

# Zirconia Dental Implants as a Different Alternative to Titanium: A Literature Review

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**ABSTRACT** **Aim:** This article aims to provide an overview of the scientific evidence comparing zirconium dental implants with titanium implants. **Materials and Methods:** A comprehensive literature review was conducted using the MEDLINE database accessed through PubMed and Scopus. The search included the keywords “dental implant,” “zirconia dental implant,” and “titanium dental implant” without any date restrictions. **Results:** The review examined research articles focusing on the physical and chemical characteristics of titanium and zirconia dental implants. Additionally, studies investigating the strength and translucency of zirconia, as well as the osseointegration of both materials, were analyzed. However, no conclusive evidence demonstrating the superiority of either material was found in the current literature. **Conclusion:** Taking into account the findings of this narrative study, no significant differences were identified between zirconium and titanium dental implants. Further scientific research is required to establish a definitive recommendation regarding the use of one material over the other.

**KEYWORDS:** Dental implants, titanium, zirconia

## INTRODUCTION

The installation of osseointegrated implants is a widely utilized restorative technique for replacing missing teeth. Whether it is a single tooth loss or extensive tooth loss resulting in complete edentulism, these implant-supported prostheses serve as an alternative to traditional bridges or removable dentures. Implant therapy has demonstrated remarkable success and longevity, especially after achieving the stage of osseointegration.<sup>[1]</sup>

The utilization of titanium and its alloys is prevalent in dentistry, particularly in implant dentistry, due to their superior biological compatibility, osseointegration properties, and enhanced mechanical and corrosion resistance compared to other metallic biomaterials. Nonetheless, there are instances where titanium dental

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implants may exhibit inadequate osseointegration. To enhance the biological and mechanical characteristics of implants, extensive research has been conducted on surface modifications, primarily aiming to improve the implant-bone connection, particularly in areas with low bone density.<sup>[2]</sup>

Considering the limitations, new technologies have emerged that involve the production of ceramic implants. Nonetheless, ceramics are known to be susceptible to shear and stress due to their brittleness, and surface issues can lead to premature failure, posing a high risk of fracture.<sup>[3]</sup> Recently, high-strength zirconia ceramics have gained attention as a promising material for dental implants. These ceramics are biologically inert and have minimal ion release, making them favorable compared to metal implants. Yttria-stabilized tetragonal zirconia polycrystals, in particular, offer several advantages over aluminum oxide dental implants, including superior fracture and bending resistance.<sup>[4]</sup> Zirconia demonstrates suitability for dental implants due to its tooth-like color, favorable mechanical properties, and biocompatibility.<sup>[5]</sup> Furthermore, ceramics induce lower inflammation and bone resorption compared to titanium particles, indicating their biocompatible nature.<sup>[6]</sup>

The aim of this literature review was to describe the scientific evidence performed on zirconia dental implants as a different alternative to titanium.

## MATERIALS AND METHODS

### SEARCH STRATEGY

In this narrative review, a search was carried out in PubMed and Scopus based on the design of a search strategy presented below, which was adapted according to the database: “Dental Implants” [Title/Abstract] OR “Implant Dental” [Title/Abstract] OR “Implants Dental” [Title/Abstract] OR “Dental Implant” [Title/Abstract] OR “Dental Implants Mini” [Title/Abstract] OR “Dental Implant Mini” [Title/Abstract] OR “Mini Dental Implant” [Title/Abstract] OR “Mini Dental Implants” [Title/Abstract] OR “Dental Prostheses Surgical” [Title/Abstract] OR “Dental Prosthesis Surgical” [Title/Abstract] OR “Surgical Dental Prostheses” [Title/Abstract] OR “Surgical Dental Prosthesis” [Title/Abstract] OR “Prostheses Surgical Dental” [Title/Abstract] OR “Prosthesis Surgical Dental” [Title/Abstract] OR “Zirconia Dental Implant” [Title/Abstract] OR “Titanium Dental Implant” [Title/Abstract].

Additionally, a supplementary manual search was conducted, which involved examining the reference lists

of the initially retrieved articles and exploring relevant journal websites. The electronic search was not limited by any specific date range.

### INCLUSION CRITERIA

In this review, we searched exclusively for articles dealing with titanium and zirconium implants, with almost all articles being from recent years, and selected those that discussed relevant aspects of each material, including their advantages and disadvantages.

### EXCLUSION CRITERIA

Specific exclusions were made during the search and selection of articles for the review. Review articles, meta-analyses, and case reports were systematically excluded, and the search was limited to articles written in English.

Two reviewers conducted the search and selection process independently, with a deadline set for completion of the process. After an exhaustive review of the titles, abstracts and full texts of the articles, those that met the defined inclusion and exclusion criteria were selected. The selected articles were discussed and evaluated by the review authors.

## RESULTS

The findings of the reviewed studies were categorized and presented in two primary sections: (1) a comprehensive analysis of articles pertaining to titanium-based implants, and (2) a thorough examination of articles focused on zirconium-based implants [Table 1].

