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RESEARCH ARTICLE

RETROSPECTIVE MULTICENTER CLINICAL TRIAL ON 101 FDS76® DENTAL IMPLANTS

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Abstract

Background: Dental implants restore functionality and aesthetics in patients with missing teeth. Osseointegration, the direct structural and functional connection between living bone and the implant's surface, is essential for implant stability and success. This retrospective multicenter clinical trial aimed to assess the survival rate and effectiveness of FDS76® dental implants.

Materials and Methods: A total of 101 FDS76® dental implants were placed in patients by ten different clinicians across multiple centers in southern Italy. Patients included were classified from ASA1 to ASA3 and did not have conditions affecting bone metabolism or undergoing treatment for oncological diseases. The implants were evaluated using various surgical and prosthetic protocols, including immediate and delayed placement, conventional implantology, and loading protocols. Follow-up periods extended up to 24 months, and outcomes were assessed based on implant survival rates and peri-implant bone resorption.

Results: The study found that the overall survival rate of the FDS76® dental implants was consistent with international standards, with a failure rate of 1.98% at the 24-month follow-up. Immediate post-extraction implants showed longer average follow-up times than delayed ones. Cemented prosthetic rehabilitations were used in 41 cases (40.59%), while screwed prosthetic rehabilitations were employed in 60 cases (59.41%).

Conclusions: FDS76® dental implants demonstrated high survival rates and effective osseointegration, comparable to other leading implant systems. The study supports the reliability of these implants and highlights the importance of standardized protocols to optimize outcomes. Future research should focus on larger sample sizes and more extended follow-up periods to validate these findings further.

Key-words: Dental implants; osseointegration; implant survival rate; retrospective multicenter study

Introduction

Implant devices are inserted in bone tissue, obtaining osseointegration. Initially characterized by Brånemark, this process is described as the direct, structured, and functional amalgamation between living bone and the surface of implant-bearing loads.¹ The procedure of inserting endosteal implants triggers a multifaceted cascade of biological responses linked to the healing of wounds: inflammation, cell proliferation, and tissue maturation. The regeneration of osseous and soft tissues surrounding endosteal implants is a dynamic activity influenced by multiple elements, including the minimally invasive surgical method, osteotomy design, the patient's immune response, the macro and micro architecture of the dental implants, how well the implant fits within the osteotomy, the occurrence of wound dehiscence, and the protocol for applying load. To ensure superior functionality, dental implants must possess adequate mechanical robustness, be biocompatible, and maintain biostability in the human body.²⁻⁴ The topography of implant surfaces has undergone extensive examination for an extended period. It plays a significant role in their integration with the hard and soft tissues of the oral cavity. According to scholarly texts, implants with a textured surface exhibit higher osseointegration rates than those with a smooth exterior. Advancements in the domain of implants have led to an evolution in the standards for surface treatment of these components, transitioning from smooth machined exteriors to textured surfaces to enhance osseointegration through the osteoconductive characteristics offered by such manufacturing techniques.⁵⁻⁷ Cochran and colleagues assessed 36 implants featuring a smooth trans gingival route and 36 with a textured implant neck, conducting their study on canine subjects. Their findings revealed successful osseointegration of all 72 implants, achieving clinical efficacy; radiographic and histological examinations demonstrated that implants with a textured transmucosal path secured superior bone level stability compared to their smooth counterparts, a statistically notable disparity. The secondary stability of the implant showed an increase over time following the Wolf curve in both scenarios, although the levels attained by implants with textured necks were marginally elevated. Histological assessments indicated that peri-implant soft tissues exhibited increased inflammation levels in textured implants, a

variation that resolved after three months, aligning equivalently by the 12-month mark.⁸ The requirement for a dental implant emerges from the absence of one or more dental elements within a patient's dental arch. Immediate restoration and the enduring stability of outcomes are contingent upon numerous factors, from the practitioner's expertise to the specific characteristics of the implant system and the patient's health status. Variables associated with the clinician encompass accurate diagnosis, the formulation of a comprehensive treatment strategy—essential for therapeutic success—the execution of a precise surgical method, and the fitting of an appropriate dental prosthesis. Factors about the patient primarily include systemic health conditions, medication usage, tobacco use, oral hygiene practices, and local customs, such as the volume and quality of existing bone, microbiological components, and periodontal health. Critical elements of the implant are its design, macro and micro geometry, surface type, and connection between the implant and abutment. Successfully integrating these numerous factors necessitates meticulous and detailed attention to each aspect. The widely recognized standards for determining implant success, proposed by Albrektsson and Zarb, focus predominantly on the osseous characteristics of the implant.^{9,10} Additional criteria consider various facets, including the stability of the prosthesis-implant connection, aesthetic considerations, particularly in the anterior region, and patient satisfaction. This study aimed to assess the survival rate of FDS76® dental implants through a multicentric collection of results.

