

# 3-Year Randomized Controlled Prospective Clinical Trial on Different CAD-CAM Implant Abutments

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## ABSTRACT

*Background:* Zirconia abutments were introduced to restore esthetic regions and showed sufficient stability to support implant restorations. Nonetheless, to date the observation periods are shorter than those of titanium abutments.

*Purpose:* To assess the survival of implant crowns supported by computer aided design-computer aided manufacturing (CAD-CAM) abutments after 3 years.

*Materials and Methods:* Fifty-six patients were selected for this prospective clinical study. Each patient received at least 1 titanium implant for a total of 89 fixtures. A two-stage surgical technique and no additional soft or hard tissue graft were used. The implants were randomly divided into 3 groups receiving different CAD-CAM abutments: titanium, titanium nitride, and zirconia. Zirconia or metal-ceramic crowns were used as final restorations. Cementation was the baseline and the restorations were checked after 6 months, 1, 2, and 3 years, assessing any mechanical complication. Statistical analyses were performed to evaluate the 3-year success rates.

*Results:* Five failures were reported in the zirconia group; all the failed restorations showed fractures of the abutment connection. Four failures occurred in posterior regions and one more occurred while screwing the abutment. Titanium and titanium nitride abutments had significantly higher 3-year success rates than zirconia abutments ( $p < .05$ ).

*Conclusions:* Atlantis titanium and titanium nitride abutments showed optimal clinical performances after 3 years. Conversely, Atlantis zirconia abutments should be avoided to restore posterior regions.

**KEY WORDS:** clinical trial, implant abutment, computer aided design-computer aided manufacturing, prosthodontics, zirconia

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## INTRODUCTION

The replacement of single missing teeth with osseointegrated implants in highly esthetic demanding anterior areas is nowadays a predictable treatment option with high survival rates.<sup>1,2</sup> Clinical longevity over time relies on both the effectiveness of implant osseointegration as well as the biological and mechanical reliability of the prosthetic components.<sup>3,4</sup> Due to the increasing patients' demand for esthetics, different materials were proposed to fabricate implant abutment and crowns.<sup>3-6</sup>

To date, titanium abutments have been considered the gold standard for the longevity of implant-supported restorations in all areas of the jaws.<sup>2,3</sup> Very high survival rates were reported by clinical investigations and systematic reviews noticed that only few

mechanical complications occurred on metal abutments supporting fixed implant restorations, just like screw loosening.<sup>2</sup> Nonetheless, although no consensus exists in the literature, the possible grayish or bluish appearance of peri-implant soft tissues was recognized as the most common esthetic drawback due to the presence of metal abutments.<sup>7,8</sup> Consequently, despite their excellent mechanical performances, according to several authors, implant metal abutments show limited indications in esthetic areas.<sup>3,7</sup> However, it is worth noticing that the dark gray color of peri-implant mucosa is significantly influenced by the buccal-palatal position of the implants as well as by the thickness of the soft tissues.<sup>3,7,8</sup>

To overcome such esthetic limitations, alternative abutment materials were developed and high-strength zirconia abutments were introduced to restore highly esthetic demanding regions.<sup>3,6-12</sup> Besides the esthetic benefits related to their white color and reduced mucosal discoloration, zirconia abutments showed insolubility in water environment, radiopacity and excellent biocompatibility and proved to limit bacterial adhesion in comparison with metal ones, resulting in soft tissue integration comparable to that of titanium abutments.<sup>3,6,13-17</sup>

Very promising survival rates were reported in clinical studies on zirconia abutments, reaching 100% under single crowns in anterior and premolar regions<sup>18</sup>; similarly, 100% survival rate was noticed in posterior regions after 3 years of function.<sup>19</sup> Consequently, zirconia abutments showed sufficient stability to support implant-supported reconstructions and were claimed as a viable alternative to metal ones because of their satisfactory mechanical strength.<sup>2,5,19</sup> Nonetheless, the reported clinical observation periods were shorter than those known for titanium abutments. The information collected on ceramic abutments was scarce with regard to both number of published studies and analyzed abutments and the follow-up time was also limited.<sup>1,2,20</sup> Overall, the data were not sufficient to provide a conclusive evidence about indications and performance limits of zirconia abutments.<sup>3,20</sup>

