Survival Analysis up to 8 Years of 304 Anatomic-Contour Implant Zirconia Crowns Fabricated with a Fully Digital Cast-Free Workflow and Directly Screwed on External Hexagonal Implant Connections without the Interposition of a Ti-Base: A Multicentric Retrospective Study

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Submitted January 1, 2024; accepted March 18, 2024.

Abstract

Statement of Problem: Data on the clinical performance of monolithic Zirconia screw-retained crowns on external hexagon implants fabricated from digital scans through a cast-free, fully digital workflow is lacking and needs to be included. ***Purpose:*** This retrospective multicentric study aimed to evaluate the real-life clinical results of monolithic Zirconia screw-retained crowns without the interposition of a Ti-base on external hexagon implants fabricated from intraoral scans and a cast-free approach in private practices. ***Materials and Methods:*** Single external hex implant fixtures were restored with monolithic zirconia crowns without the interposition of a Ti-base. The crowns were directly screwed on external hexagonal implant connections with a cast-free, fully digital workflow. Data were analyzed using descriptive statistics and the Kaplan–Meier test. Between September 2022 and March 2023, the California Dental Association

modified criteria were adopted for clinical evaluation after recalling all patients. ***Results:*** A total of 304 single tooth restorations in the maxillary and mandibular posterior regions fabricated between July 2014 and July 2022 in 252 patients (120 males and 132 females, mean age 53.6 years, SD 23.3). Seven crowns were excluded because of patient dropout. The most common minor technical complications were screw loosening (3 crowns) and loss of the screw-access hole filling (3 crowns). Four failures included two implant failures with mobility and two fractured crowns. No screw or implant fractures were recorded. The overall cumulative survival rate was 98.6% and the average success rate (crowns experiencing no failures or complications) was 96.0%. The mean overall survival time was 101.3 months (standard error, 0.847; 95% confidence interval for the mean, 99.67-102.99). The overall survival probability was 87.9% up to 97 months. ***Conclusions:*** With careful case selection and comprehensive periodontal maintenance program, single crowns directly screwed onto an external hexagon platform have shown to have excellent survival and success (complication-free) rates, comparable to available data regarding single crowns with a metal implant- prosthetic interface. *Int J Oral Maxillofac Implants 2024. doi: 10.11607/jomi.10898*

Introduction

Single crowns on implants were introduced in the 1980s and have shown high medium and long-term survival rates.[1] Various factors potentially influencing clinical outcomes have been considered in systematic reviews.[2] Internal connections have shown a slight mechanical advantage over external connections, but precise components and tightening protocols of the final retention screw have reduced screw loosening.[3–5] Screw-retained restorations appeared to have fewer complications compared to cement- retained ones but studies have not shown any

statistical difference in terms of survival or failure rates.[6,7] Veneer chipping was the most typical technical complication in screw-retained bilayer restorations.[8,9] The use of monolithic ceramic material cemented on a titanium base was introduced to overcome this complication.[10,11] A new manufacturing concept has been introduced, utilizing monolithic Zirconia directly connected to implants to fabricate screw-retained crowns,[12,13] offering simplified fabrication and reduced risk of debonding of titanium components and fabrication cost. A direct connection of screw-retained zirconia crowns seems contraindicated for internal connection implants.[14,15] Conversely, the flat-to-flat geometry of external hexagons ensures adequate zirconia thickness and provides sufficient strength to fabricate zirconia restorations without a Ti-base.[16–18] Integrating the use of intraoral scanners (IOSs)[19,20] in a fully digital cast-free workflow has the potential to significantly enhance the efficiency of clinicians while ensuring greater accuracy throughout the workflow process.[21–23]

This clinical retrospective study recorded and analyzed data regarding single-tooth implant-supported restorations fabricated in monolithic Zirconia placed in 3 private dental practices. An IOS allowed the acquisition of digital scans, and a computer-aided design and computer-aided manufacturing (CAD-CAM) cast-free workflow was used by the dental technician to fabricate the crowns.

The purpose of this multicentric, cross-sectional, and retrospective clinical study was to assess the clinical efficacy of anatomic-contour implant zirconia crowns directly screwed on external hexagonal implant connections omitting the use of a Ti-base component, and fabricated through an entirely cast-free digital workflow. This investigation was conducted in a private practice setting where different clinicians adhered to a uniform clinical protocol.