Materials and Methods

Sample

101 dental implants were placed to perform prosthetic implant rehabilitations in different patients. The multicenter study involved the collaboration of 10 different clinicians in southern Italy. Clinicians with experience in implantology have performed implant insertion maneuvers using different surgical and prosthetic protocols with a maximum follow-up of 24 months. In the following paragraphs, the characteristics of the materials used and the protocols are detailed. All patients were from ASA1 to ASA3, and they were not taking drugs that affect bone metabolism or antiepileptic drugs and are not yet being treated for oncological diseases. As regards the

pharmacological protocol, pre-surgical antibiotic prophylaxis was proposed, and subsequently, no topical disinfection protocols with chlorhexidine were applied.¹¹⁻¹³

Dental Implants

FDS76® is a dental implant distributor based in Italy. They have three series of dental implants: K2 (wide spire), K3 (tight spire), and V4 (internal conical connection). All products are made of titanium grade Ti-6Al-4 and certified by CE, ISO, ECC, and the Italian Ministry of Health. The fixture's surface design

is complex, allowing a considerable enlargement of the area in contact with maxillary bone to improve osseointegration. All dental implants are treated with a coarse sandblasting technique that generates a macro-roughness of the titanium surface. The stability of the implant-abutment connection is crucial to minimize mechanical and biological complications. The microgap behavior and abutment displacement were assessed with a MicroTC analysis (Figure 1, 2).¹⁴⁻¹⁶ Dental implants were placed only in later-posterior sectors, and the dimensions used are shown in Table 1.

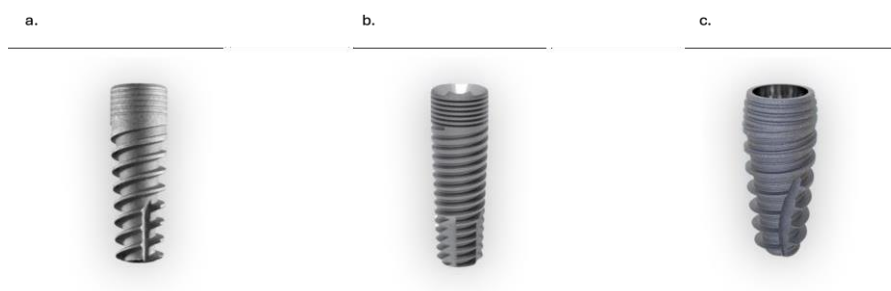


Figure 1. FDS76® Dental implants. a. K2, b. K3, c. V4.

Table 1. Dental implants used measures

FDS76® Dental implant type	Diameter (mm)	Length (mm)
K2	4.2/5	8/10/11.5
K3	4.2/5	8/10/11.5
V4	4.3/5	8/10/11.5

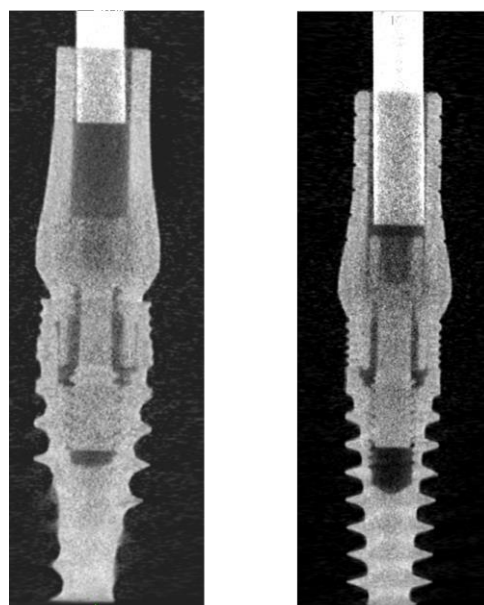


Figure 2. Micro-TC of V4 (left) and K2 (right) FDS76® dental implant with connection detail. Both with internal connections, but the V4 presents a platform switching.