Although zirconia exhibits the highest fracture load values among dental ceramics ranging from 444 N to 738 N,<sup>21,22</sup> it is a brittle material characterized by limited mechanical resistance to tensile forces and prone to fracture under mechanical fatigue over time.<sup>3,5,6,13,14,23,24</sup> Moreover, zirconia could be nega-

tively affected by low temperature degradation (LTD) that could accelerate the aging of the material.<sup>6,13,14,24</sup> As a consequence, the mechanical performances of ceramic abutments were considered to be more risky in comparison with the longevity of titanium abutments. Particularly, microstructural defects within zirconia as well as limited thickness of the material could result in cracks and flaws in the presence of tensile loads, causing screw loosening or fracture of both abutments and connections.<sup>3,4</sup> Tensile forces on metal abutments usually result in deformation and then fracture of the abutment screws; conversely, the same forces could cause the fracture of the abutment itself before fracture of the abutment screw due to the brittleness of zirconia.<sup>23,25,26</sup>

Different designs of the implant-abutment connection of zirconia abutments could influence the mechanical stability and clinical performances of the entire restorative system.<sup>3-5</sup> Different systems were proposed to join the zirconia abutment to the implant body with both external and internal connections, the latter being represented by the abutment itself (one-piece) or by a secondary metallic component (two-piece).<sup>4</sup> To date, most clinical data regard zirconia abutments with external implant-abutment connection<sup>4</sup> and only few investigations were performed on internal zirconia connections.<sup>27,28</sup> Similarly to titanium abutments, the internal connection in the configuration of the two-piece joint showed greater stability and mechanical advantages with zirconia abutments in *in vitro* studies.<sup>2,29,30</sup> However, a recent laboratory investigation demonstrated that the type of connection only had minor effects on the bending and stability of restored zirconia abutments, concluding that, irrespective of the type of connection, zirconia abutments could be considered a viable option to support single crowns particularly in anterior regions; however, it is worth noticing that titanium abutments showed the highest bending moments.<sup>4,31</sup>

The design and dimensions of zirconia abutment and implant connections significantly influence the stability and the mechanical performances of the restorative system.<sup>11,26,32</sup> Most authors agree in stating that the weak point of the connection of zirconia abutments where microcracks and fractures usually origin is represented by the thinner part of the transition zone as well as by the engaging area.<sup>2-4,20,23,33</sup> A recent *in vitro* investigation showed that zirconia

connections fractured in the prefabricated standardized parts and not in the customized areas of the abutments.<sup>4</sup> Consequently, to properly withstand occlusal forces, minimal thickness of abutment walls and internal connections have to be strictly respected according to the manufacturers' indications.<sup>3,4</sup>

The present randomized, controlled, prospective, clinical trial aimed at verifying the clinical performances of three different implant abutment materials, evaluating the survival of implant-abutment-crown complexes under functional occlusal loading and wear. The null hypothesis stated that there was no association between the abutment type and the 3-year survival rates of the restorations.

## MATERIALS AND METHODS

### Study Design

The present investigation was conducted according to the CONSORT statement<sup>34</sup> for improving the quality of reports of parallel-group randomized trials. The study was a parallel, randomized, single-center, clinical trial on the effect of different computer aided design-computer aided manufacturing (CAD-CAM) implants abutments on peri-implant soft tissue variables. Three different prosthetic materials were compared: titanium, titanium nitride, and zirconia.

