetic overlays of approved prosthesis, position of implants, and soft tissue.

Figure 3. CAD/CAM image showing 4 locator attachments planned along implant bar drawing trapezoidal configuration.

Figure 4. CAD/CAM titanium bar without cast cobalt-chromium alloy metal framework.

the patient. The definitive cast and the occlusion rim with the record base were digitalized with an optical scanner (NobelProcera; Nobel Biocare).

The CAD/CAM titanium bar was anatomically designed with software by an experienced dental technician, according to the ridge and prosthetic contours and implant position and without a conventional bearing area on the edentulous ridge (Fig. 2). The titanium bar was shaped in order to enhance a vertical path of insertion of between 4 and 6 degrees. Four attachments (Zest Locator; Zest Anchors LLC) were planned along the implant bar in a trapezoidal configuration (Fig. 3). The virtual bar design was transmitted to the production center (NobelProcera Innovation Center; Nobel Biocare), where a 1-piece titanium bar was manufactured from a homogenous solid block of medical titanium alloy (Ti6Al4V). The fit of the implant bar was clinically and radiographically tested in the patient's mouth according to established criteria.²⁷⁻²⁹ A cast cobalt-chromium alloy metal framework (Vitallium; Dentsply Intl) was

conventionally fabricated onto the CAD/CAM titanium bar as a counterpart (Figs. 4-7), sealing the borders to minimize food impaction and saliva and air leakage.

The metallic counterpart was fabricated with 3 to 5 pins fitting along the related channels modeled on the buccal wall of the titanium CAD/CAM bar to gain retention by friction and enhance proper insertion and removal by the patient (Fig. 8). The attachment systems (Locators; Zest Anchors LLC) were screwed into the titanium bar, with the counterparts (Denture Cap; Zest Anchors LLC) housed in the cobalt-chromium alloy metallic framework. Initially, extra light retentive males (Dual Retention 0-10 degrees, blue color, 1.5 lbs [6.7 N], Zest Anchors LLC) were placed into the anterior denture caps, and strong retentive males (clear color, 5.0 lbs [22.2 N]) into the posterior ones. After 1 month of function, the extra light retentions were replaced with the mid-retentive ones (pink color, 3.0 lbs [13.3 N]). The titanium bars were screwed at the abutment level according to the manufacturer's instructions, and all the

Figure 5. Cast cobalt-chromium alloy metal framework fabricated onto CAD/CAM titanium bar.

Figure 6. Maxillary CAD/CAM titanium bar screwed to implant replicas.

Figure 7. Seated CAD/CAM titanium bar screwed to implants.

Figure 8. Metallic counterpart of All-on-4 overdenture.

4IOs were delivered within 3 months of implant placement. The occlusion was developed to deliver a mutually protected articulation and adjusted to avoid any premature contacts. In all the participants, the opposing arches were natural dentition or FDP.

Follow-up visits were scheduled at 1 and 6 months after prostheses delivery and then annually (Figs. 9, 10). At every follow-up visit, occlusal adjustment was performed if needed, and periapical radiographs were made annually (Fig. 11). The participants were instructed on daily maintenance hygienic procedures and underwent a professional cleaning by a dental hygienist every 4 to 6 months.

An implant was classified as successful when the following criteria³⁰ were fulfilled: it did not cause pain, suppuration; did not show any mobility; did not show any signs of radiolucency; did not show periimplant bone loss >1.5 mm (first year) and then >0.2 mm (yearly). An implant was classified as surviving when the implant remained in the jaw and was stable after the prosthesis was removed. A complete implant-supported FDP was defined as successful when the dental prosthesis

remained in function and the esthetic evaluation was satisfactory. Biologic (pain, swelling, or suppuration) and/or technical complications (fracture of the framework and/or the veneering material, screw loosening, or screw and/or implant fracture) were recorded.

Marginal bone loss (MBL) was evaluated on intraoral digital radiographs made with the paralleling technique using a film-holder (Rinn XCP; Dentsply Intl) between implant placement (baseline) and after 1-year in function.^{25,26} All readable radiographs were displayed in an image analysis program (DFW2.8 for Windows; Soredex) that was calibrated for every image using the known pitch of 2 consecutive implant threads. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. Mesial and distal bone level changes were calculated to the nearest 0.01. The patient was used as the statistical unit of the analysis.