Protocols

This multicenter study investigated different surgical and prosthetic protocols regarding the placed implants. Different clinical centers were asked to note

the type of protocol used and the results obtained to compare them with the available literature. The protocols are shown below in Figures 3 and 4:

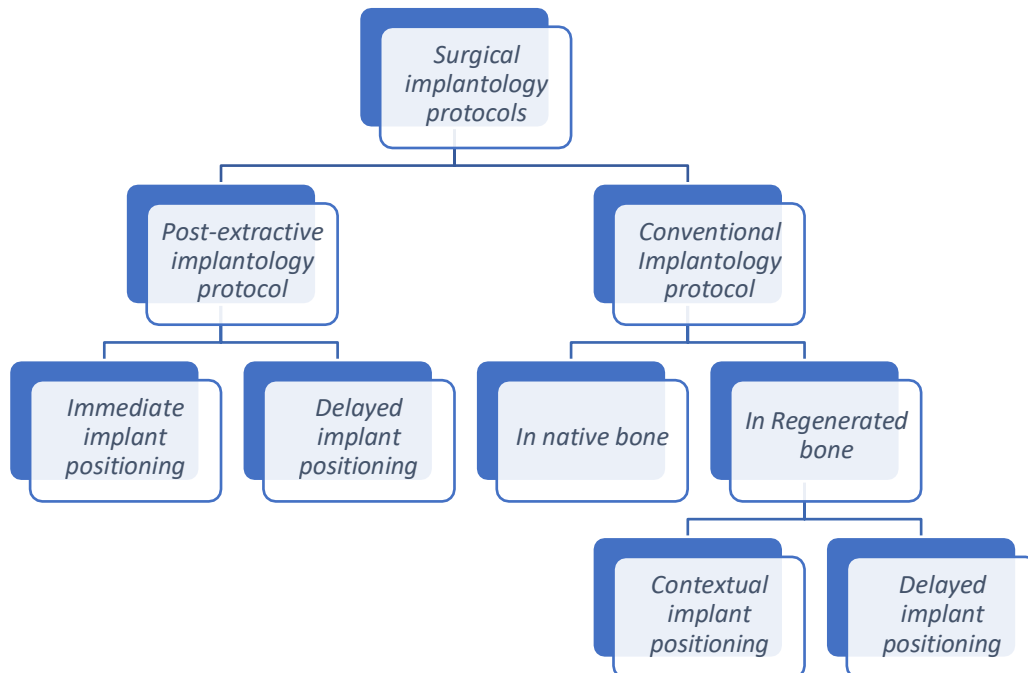


Figure 3. Surgical dental implants investigated protocols

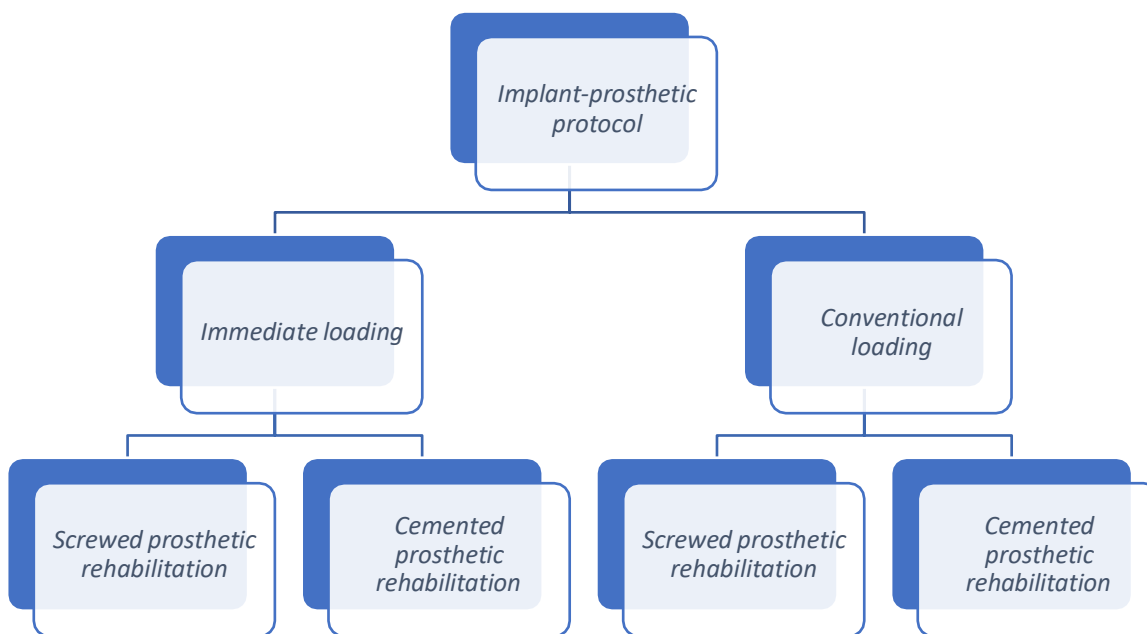


Figure 4. Prosthetic rehabilitation investigated protocols

Results

This section will illustrate the results obtained by the different clinicians on implants, as described in the previous chapter. Table 2 presents these results with a

breakdown that mirrors Figures 3 and 4. The conventional protocol was used for 36 implants (31,68%), immediate post-extractive placement for 11 (10,89%) and delayed post-extractive placement for 50 (49,50%).

Regarding implants placed on regenerated bone after healing was 4 (3,96%); the same during the bone regeneration procedure was 4 (3,96%).

The clinicians' choice of timing for prosthesis placement was the conventional protocol for 47 (46,53%) and the immediate loading protocol for 54

(53,47%).

The dental prosthesis related was cemented for 41 (40,59%) implants and screwed for 60 (59,41%).

All results are shown in Table 2,3,4; this is a summary Table subdivided in this way:

Synthesis of Results

Table 2. Summarized synthesis of Results according to Materials and Methods

			Sample size	Complications		Follow-up (in months)
				Short-time	Long-time	
Surgical Protocol	Post extractive Dental implants	Immediate	11			24
				Description	Number	
		Peri-implant bone reabsorption	7			
		Delayed	50			8
	Conventional Dental implants		32	Description	Number	15
				No- osseointegration	2	
Regenerated Bone	Delayed	4			12	
	Contextual	4			12	
Loading Protocol	Conventional		47			24
	Immediate		54			8-15
Prosthetic Protocol	Cemented		41			12-24
	Screwed		60			8-15

Statistical Data

On 101 dental implants placed, the following data were extrapolated:

Table 3. Surgical protocol percentual

Surgical Protocol	Incidence
Conventional surgical protocol	31.68%
Immediate Post-extractive Dental implants	10.89%
Post-extractive delayed Dental implants	49.50%
Bone regeneration contextual to dental implant insertion	3.96%
Dental implant positioned in regenerated bone	3.96%