### Participants

Subjects were enrolled at the Department of Prosthodontics of the University of Siena (Italy) between September 2010 and December 2011. The Ethical Board of the same University approved the study protocol (ClinicalTrials.gov NCT02090647). Informed written consent was obtained from all the subjects included in the study. As regards the informed consent and the study development, the principles outlined in the Declaration of Helsinki on experimentations involving human subjects were adhered to as revised in 2008.<sup>35</sup>

Participants in need of at least 1 dental implant and satisfying the following inclusion criteria were recruited:

- age  $\geq 18$  years;
- no active intraoral or systemic disease;
- no pregnancy or lactation;
- smoking  $\leq 10$  cigarettes/day;
- controlled periodontal conditions (no Pocket Probing Depth index superior to 4 mm, no

Bleeding On Probing and Plaque Index inferior to 20%);

- adequate bone volume to place an implant (length 10–13 mm, diameter 2.5–4 mm, class I to III bone quality according to Lekholm and Zarb<sup>36</sup>);
- occlusal function with a natural tooth.

Consequently, heavy smokers ( $>10$  cigarettes/day), patients requiring hard/soft tissue augmentation, with severe bruxism or untreated periodontal disease/poor compliance were excluded from the study.

Fifty-six consecutive patients were finally selected for the prospective study, in need of a total of 89 implant abutments.

### Randomization, Allocation Concealment, Masking of Examiners

Each patient was randomly assigned to 1 of the 3 experimental groups; consequently, if a patient was in need of a fixed dental prostheses (FDP), all the relative abutments were made using the same experimental material. The treatment regimen was noted in the registration and treatment assignment form that was kept by the investigators. Allocation concealment was performed by opaque sealed, sequentially numbered envelopes. The statistician generated the allocation sequence by means of a computer-generated random list and instructed a different operator to assign a sealed envelope containing the type of abutment (i.e., titanium, titanium nitride or zirconia). The opaque envelope was opened before abutment selection and treatment assignment communicated to the prosthodontist. Blinding of the examiners was maintained throughout all experimental procedures.

### Surgical and Prosthetic Procedures

All the surgical procedures were performed by the same expert implant surgeon and all the prosthodontic procedures were carried on by another expert prosthodontist. The experimental procedures were performed in the same clinic with high experience in providing implant-prosthetic treatments. Each patient received at least 1 endosseous dental implant with a maximum of 3 fixtures (Osseospeed, Astra Tech Dental Implant, Dentsply, Molndal, Sweden). A single, calibrated examiner, blinded to the experimental procedures, assessed all the clinical outcomes of the investigation both at the baseline and at the follow-up examinations.

A 2-stage surgical technique with submerged fixtures and no additional soft or hard tissue grafts were planned for all the patients. Removable or FDPs were adjusted and used as interim restorations during the healing period.

Six months after implant placement, surgical re-entry was performed and a trans-mucosal healing abutment (Healing Abutment, Dentsply) was inserted (Time 0). Implant stage 2 was performed by the same surgeon who had made stage 1.

Two weeks after surgical re-entry, a fixture-level impression was taken with vinyl-polyether-silicone impression materials (EXA'lence, GC, Tokyo, Japan) to fabricate a screw-retained temporary restoration (Time 1). The provisional restoration was inserted 1 week after the fixture-level impression (Time 2). After 8 weeks of soft tissue conditioning by means of the provisional restoration, a final fixture-level impression was taken as previously described. Soft tissue dimensions were recorded with peri-implant probes and the thickness of the buccal peri-implant soft tissues was measured at level of the implant neck using a caliper (Time 3). The pick-up impression coping was customized by adding a dual cure flowable resin composite (Gaenial Universal Flow, GC), to replicate the emergence profile of the provisional restoration in the definitive cast (New Fuji Rock, GC). The peri-implant mucosa was replicated by using a light consistency silicon material around the implant analog before pouring type IV dental stone, so as to reduce any possible inaccuracy of the soft tissue reproduction.

The CAD-CAM abutments (Atlantis, Dentsply) were made strictly following the manufacturer's instructions; 31 titanium, 30 titanium nitride, and 28 zirconia abutments were fabricated.