The hypothesis posited that implant-supported restorations manufactured through a fully digital, cast-free workflow would demonstrate clinical outcomes comparable to those achieved through alternative techniques.

Materials and Methods

This study reports clinical results of 304 posterior teeth restored with cast-free single crowns on implants. The study followed the principles of the Helsinki Declaration of 1964, as revised in 2013. As Good Clinical Research Practice requires, all patients gave full and informed consent before commencing treatment protocol.

Four clinicians (##, ##, ##, and ##) individually conducted this retrospective cross-sectional study working with a shared clinical protocol, in their general dental practice in Riccione, Milan, and Pordenone, Italy. The authors revised all the cases of external hexagon implants requiring single full anatomic crowns that had been previously placed and were loaded between July 2014 and July 2022. Recalls for professional oral hygiene for these patients were scheduled every 3–6 months, depending on their overall periodontal condition at the beginning of the treatment. Table 1 shows the number of crowns and implant diameter distributed per tooth position. All external hexagon implants (Biomet 3i External hex) requiring single full anatomic crowns that had been previously placed and were loaded between July 2014 and July 2022 entered the study.

Table 1 Initial distribution of crowns, failures and complications.

Crowns provided		Tooth			
	Total	First premolar	Second premolar	First molar	Second molar

Maxillary	132 (1F, 3C)	29 (1C)	37 (1F,1C)	53 (1C)	13
Implant diameter		3(3.25), 26(4.1)	37 (4.1)	43 (4.1),10(5.0)	6(4.1),7(5.0)
Mandibular	165 (3F, 6C)	21 (1C)	30 (1C)	95 (3F,3C)	19 (1C)
Implant diameter		7(3.25) 14(4.1)	30 (4.1)	68 (4.1), 27(5.0)	12(4.1),7(5.0)
Total	297 (4F,9C)	50 (2C)	67 (1F,2C)	148 (3F, 4C)	32 (1C)

Number of failures F or complications C and implant diameters in parentheses.

When required, interim restorations were placed two to four months after implant placement, depending on the location and condition of the site, but not all implants received one. After 1 to 6 months of successful loading, the final digital scan was made with intraoral scanners, continually updated to the latest software version.

The dental technician designed all crowns using specific computer-aided design software (Dental System; 3shape) and fabricated them with a cast-free full digital workflow according to a protocol that has been described in detail elsewhere.[18] In brief, the intaglio surface of the crown was designed to embed the hexagonal implant connection. The restoration design was modified to ensure thick enough walls in the connection area to avoid the use of a Ti-base. High - strength tetragonal zirconia (Katana Zirconia, Noritake) with a fracture resistance greater than 1000 MPa was used to fabricate the restorations (ML until 2018, and HTML from 2019 onwards). Only restorations with a required thickness of at least 1.5mm in the flat-to-flat lodging area of the screw head were fabricated using this protocol and entered this study. Each crown was carefully checked for proximal contacts, occlusal relationships, shade matching, and precise adaptation to the fixture platform (Figs 1-6). The screw was tightened at 30N with a prosthetic component dynamometric torque wrench. Small occlusal adjustments were performed when clinically

necessary using fine to medium grit burs (30- 125 μm). Diamond grit interspersed polishers (ZR Flash Polishers kit; Brasseler–Komet) were then used to polish the restorations.

Fig 1 Representative first mandibular molar monolithic zirconia crown before placement showing good esthetic outcome and healthy peri-implant tissues.

Fig 2 Scanned lower arch with scanning abutment in situ.

Fig 3 Representative first mandibular molar monolithic zirconia crown after placement showing good esthetic outcome and healthy peri-implant tissues.

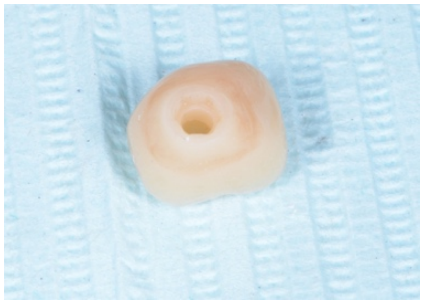

Fig 4 Intaglio surface of delivered crown.