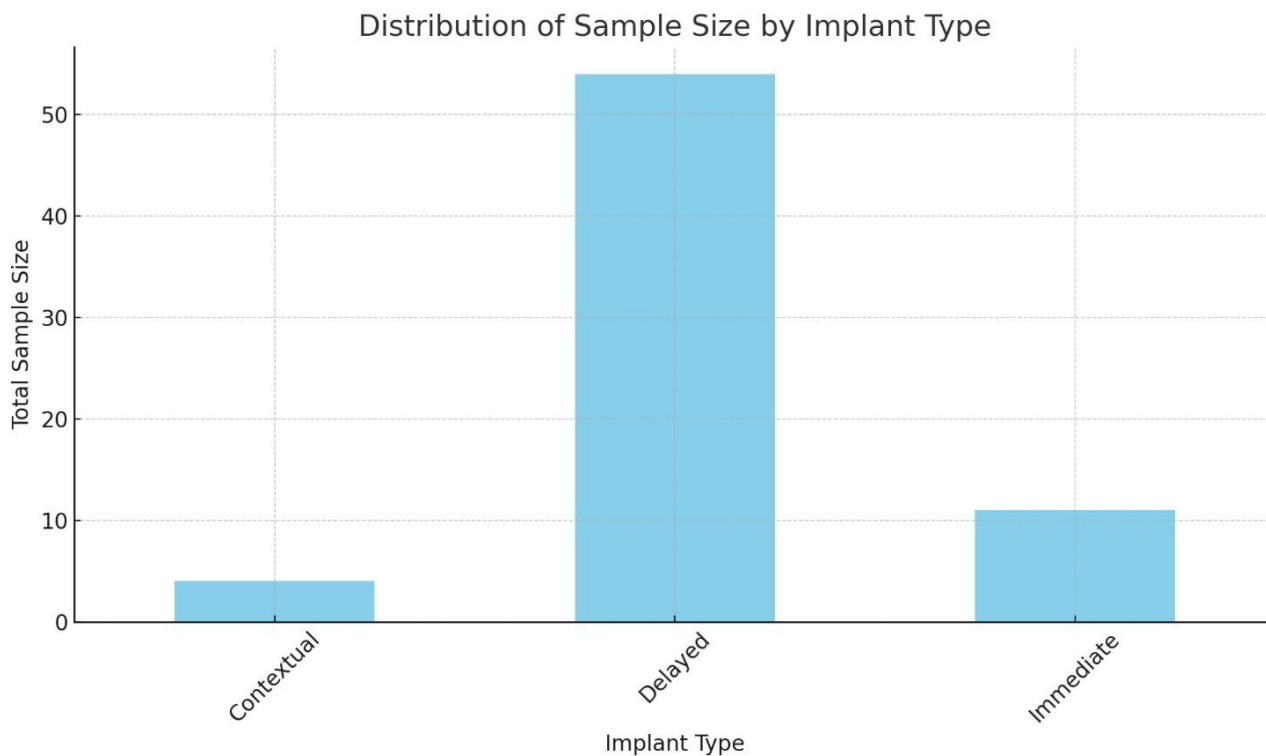


Figure 5. Distribution by dental implant protocol type

Table 4. Prosthetic protocol percentual

Prosthetic Protocol	Incidence
Conventional Loading Protocol	46.53%
Immediate Loading Protocol	53.47%
Cemented Prosthetic rehabilitation	40.59%
Screwed Prosthetic rehabilitation	59.41%

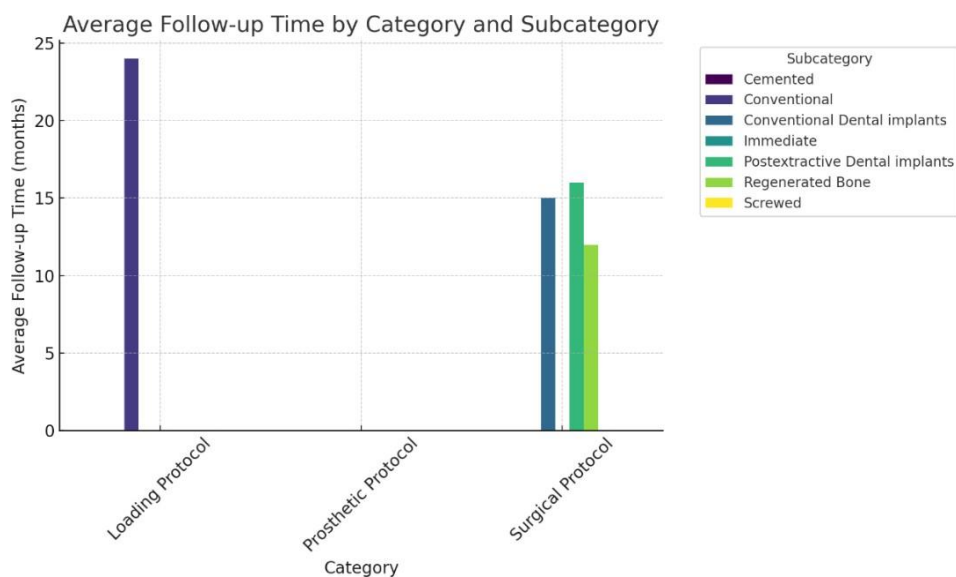


Figure 6. Average follow-up time by category

The median follow-up time was 12.3 months, between 8 and 24 months. 98,2% of implants didn't show any problems. Two implants (1.98%) had short-term complications with no osseointegration in the conventional protocol group. Seven had an average bone resorption of 1.3 mm in 24 follow-up months.