Implant-supported single crowns or short-span (i.e. up to 3 dental units) FDPs were used as final restorations, according to the individual clinical condition of each patient. Such restorations were produced using metal or zirconia copings/frameworks (Aadva, GC) veneered with dedicated feldspathic ceramic, depending on the treatment plan of each patient. The prostheses were cemented with a self-adhesive dual-curing resin cement (Link Ace, GC). The buccal margin of the final restorations were placed 1 mm subgingival, while interproximal and lingual margins were iuxtagingival.

## Follow-up Examinations

All patients were enrolled in a supportive periodontal care program, with 4- to 6-month professional recalls. Restorations were checked after 6 months, 1 year, 2 years, and 3 years of clinical service. The overall observation time was 3 years.

To avoid misunderstanding between definition of success and survival, "success" was defined by percentage of restorations that remained in situ without any modification, "survival" was defined by percentage of restorations that remained in situ with modifications but still under clinical acceptability, while "failure" was defined by percentage of restorations that needed to be replaced.<sup>3,37</sup>

## Statistical Analysis

To verify whether statistically significant differences were found among the three tested groups of abutments, the Fisher's Exact test was applied.

In all the analyses, the level of significance was set at  $\alpha < 0.05$  with Bonferroni's correction.

## RESULTS

After 3 years of clinical service, all the abutments were available for the follow-up examinations. Five failures were reported in the zirconia group, resulting in a 3-year success rate of 82.2%; differently, no complications were evidenced in both the titanium and titanium nitride groups, showing 100% 3-year success rates (Table 1). In all the failed restorations, fractures of the abutment connection were evidenced at level of the stem. Two out of 5 failures occurred in the same patient, while all the other fractures took place in different subjects. Four failures occurred under occlusal loading during clinical service and involved posterior restorations (1 maxillary premolar after 6 months of function and 3 mandibular molars, 2 after 1 year of service in the same patient and 1 at the 2-year recall); 1 more fracture was noticed on a maxillary canine at the intraoral try-in of the restoration, while screwing the abutment onto the implant.

The statistical analysis showed that titanium and titanium nitride abutments had significantly higher 3-year success rates than zirconia abutments ( $p < .05$ , Table 1).

**TABLE 1 Clinical and Statistical Outcomes of the Experimental Abutments**

|          |                  | Outcome |         |       | Significance<br>( $p < .05$ ) | 3-year<br>success rate |
|----------|------------------|---------|---------|-------|-------------------------------|------------------------|
|          |                  | Success | Failure | Total |                               |                        |
| Abutment | Titanium         | 31      | 0       | 31    | A                             | 100%                   |
|          | Titanium nitride | 30      | 0       | 30    | A                             | 100%                   |
|          | Zirconia         | 23      | 5       | 28    | B                             | 82.2%                  |
|          | Total            | 84      | 5       | 89    |                               |                        |