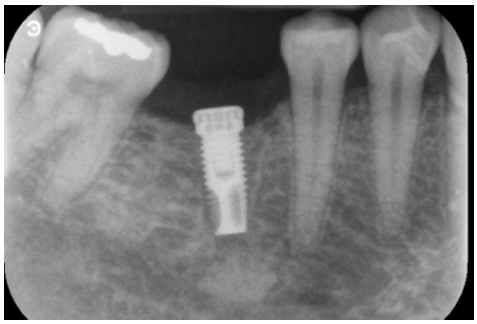

Fig 5 Radiograph (same case shown in Figure 1) after surgery.

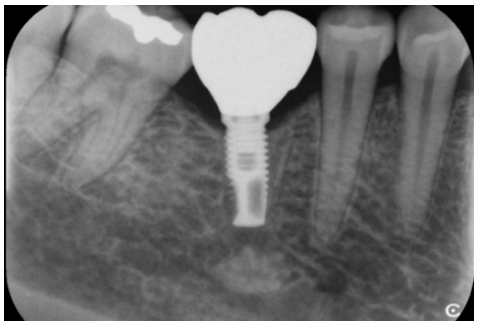

Fig 6 Radiograph (same case shown in Figure 1) 6 months after crown placement.

A Teflon (PTFE) tape was compacted inside the screw access tunnel to prevent leakage. The access hole was then treated with an adhesive containing MDP (Vivapen; Ivoclar) and closed with composite. Light polymerization was performed for 20 seconds using a light-emitting diode curing light in standard power mode (1000 mW/cm2).

A first baseline evaluation was performed at the time of delivery. At recall (follow-up), all patients were then re-evaluated during routine professional hygiene appointments, which were

performed once every 3–6 months, depending on the specific periodontal condition of the patients. The Restorations were clinically inspected using an intraoral mirror, a double-sided instrument with a sharp explorer, and a periodontal probe (XP23/OW probe; Hu-Friedy), as well as radiographs. In some cases, recorded documentation included photographs.

Recalls were performed between September 2022 and March 2023; analyses were carried on by a different well-trained clinician working in the same practice. The main criteria for irreparable mechanical failure were screw, crown, connection, or implant fracture. The main criteria for biological failure were periimplantitis or implant mobility.

A Kaplan-Meier[24] analysis was conducted to assess the durability of ceramic crowns, utilizing Medcalc 12.1 software by Medcalc Software Ltd. The period of survival for each crown was determined from the initial time of placement until the point at which the clinician declared the crown or the implant to be irreparably failed. Crowns deemed failures were substituted with new ones, which were not incorporated into the present study.

Results

All external hexagon implants requiring single full anatomic crowns that had been previously placed and were loaded between July 2014 and July 2022 entered the study. A total of 252 patients (120 males and 132 females, mean age 53.6 years, SD 23.3) received 304 single tooth restorations in the maxillary and mandibular posterior regions with a mean follow–up time of 48 months (standard deviation 25.4). Seven crowns were excluded because of patient dropout. Most of the remaining 297 crowns (Figs 1-6) were located in the molar area (180 crowns in total, 66 in the upper and 114 in the lower arch), while 117 crowns were in the premolar area (66 in the upper and 51 in the lower arch). Complications were recorded and divided into biological and

technical complications. Mild to moderate peri-implantitis with inflammation (mucositis) of the tissues was found in the soft tissues surrounding 2 crowns. Tissue inflammation was resolved with a standard dental hygiene recall appointment and the use of Chlorhexidine-based mouthwash for one week. The most common minor technical complications were screw loosening (4 crowns) and loss of the screw-access hole filling (3 crowns). In these cases, after removing the filling if needed, the screw was re-tightened at 30N with a prosthetic component dynamometric torque wrench, and the hole was newly filled following the same procedure adopted initially. These complications were not considered failures. More severe complications occurred, which needed replacement of the restorations and therefore considered failures. Two implants were lost and removed when they gained mobility, and 2 crowns fractured (one at the connection level). The failed implants and crowns could be replaced successfully but were not reintroduced in the study (Table 1). No screw or implant fractures were recorded. The overall cumulative survival rate was 98.6 and ranged from 96.8 (mandibular first molars) to 100 for first premolar and second molar locations in both arches, mandibular second premolars, and maxillary first molars (Table 2). The overall success rate (crowns experiencing no failures or complications) was 95.6. The success rates varied from the lowest at mandibular first molar (93.7) to the highest at maxillary molars (100.0). In general, failures were present only in the lower first molar and upper second premolar areas. Only crowns in the upper second molar area were free of complications. (Table 2).