- Sample size distribution by dental implant protocol type:
 - Regenerated and conventional dental implants represent the main categories, with significant sample sizes.
- Average follow-up time by category and subcategory:
 - Immediate post-extraction implants have a longer average follow-up time than delayed ones.
- Comparison Between Immediate and Delayed Post-Extraction Implants:
 - Immediate postextraction implants have a smaller sample but longer follow-up than delayed ones.

Discussions

The contemporary analysis of specific dental implant systems reveals noteworthy findings regarding their performance over a follow-up period of 24 months. Notably, these implants exhibit a bone resorption rate within acceptable clinical thresholds. Cumulative data delineate that the failure rate does not exceed 1.98% at the 24-month evaluation point. This rate is comparable to the outcomes documented for other dental implant systems employed globally. Such consistency in performance underscores the reliability and efficacy of this implant technology in maintaining skeletal integrity adjacent to the implant site, thus reflecting a standard observed across the international spectrum of dental implantology.

Dental implantology has experienced substantial advancements over the years, significantly influenced by the evolution of implant surface characteristics and geometry. Initially, dental implants had smooth surfaces and were primarily machined. However, to enhance osseointegration and success rates, the surfaces were modified to become rougher through various techniques such as sandblasting, acid-etching, and plasma spraying. These modifications increase the surface area in contact with bone and improve biological compatibility, facilitating faster and

stronger bone integration.¹⁴

The geometry of dental implants has also evolved to address different clinical scenarios and bone qualities. Early implants were often uniform in shape, but today's implants come in various lengths, diameters, and thread designs to optimize load distribution and bone contact. Tapered implants, for instance, can provide better primary stability in soft bones than the cylindrical designs of the past.^{17,18}

Dental implants' success and survival rates have improved significantly with these advancements in surface and geometry. Modern dental implants exhibit high success rates, typically above 90% over 10 years. The survival rate, which refers to the implant remaining in situ regardless of complications or the outcome, also tends to be high, with many studies reporting rates of 95% or greater after 10 years. These outcomes can vary based on implant location, patient health, bone quality, and maintenance care. For instance, implants placed in the maxilla (upper jaw) tend to have slightly lower success rates than those in the mandible (lower jaw) due to differences in bone density. Recent studies indicate that implant surface micro and nano-scale modifications may further enhance osseointegration. Such innovations aim to increase the bioactivity of the implant surface, potentially leading to quicker and more robust bone healing around the implant. Additionally, introducing materials like zirconia instead of titanium for certain applications reflects ongoing research and adaptation in implant material sciences to improve aesthetic outcomes and biocompatibility.¹⁹⁻²¹

Thoma DS et al.²² conducted a randomized, controlled multi-center study to compare the efficacy of shorter dental implants (6 mm) to longer implants (11-15 mm) with sinus floor elevation over 10 years. Their findings indicate no significant difference in implant survival rates between the two groups, suggesting that shorter implants could be a viable alternative, particularly for patients with limited ridge height in the posterior maxilla. This study emphasizes the potential benefits of using shorter implants, such as reduced patient morbidity and lower costs, without compromising clinical outcomes, presenting a compelling case for considering shorter implants in suitable clinical scenarios. Chacun D et al.²³ focused on the survival rates and marginal bone level changes surrounding tissue-level (TL) dental implants with a novel hybrid design. Over up to 4.5 years, these