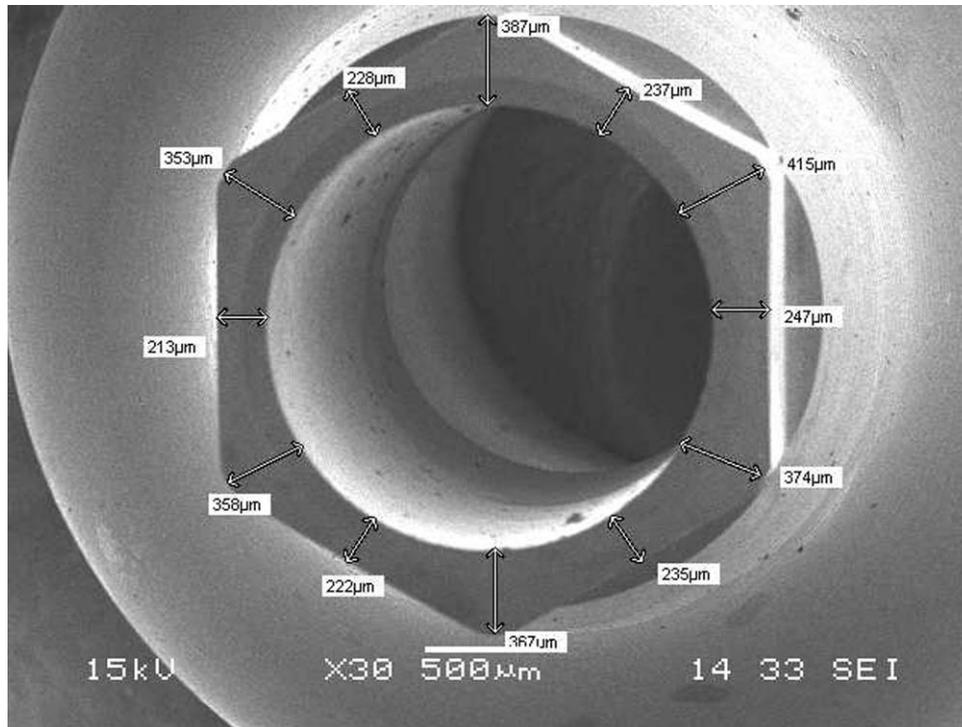
## DISCUSSION

The present randomized controlled prospective clinical trial aimed at assessing the clinical performances of Atlantis CAD-CAM implant abutments made up of different prosthetic materials; the study population was randomly allocated to receive titanium, titanium nitride, and zirconia abutments. On the basis of the clinical results, the null hypothesis stating that the different tested abutments would provide statistically similar survival rates of the restorations over a 3-year follow-up period was rejected.

To better fulfill the clinical characteristics of the present double-blind research, the randomization was performed per patient and not per abutment; once a patient met the inclusion criteria, the number of fixtures and the type of prosthesis were set according to the clinical need of each case. Consequently, if a patient was in need of a FDP, all the relative abutments were made using the same experimental material. Although they could dissipate occlusal loads differently, the experimental abutments were used to either support implant single crowns and FDPs; all the prostheses were designed with careful analysis and design of prosthetic occlusal schemes.

Possible different clinical behavior of titanium and ceramic implant abutments were recently investigated and discussed in the literature.<sup>1,3,4,6,20,33</sup> Particularly, titanium nitride and zirconia abutments were introduced in clinical practice to overcome the esthetic limitations due to the possible grayish or bluish appearance of peri-implant soft tissues in the presence of titanium abutments.<sup>3,6,12</sup> An experimental study compared the effects of titanium and zirconia abutments on light reflection of peri-implant soft tissues, showing that no differences were noticeable for the human eye when the mucosa thickness exceeds 2 mm.<sup>8</sup>

In a classical study on beagle dogs evaluating the biological integration of gold, titanium, and ceramic abutments, it was shown that titanium and ceramic abutments allowed for the formation of a mucosal seal made up of an epithelial tissue attachment and a connective tissue integration, while other abutment materials were associated with lack of attachment, soft tissue recession and bone resorption.<sup>15</sup> More recently, the influence of peri-implant variables were evaluated in vivo after 2 years of clinical service and the investigation showed that the abutment type is not an influencing factor for the success of a restoration, thus supporting the concept that the specific control of plaque is the real key factor to maintain peri-implant health; the abutment type was reported not to be a predictor of peri-implant soft tissue recession after 2 years of clinical service.<sup>38</sup> Moreover, the use of zirconia abutments did not improve the quality of peri-implant soft tissues when compared with titanium and titanium nitride abutments; consequently, the indication for zirconia abutments was restricted only to anterior regions with high esthetic demand, particularly when the buccal tissues covering the fixture present with a very thin biotype.<sup>38</sup> From a mechanical point of view, although the fracture resistance of both titanium and zirconia abutments was described as adequate to withstand physiologic chewing forces in the premolar area,<sup>20,37</sup> zirconia abutments had significantly lower strength than titanium abutments.<sup>5</sup> Nonetheless, a systematic review on single crowns supported by implant zirconia abutments reported satisfactory technical and biological success rates after 5 years of service.<sup>1</sup> Similarly, other systematic reviews on single implants, abutments and crowns did not find any significant difference in survival and failure rates of metal and ceramic abutments after 5 years of service. No significant