Patient satisfaction with function and esthetics was assessed by using a scale with ratings 1-10 with 10=fully satisfied, 5=satisfied, and 1=not satisfied. The quality of life was assessed by the Oral Health Impact Profile (OHIP-21) questionnaire, which was completed by the

Figure 9. One-year follow-up of mandible CAD/CAM titanium bar screwed to implants.

Figure 10. One-year follow-up.

participants. The questionnaire consists of 7 subscales (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap), with 2 to 4 questions each. Participants chose among 5 possible responses for each question as follows: never, hardly ever, occasionally, fairly often, and very often. Items were scored on a 5-point, ordinal-type scale ranging from 1 (never) to 5 (very often). Lower OHIP total scores are suggestive of improvement in oral health-related quality of life (OHRQoL). The questionnaire was administered on 3 occasions: pretreatment examination (T_0), 2 weeks after prosthesis delivery (T_1), and 1 year after treatment (T_2).

Soft tissue parameters around the implant/abutment interfaces were assessed at the 1-year examination with a plastic periodontal probe (Plast-o-Probe; Dentsply Maillefer). The bleeding index (BI) was evaluated at 4 sites around each implant according to the Mombelli index,²² and the plaque index (PI) was evaluated for each implant according to the same author.³¹

An independent dentist (M.T.) 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 (A.P.), 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 periodontal measurements.

All data analysis was carried out according to a pre-established analysis plan using software (IBM SPSS Statistics for Mac, v22.0; IBM Corp). Descriptive analysis was performed using means, standard deviations (SD), and 95% confidence interval (CI). A comparison of means for periimplant bone level changes, patient satisfaction, and OHIP scores between the baseline and 1-year follow-up examinations was made by paired tests. Differences of means for periimplant bone level changes

Figure 11. Periapical radiographs obtained at 1-year follow-up examination.

between the mandibular and maxillary measurements were determined by independent sample *t* tests. All statistical comparisons were 2-tailed ($\alpha=.05$). Proportion, mean, SD, median, and 25th and 75th percentiles (P) were used with the boxplot as summary statistics. A biostatistician with expertise in dentistry analyzed the data.

RESULTS

A total of 72 NobelReplace Conical Connection implants (eight narrow and 48 regular) were placed in 18 consecutive edentulous participants recruited and treated in a private dental clinic between March and September 2013. Twenty participants were initially selected for this single cohort prospective study, but only 18 were included: 2 participants were excluded because of the presence of major bone defects that needed a guided bone regeneration procedure at the same time as implant placement. These participants were treated with a conventional loading protocol 6 months after submerged healing. The remaining 18 participants were followed-up

Table 2. Main participants and implant characteristics

Characteristic	Total (N=18)
Female participants, n (%)	11 (61.1)
Age (y) at insertion, n (range)	65.4 (58-73)
Total smokers (≤ 10 cigarettes/d), n (%)	2 (11.1)
Participants treated in maxilla, n (%)	9 (50.0)
Implants placed in maxilla, n (%)	36 (50.0)
Participants treated in mandible, n (%)	9 (50.0)
Implants placed in mandible, n (%)	36 (50.0)
Total implants placed, n (%)	72 (100)
RP (4.3 mm) diameter and 10-mm-long implants	6 (8.3)
RP (4.3 mm) diameter and 11.5-mm-long implants	22 (30.6)
NP (3.5 mm) diameter and 13-mm-long implants	20 (27.8)
RP (4.3 mm) diameter and 13-mm-long implants	8 (11.1)
RP (4.3 mm) diameter and 16-mm-long implants	16 (22.2)
Total NP (3.5 mm) implants	8 (11.1)
Total RP (4.3 mm) implants	64 (88.9)

NP, narrow platform; RP, regular platform.

at a minimum 1 year (mean 16.8 months, range 12 to 18). Participants were of both sexes with an average age of 65.4 years. The main patient and implant characteristics are shown in Table 2.