Table 2 Cumulative Survival Rate and Success Rate.

Crowns provided	Tooth

	Total	First premolar	Second premolar	First molar	Second molar
Maxillary	99.2 (98.5)	100.00 (96.5)	97.3 (94.6)	100.0 (98.1)	100.0 (100.0)
Mandibular	98.2 (93.9)	100.00 (95.2)	100.0 (96.7)	96.8 (93.7)	100.0 (94.7)
Total	98.5 (95.6)	100.0 (96.0)	98.5 (95.5)	98.0 (95.3)	100.0 (96.9)

Cumulative survival rate and success rate (complication-free).

The survival analysis was performed on 297 crowns. The total failure rate was 1.35% (4/297). The mean survival was 101.33 months. Kaplan–Meier survival estimation method resulted in an overall survival probability for the 297 crowns of 87.9% at up to 97 months (Fig 7).

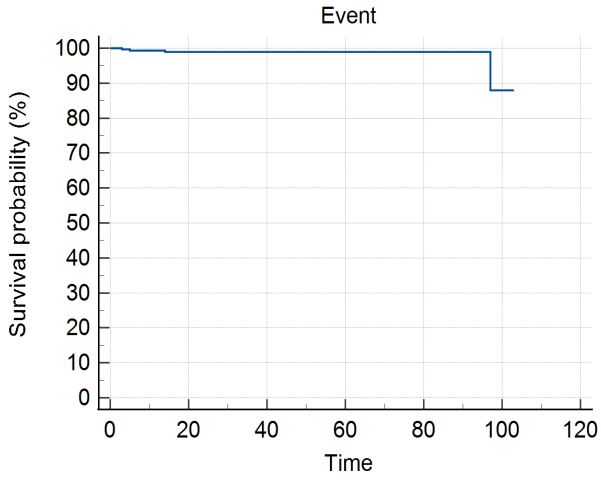

Fig 7 Survival probability analysis according to Kaplan-Meier.

Discussion

Cementing crowns onto prefabricated or custom abutments remains a common practice in implant dentistry, although it presents clinical challenges that can lead to bone loss and, in severe cases, implant failure.

Various strategies have been devised to address these issues, but there is a prevailing trend in implant dentistry to favor screw-retained crowns whenever feasible, especially when the implant position allows placing the screw-access hole in an aesthetically and mechanically advantageous location, for example at a distance from the visible buccal aspect of the crown in anterior regions.[12,13]

Screw-retained restorations have emerged as the preferred option in implant dentistry due to numerous clinical benefits. Typically, these restorations are monolithic disilicate or zirconia crowns cemented onto a titanium base. However, an alternative approach has been developed for implants with an external hex configuration. Monolithic zirconia has a sufficiently high mechanical resistance to incorporate the anti-rotational hex in its intaglio surface. A few specific conditions must be met to be clinically successful. First, the external hex is the only implant connection suitable for this type of solution. Studies have demonstrated that zirconia abutments yield clinically comparable results to titanium abutments both in vitro and in vivo.[14,15] The Zirconia type at the interface should have a high - strength of at least 1000 MPa. Moreover, the restoration design should have a minimum thickness of 1.5mm in the area accommodating the screw head, which should be flat to flat.[18] Inadequate thickness may predispose the restoration to failure. Despite adequate axial wall thickness, two crowns in our study experienced catastrophic mechanical failure, one at the connection level.

Concerns have been raised regarding the interaction between the implant surface and zirconia, particularly the possibility of zirconia causing wear on the titanium and rounding off the anti-rotational vertices of the hex. However, clinical observations from our study do not support this theory, as no crown exhibited significant loss of anti-rotational capacity. Nonetheless, as with monolithic crowns with a titanium base screw, loosening may occur, necessitating re-intervention.