**Figure 1** Reduced thicknesses of zirconia at the internal hexagonal connection.

differences were found for technical, biologic and esthetic complications of internally and externally connected abutments. It was concluded that the 5-year survival rates estimated from annual failure rates were similar for metal and ceramic abutments; nonetheless, the information regarding ceramic abutments was limited in number of studies and abutments analyzed as well as the overall follow-up time.<sup>1,39</sup>

Standardized methods to evaluate the abutment strength are needed.<sup>3</sup> To date, the majority of systematic reviews and investigations on zirconia abutments refer to external hexagonal connection while almost no data are available about the same type of abutment with internal hexagonal connection.<sup>3</sup> The present study was designed to compare the clinical performances of 3 types of CAD-CAM Atlantis abutments with internal hexagonal connection made up of different prosthetic materials. The results of this prospective study showed superior clinical behavior of titanium and titanium nitride abutments in comparison with zirconia ones. It could be speculated that a possible explanation for the recorded failures in the zirconia abutment group can be related to the specific internal hexagonal connection used in this study (Figure 1). The geometry and dimensions of zirconia

abutment connections significantly affect the technical serviceability of the restorations: the thinner the transition zone, the higher the risk of fracture and mechanical complications.<sup>2–4,11,20,23,26,32,33</sup> To overcome such problems, minimal thickness of abutment internal connections have to be strictly preserved.<sup>3,4</sup> The fractures of the connections evidenced in the failed zirconia abutments of the present study might be due to inadequacy of milling or micromotions, possibly leading to internal deformation of the implants, as evidenced by the metallic staining observed on the retrieved abutments. However, in a recent study,<sup>3</sup> the internal connections of titanium and zirconia abutments as received by the manufacturers were observed microscopically: the thickness of such internal connections appeared to be satisfactory in titanium abutments but weak in the zirconia ones. Particularly, a mean thickness of 375  $\mu$  was measured in the connection area of zirconia abutments and a minimum thickness of 200  $\mu$  at the thinnest vertex of the connection hexagon; assuming 1000 MPa as the flexural strength of dental zirconia after sintering according to ISO standard tests, this determines a fracture load limit of 11.5 N. It can be speculated that reduced thicknesses of zirconia at the internal hexagonal connection due to inadequate milling

and/or wear due to micromovements could represent a weak point of the transition area between the abutment and the fixture that could not withstand both the screwing torque (25 Ncm) and the occlusal forces. Such considerations could be confirmed by the good clinical behavior and success rates showed by some other zirconia prefabricated abutments with external hexagonal connection available on the market.<sup>1,18,20,40</sup>

According to the experimental design of the present *in vitro* investigation, the obtained results and indications only apply for the Atlantis zirconia abutments with internal zirconia connection used in this study.

## CONCLUSIONS

Within the limitations of the present randomized controlled prospective clinical trial, it can be concluded that both Atlantis titanium and titanium nitride abutments with internal hexagonal connections can be safely used in daily practice for the restoration of all intraoral sites, since they showed excellent clinical behavior after 3 years of service. Differently, Atlantis zirconia abutments with internal hexagonal connections showed several mechanical failures; as a consequence, they cannot be considered as a routinary solution in daily clinical practice and their use should be limited to the esthetic rehabilitation of anterior regions and avoided in posterior load bearing areas.

Thereby, the clinical performances of ceramic restorations supported by implant zirconia abutments with internal hexagonal connection need to be further investigated, as the *in vivo* evidences so far collected are largely defective.

## CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflict of interest.

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