No participants dropped out, and no deviation from the original protocol occurred. At the 1-year follow-up, no implants and/or prosthesis had failed, resulting in cumulative implant and prosthetic survival rates of 100%. No biologic or technical complications occurred during the follow-up, resulting in a cumulative implant and prosthetic success rate of 100%. After an initial mean marginal bone loss of 0.35 ± 0.34 mm, the implants lost a mean of 0.64 ± 0.21 mm at the 1-year follow-up. The mean difference was statistically significant (0.29 ± 0.16 ; $P=.003$). No statistically significant differences were found between mandibular (0.28 ± 0.18 (CI 95% 0.04–0.32) and maxillary (0.25 ± 0.14 (CI 95% 0.05–0.25) marginal bone levels ($P=.831$) (Table 3).

Tables 4 and 5 show the OHIP scores for all treatments at baseline and follow-ups. Subscale scores of the pretreatment analysis revealed that functional limitations, physical pain, and physical disability domains had the greatest negative impact on OHRQoL, while the handicap domain had the smallest effect. OHIP summary scores in all subscales demonstrated a significant decrease ($P<.001$) throughout the study but was more evident in the first 2 weeks (Table 4).

At the 1-year follow-up session, bleeding on probing was detected in 2 participants (11.1%) around 3 implants (4.1%). Three participants (16.6%) accounting for 5 implants (6.9%) showed a slight amount of plaque around the implant-abutment interfaces.

DISCUSSION

This prospective study was designed to evaluate the 1-year clinical and radiological outcomes of the 4-implant

Table 3. Marginal bone level changes, mean $\pm$ SD (95% CI)

Baseline	1-Y Follow-Up	Difference
0.35 ± 0.34 (0.14-0.56)	0.64 ± 0.21 (0.51-0.77)	0.29 ± 0.16 (0.19-0.39)*

*Statistically different: $P=.003$.

Table 4. OHIP changes between follow-up sessions, mean $\pm$ SD (95% CI)

Pretreatment Examination (T ₀)	2 Wk After Prosthesis Delivery (T ₁)	1-Y Follow-Up (T ₂)
62.3 ± 12.6 (54.5-70.1)	23.5 ± 8.5 (18.2-28.7) ^a	20.8 ± 6.9 (16.5-25.1) ^b

OHIP, oral health impact profile.

^aStatistically significant differences between T₀ and T₁ ($P<.001$).

^bStatistically significant differences between T₁ and T₂ weeks after prosthesis delivery ($P=.016$).

Table 5. OHIP changes: subscale scores between follow-up sessions, median (25th - 75th percentile)

Subscales	Pretreatment Examination (T ₀)	2-Wk Follow-up Prosthesis Delivery (T ₁)	1-Y Follow-Up (T ₂)
Functional limitation	13.5 (10.5-15.75)	6.0 (5.25-6.75)	5.0 (4.25-5.75)
Physical pain	13.0 (11.25-14.00)	4.5 (4.0-5.0)	4.0 (2.5-4.0)
Psychological discomfort	8.0 (7.25-8.75)	2.5 (2.0-3.0)	2.0 (2.0-3.5)
Physical limitation	12.5 (12.0-14.5)	4.0 (4.0-4.0)	4.0 (4.0-4.0)
Psychological limitation	5.5 (3.5-6.75)	2.0 (2.0-2.75)	2.0 (2.0-2.0)
Social limitation	7.5 (4.75-8.75)	3.0 (3.0-3.0)	3.0 (3.0-3.0)
Incapacity (handicap)	4.5 (4.0-5.75)	2.0 (2.0-2.0)	2.0 (2.0-2.0)

overdenture supported by a CAD/CAM titanium bar for the rehabilitation of the edentulous maxilla and mandible. Because it was designed as a single cohort study, a chief limitation was the lack of a control group. Hence, this investigation should be considered as a proof-of-concept study to act as a pilot for future multicenter RCTs. Nevertheless, 18 participants were treated with 18 complete RDP fully supported by a CAD/CAM titanium bar screwed on 4 implants and followed for 1 year, allowing some preliminary conclusions.