implants exhibited high cumulative survival rates and stable peri-implant marginal bone levels. Their findings support the use of these TL implants as a reliable option for restoring partially or fully edentulous patients, with the study calling for future prospective studies to validate these results in a real-world setting further. Xiong Y et al.²⁴ provided a bibliometric analysis of global research trends on peri-implantitis from 2001 to 2020. This study highlighted the most frequently discussed topics and emerging trends in peri-implantitis research, revealing a strong focus on epidemiology, treatment options, and outcomes. The authors suggest that future research should prioritize international multicenter studies to understand the prevalence and management of peri-implantitis better, reflecting a growing need for global collaboration. Müller F et al.²⁵ compared 10-year outcomes of small-diameter titanium-zirconium (TiZr) and grade IV titanium (Ti) implants in a randomized, controlled, double-blind split-mouth study. The results demonstrated both materials' high implant survival and success rates, with TiZr showing slightly better performance. This study underlines the effectiveness of using small-diameter implants, particularly TiZr, for long-term stability in mandibular implant-overdentures. It provides a solid foundation for continued clinical practice use.^{26,27} Nickenig HJ et al.²⁸ assessed the impact of dental implants on oral health-related quality of life (OHRQoL) across different implant indications through a large-scale multicenter study. The significant improvements noted in OHRQoL post-implantation, especially for patients with edentulous jaws, underline dental implants' profound impact on patients' quality of life. The study emphasizes the need for clinicians to focus on the psychological aspects of implant therapy to enhance patient satisfaction and treatment success. Mokhtari RA et al.²⁹ evaluated the safety and performance of zoledronate-coated versus uncoated dental implants in a randomized, multicenter study. The findings at the 1-year mark showed no significant differences in implant stability or marginal bone levels, confirming the safety and effectiveness of zoledronate-coated implants in clinical practice. This study adds to evidence supporting bisphosphonate coatings to enhance implant outcomes. In a retrospective multicenter study, Klein M et al.³⁰ reported on the clinical performance of a novel digital workflow for full-arch restorations using the NEXUS IOS® system. The successful

integration and minimal complications observed over a one-year follow-up period highlight the potential of digital workflows in enhancing the precision and efficiency of implant-supported full-arch restorations. The study advocates for adopting such innovative technologies in routine clinical practice.¹² Walter C et al.³¹ investigated the use of narrow-diameter implants for single-tooth restorations in areas with limited space, reporting a high survival rate and favorable aesthetic outcomes after one year. This study reinforces the utility of narrow-diameter implants in challenging clinical situations, providing evidence of their safety and effectiveness for practitioners looking to optimize aesthetic outcomes in tight interdental spaces. In a retrospective multicenter study, Lisa K et al. compared the outcomes of maxillary sinus floor augmentation using allografts versus xenografts. Both materials showed similar implant survival rates, although allografts were associated with a higher incidence of complications. This study contributes to the ongoing debate on optimal sinus augmentation materials, suggesting that allografts and xenografts can be effective but may present different clinical challenges.³²⁻⁴¹

The dynamic advancements in dental implantology, particularly in implant surface characteristics and geometry, have significantly improved their success and survival rates. These innovations have tailored implant designs to better suit varying anatomical and bone conditions, thereby enhancing osseointegration and overall clinical outcomes. The introduction of modifications at the micro and nano-scale levels and the exploration of alternative materials such as zirconia further demonstrate the field's ongoing commitment to optimizing both functional and aesthetic results for patients.⁴¹⁻⁴⁴

However, while the results from multicentric studies like those conducted by Thoma DS et al., Chacun D et al.,^{22,23} and others provide valuable insights into the efficacy of different implant designs and configurations, these studies also highlight inherent limitations. Multicentric studies often involve diverse patient populations and variable clinical settings, which can introduce inconsistencies in data collection, methodology, and outcome measures. The logistical complexities and potential biases associated with coordinating multiple centers can affect the generalizability of the findings. Additionally, these studies typically require extensive resources and time,

limiting the frequency and scope of such research. To address these challenges, future research should aim for standardized protocols across centers and incorporate advancements in digital and diagnostic technologies to streamline data collection and analysis, ensuring more robust and replicable results. This approach will not only refine current methodologies but also enhance the reliability of outcomes, driving forward the field of dental implantology with scientifically sound evidence.

Conclusions

In summary, the clinical trial results were consistent with the findings proposed in the international scientific literature. The implants exhibited an optimal survival rate and were per the established standards, with some instances even reporting superior results. The implications of this study extend beyond the immediate findings, as it serves as a cautionary example for future clinical trials and underscores the importance of identifying and

evaluating factors that may influence the results. This study provides valuable insights into the efficacy and reliability of the implants used in the clinical trial.

Declarations

Conflicts of interest and financial disclosures

The author declares that he has no conflict percent and there was no external source of funding for the research in question.

Ethical approval

The study was approved by the University ethics committee and was conducted in accordance with the Declaration of the World Medical Association.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Source of funding

The work was not funded.

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