In our sample, four crowns required re-intervention, a relatively straightforward procedure involving the removal of composite, sealing of the screw access hole, removal of previously compacted Teflon tape from the screw channel, torquing a new screw at 30 Ncm as per manufacturer instructions, and resealing the channel and screw access hole. Such interventions typically take around 10 minutes to complete. In three cases, only the access hole filling was lost, requiring an even shorter session.

The potential elimination of the titanium base is pivotal for maintaining a fully digital workflow and eliminating the need for master models in fabricating single crowns. Cementation procedures performed in dental laboratories can be cumbersome and operator-dependent, increasing the risk of misfit and imperfect contact points with adjacent teeth. A fully digital workflow enables the creation of perfectly fitting crowns entirely designed and fabricated digitally.

Although color-matching monolithic zirconia with adjacent teeth can be challenging, advancements in material technology have improved the ability to mimic natural teeth through a gradient in translucency and sophisticated superficial coloring techniques. Esthetic challenges are typically more manageable for posterior teeth restorations.

Manual polishing of subgingival areas of restorations, coupled with the single-component, single-material combination, appears highly effective in ensuring excellent biocompatibility.[25,26]

Conclusions

Following meticulous case selection and implementation of a thorough periodontal maintenance program, single crowns directly secured onto an external hexagon platform have demonstrated favorable survival and success rates, devoid of complications. These outcomes are comparable to those achieved with alternative materials and techniques employed in implant prosthetic dentistry.

Acknowledgments

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. The authors declare no conflicts of interest.

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References

1. Corbella S, Alberti A, Calciolari E, Francetti L. Medium- and Long-Term Survival Rates of Implant-Supported Single and Partial Restorations at a Maximum Follow-up of 12 Years: A Retrospective Study. Int J Prosthodont 2021;34:183-91.

2. Sailer I, Mühlemann S, Zwahlen M, Hämmerle CHF, Schneider D. Cemented and screw-retained implant reconstructions: a systematic review of the survival and complication rates. Clin. Oral Implants Res 2012;23:163-201.

3. Lee KY, Shin KS, Jung JH, Cho HW, Kwon KH, Kim YL. Clinical study on screw loosening in dental implant prostheses: a 6-year retrospective study. J Korean Assoc Oral Maxillofac Surg 2020;46:133-42.

4. Varvara G, Sinjari B, Caputi S, Scarano A, Piattelli M. The Relationship Between Time of Retightening and Preload Loss of Abutment Screws for Two Different Implant Designs: An In Vitro Study. J Oral Implantol 2020;46:13-7.

5. Lai HC. [Prevention and management of hardware and biological complications in implant dentistry]. Zhonghua Kou Qiang Yi Xue Za Zhi 2020;55:814-8.

6. Wittneben JG, Millen C, Brägger U. Clinical performance of screw- versus cement-retained fixed implant-supported reconstructions--a systematic review. Int J Oral Maxillofac Implants 2014;29:84-98.

7. Vigolo P, Mutinelli S, Givani A, Stellini E. Cemented versus screw-retained implant-supported single-tooth crowns: a 10-year randomized controlled trial. Eur J Oral Implantol 2012;5:355-64.

8. Millen C, Brägger U, Wittneben JG. Influence of prosthesis type and retention mechanism on complications with fixed implant-supported prostheses: a systematic review applying multivariate analyses. Int J Oral Maxillofac Implants 2015;30:110-24.

9. Chrcanovic BR, Kisch J, Larsson C. Retrospective clinical evaluation of implant-supported single crowns: Mean follow-up of 15 years. Clin Oral Implants Res 2019;30:691-701.

10. Guncu MB, Aktas G, Guncu GN, Anıl D, Turkyilmaz I, Antonoff LR. Clinical, Technical, and Radiologic Outcomes of 182 Implant-Supported Zirconia Single Crowns Using Titanium-Base Abutments: A Retrospective Study. Int J Prosthodont 2022;35:553-9.

11. Atsü SS, Aksan ME, Bulut AC. Fracture Resistance of Titanium, Zirconia, and Ceramic-Reinforced Polyetheretherketone Implant Abutments Supporting CAD/CAM Monolithic Lithium Disilicate Ceramic Crowns After Aging. Int J Oral Maxillofac Implants 2019;34:622-30.