The All-on-4 treatment concept has recently been reviewed by Patzelt et al.⁹ This study of 4804 implants demonstrated high cumulative implant and prosthesis survival rates at 3 years. However, 12 of the 13 studies included were considered highly biased. In patients with moderate to severe bone resorption, the delivery of an FDP can be contraindicated because of the excessive vertical and horizontal overlap of the prosthetic flange onto the residual ridge, which can make hygienic maintenance challenging for the patient.¹³ The placement of at least 4 implants of standard length may allow the delivery of an overdenture supported by a CAD/CAM titanium bar,¹⁴ avoiding any bearing area on the soft tissue and reducing the denture base extension.³²

In the present study, the 1-year implant and prosthetic success and survival rates were 100% in both the mandible and the maxilla, and greater patient satisfaction was reported, indicating that the 4IO is a reliable treatment option. Studies of implant-supported overdentures

in the maxilla have reported poor results with regard to implant survival, biologic, technical, and prosthetic parameters, and patient-reported outcomes.^{15,16} Historically, implant overdentures in the maxilla have performed less well than in the mandible because of poorer bone quality and reduced bone volume, both of which affect the number and length of implants, and prosthesis design.^{10,33} Nevertheless, the results of the present study are in agreement with a recent systematic review¹¹ where maxillary implant overdentures with at least 4 splinted implants experienced high implant and prosthetic survival rates (>95%). In contrast, there was an increased risk of implant loss when ≤ 4 implants and nonsplinted implants were used.¹⁷ Slight marginal bone loss (0.29 mm) was reported after 1 year in function. Satisfactory periimplant soft tissue parameters were also observed at the 1-year follow-up examination. These data are consistent with earlier studies on implant overdenture and fixed implant-supported dental prostheses.^{20,21,34}

Although the use of tilted implants increased the anterior-posterior spread, splinting the implants with a rigid connecting bar may contribute to a favorable pattern of bone resorption regardless of the axial or tilted implant placement.^{12,35} The use of rigid (parallel wall) soldered gold bars resulted in fewer technical complications compared with resilient retention options.^{36,37} However, the solder joints represent the weak points of the soldered bars, a problem which can be overcome with CAD/CAM bars milled from a titanium block.³⁸ The functional effect of rigid parallel-wall CAD/CAM titanium bars investigated in this study could be associated with reduced rotational movements and comparable to fixed prosthesis, reducing the wear of the attachment system and veneering material. CAD/CAM technology provides a better fit compared with conventional fabrication.³⁹

In the present study, the CAD/CAM titanium bars was customized to accomplish the tooth arrangement and to fit the architecture of the soft tissue surface, avoiding undercuts and leaving 1 mm of clearance above the soft tissue to enhance hygiene. The straightforward removal of this prosthesis may be an advantage for elderly patients with limited dexterity. Inaccessible restorations are significantly associated with implant loss and a high rate of periimplantitis.⁴⁰ The titanium bar was shaped in order to enhance a vertical path of insertion ranging between 4 and 6 degrees and to house 4 attachments screwed onto the bar in a trapezoidal configuration (Fig. 3). The 4 to 6 degree tapered walls enhanced the fabrication of the cast cobalt-chromium alloy counterpart and facilitated fitting the titanium bar. Although no scientific data support the use of one attachment system over another,⁴¹ the locator attachments require low prosthodontic maintenance and offer high durability and long-lasting performance.⁴²

The addition of retentive grooves in the titanium bar, with matching prominences on the metallic counterpart, can enhance the proper insertion of the overdenture and increase retention of the 4IO. The use of 4 attachments plus grooved retention may yield for an overlay retention. However, the locators can assist in compensating for any lack of fit of the metal components, thus reducing the wearing of the locator components. The 4IO had fewer prosthodontic maintenance issues compared with resilient implant overdentures stabilized by means of round bars on 2-implant with clips.^{41,42}

CONCLUSIONS

Within the limitations of this clinical study and the relatively short follow-up, a 4-implant overdenture supported by a CAD/CAM titanium bar can be considered a reliable option for the treatment of the edentulous maxilla and mandible where proper lip-cheek support is needed. Oral health-related quality of life significantly improved in all the participants.

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Corresponding author:

Dr Alessandro Pozzi
 Marche Polytechnic University
 Viale Liegi 44, 00198 Roma
 Italy
 Email: studiopozzi@me.com

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