12. Moilanen P, Hjerppe J, Lassila LVJ, Närhi TO. Fracture Strength and Precision of Fit of Implant-Retained Monolithic Zirconia Crowns. J Oral Implantol 2018;44:330-4.

13. Worni A, Kolgeci L, Rentsch-Kollar A, Katsoulis J, Mericske-Stern R. Zirconia-Based Screw-Retained Prostheses Supported by Implants: A Retrospective Study on Technical Complications and Failures. Clin Implant Dent Relat Res 2015;17:1073-81.

14. Truninger TC, Stawarczyk B, Leutert CR, Sailer TR, Hämmerle CH, Sailer I. Bending moments of zirconia and titanium abutments with internal and external implant-abutment connections after aging and chewing simulation. Clin Oral Implants Res 2012;23:12-8.

15. Sailer I, Sailer T, Stawarczyk B, Jung RE, Hämmerle CH. In vitro study of the influence of the type of connection on the fracture load of zirconia abutments with internal and external implant-abutment connections. Int J Oral Maxillofac Implants 2009;24:850-8.

16. Lemos CAA, Verri FR, Noritomi PY, de Souza Batista VE, Cruz RS, de Luna Gomes JM, de Oliveira Limírio JPJ, Pellizzer EP. Biomechanical Evaluation of Different Implant-Abutment Connections, Retention Systems, and Restorative Materials in the Implant-Supported Single Crowns Using 3D Finite Element Analysis. J Oral Implantol 2022;48:194-201.

17. Gao SH, Guo DN, Zhou YS, Pan SX. [Clinical outcome of single posterior implant-supported monolithic zirconia crowns fabricated using complete digital workflow and conventional workflow: a 3-year follow-up]. Zhonghua Kou Qiang Yi Xue Za Zhi 2022;57:272-9.

18. Cortellini D, Canale A, Schmitz JH, Valenti M, Valenti A. A digital protocol for the fabrication of anatomic-contour implant zirconia crowns directly screwed on external hexagonal implant connections without the interposition of a Ti-base component. J Prosthet Dent 2023;8:S0022-3913(23)00061-6. Epub ahead of print.

19. Di Fiore A, Vigolo P, Graiff L, Stellini E. Digital vs conventional workflow for screw-retained single-implant crowns: a comparison of key considerations. Int J Prosthodont 2018;31:577-9.

20. Joda T, Brägger U. Time-efficiency analysis of the treatment with monolithic implant crowns in a digital workflow: a randomized controlled trial. Clin Oral Implants Res 2016;27:1401-6.

21. Graf T, Güth JF, Diegritz C, Liebermann A, Schweiger J, Schubert O. Efficiency of occlusal and interproximal adjustments in CAD-CAM manufactured single implant crowns - cast-free vs 3D printed cast-based. J Adv Prosthodont 2021;13:351-60.

22. Pan S, Guo D, Zhou Y, Jung RE, Hämmerle CHF, Mühlemann S. Time efficiency and quality of outcomes in a model-free digital workflow using digital impression immediately after implant placement: A double-blind self-controlled clinical trial. Clin Oral Implants Res 2019;30:617-26.

23. Valenti M, Valenti A, Schmitz JH, Cortellini D, Canale A. Survival analysis up to 7 years of 621 zirconia monolithic single crowns with feather-edge margins fabricated with a cast-free workflow starting from intraoral scans: A multicentric retrospective study. J Prosthet Dent 2023;129:76-82.

24. Kaplan EL, Meier P. Non parametric estimation from incomplete observations. J Am Stat Assoc 1958;53:457-81.

25. Linkevicius T,Vaitelis J. The effect of zirconia or titanium as abutment material on soft peri-implant tissues: a systematic review and meta-analysis. Clin Oral Impl Res 2015;00:1–9.

26. Valantijiene V, Mazeikiene A, Alkimavicius J, Linkeviciene L, Alkimaviciene E, Linkevicius T. Clinical and immunological evaluation of peri-implant tissues around ultra-polished and conventionally-polished zirconia abutments. A 1-year follow-up randomized clinical trial. J Prosthodont 2023;32:392-400.