### REVIEW OF ARTICLES ON TITANIUM IMPLANTS

#### *Cytotoxicity in commercially pure titanium (cpTi) implants*

The results indicated that, following a 10-day incubation in DMEM (Minimal Essential Medium), cells exhibited enhanced viability when exposed to commercially pure titanium (cpTi) alloys compared to Ti-6Al-4V (Titanium-Aluminum-Vanadium) alloys. Unlike the latter, direct contact between the cells and the cpTi alloy did not elicit any toxic effects. The reduced toxicity observed in cpTi may be attributed to the minimal release of vanadium ions, which have been associated with cell necrosis.<sup>[7]</sup> Furthermore, the investigation revealed that both commercial and novel titanium-based binary alloys demonstrated no statistically significant cytotoxicity.<sup>[8-11]</sup>

#### *Titanium implant osseointegration*

Various techniques have been employed to modify the surface structure of dental implants composed of titanium and titanium alloys, aiming to enhance their ability to integrate with bone (osseointegration). In general, surfaces with rough textures and thick

**Table 1: Characteristics of the studies included**

Author/year	Aim	Methodology	Main findings	Conclusions
Compton <i>et al.</i> 2017 <sup>[1]</sup>	This study investigated implant outcomes in the elderly and factors impacting dental implant success in older adults. It aimed to evaluate survival rates and identify indicators influencing outcomes.	This prospective landmark study examined the long-term performance of dental implants in a cohort of pre-1950 born patients. The study assessed the implant's stability and marginal bone levels, considering various patient and implant factors. The findings provide valuable insights into implant outcomes in this specific population.	The presence of generalized or severe periodontal disease negatively impacted the survival of dental implants. Furthermore, implants placed in sites requiring bone augmentation prior to or during surgery had a lower likelihood of long-term success compared to implants placed without prior augmentation.	The study's overall findings suggest that dental implants could be successfully placed in older adults.
Ding <i>et al.</i> 2022 <sup>[2]</sup>	To evaluate the bone response to microarc oxidation-coated titanium alloy implants containing Ag.	A total of 144 titanium alloy implants were included in the study and divided into three treatment groups: wet sandblasting and acid etching, micro-arc oxidation without Ag coating, and micro-arc oxidation containing Ag coating (MAO + Ag).	Scanning electron microscopy and cross-sectional analysis of bone segments, along with fluorescent labeling analysis, revealed that the MAO+Ag group exhibited higher levels of bone formation and greater osseointegration capacity compared to the other two groups.	The integration of micro-arc oxidation with the application of Ag coating demonstrates remarkable efficacy as a surface modification method, facilitating the formation of a porous surface structure and augmenting the hydrophilic properties of titanium alloy implants.
Andreiotelli <i>et al.</i> 2009 <sup>[3]</sup>	To evaluate the fracture toughness of zirconium oxide implants after exposure to artificial aging.	Groups were formed, consisting of 16 samples each, which had 24 samples. A subset of each implant type (eight implants) underwent thermo-mechanical cycling in a chewing simulator before being subjected to fracture testing. The specimens were loaded until fracture occurred.	Out of the 120 samples, seven failed during the chewing simulator test. The fracture strength of zirconium oxide implants without preparation ranged from 725 to 850 N, while the prepared implants fractured at 539 to 607 N. In Group A, the specimens fractured at the abutment screw level. Fracture of zirconium oxide implants occurred at the Technovit resin level, while no fractures were observed in the zirconium oxide crowns in Group G.	The study findings indicate that zirconia implants with modified surface structures exhibit comparable bone integration to titanium implants, suggesting their suitability as a viable alternative. Furthermore, the fracture toughness values of the zirconia implants fell within the acceptable range for clinical applications.
Sennerby <i>et al.</i> 2005 <sup>[4]</sup>	The objective was to assess the histological and biomechanical response of bone tissue to zirconia implants with two different surface modifications compared to unmodified zirconia implants.	Threaded zirconium implants with a machined surface and oxidized titanium implants were created for the study. A total of 96 implants were placed in twelve rabbits, with torque testing conducted on six rabbits and en bloc extraction performed on the remaining six for light microscopic analysis.	The study revealed that there were no significant differences in bone-implant contact and bone area within the threads between the surface-modified implants and the control implants. The surface modifications remained intact after the testing, and in cases of failure, the fracture occurred at the bone-implant interface rather than a separation of the bone-implant connection.	The study found that the surface-modified zirconia implants exhibited a significant four- to five-fold increase in stability compared to the machined zirconia implants. These results indicate that the surface modifications enhance the implant's ability to achieve firm stability in bone.

Table 1: Continued

Author/year	Aim	Methodology	Main findings	Conclusions
Depprich <i>et al.</i> 2008 <sup>[5]</sup>	The study aimed to compare the bone healing capacity between titanium implants and zirconium implants with rough surfaces but similar geometries.	A total of 48 zirconium and titanium implants were placed in twelve dwarf pigs. After a specific time period, the animals were euthanized, and the samples containing the implants were analyzed using ultrastructural and histological techniques.	The findings revealed direct bone contact on both titanium and zirconia surfaces. While the area of bone-implant contact was slightly higher on titanium surfaces in comparison to zirconia.	The study showcased that modified surface zirconia implants exhibit a level of osseointegration that is comparable to titanium implants.
Ichikawa <i>et al.</i> 1992 <sup>[6]</sup>	This study aimed to assess the tissue compatibility and mechanical properties of a newly developed zirconium ceramic through a 12-month subcutaneous implantation in rats, investigating tissue reactions and changes in flexural strength over time.	The study utilized zirconium and polycrystalline alumina as control materials. The animals underwent full anesthesia with ethyl ether, and a standard surgical technique was employed for the implantation procedure.	Following a six-month period of implantation, the zirconium implants were entirely enclosed by a delicate fibrous connective tissue. This tissue response resembled the observations made around zirconia ceramics and polycrystalline alumina. Even after twelve months, a similar encapsulation of tissue persisted around the zirconia implants.	During the one-year experimental period, the zirconia ceramic demonstrated good tissue compatibility and maintained its mechanical stability. These findings indicate that zirconia ceramic holds promise as a viable material for dental implants, presenting added benefits such as color customization, simplified abutment preparation, and radiographic visibility.
Ellakany <i>et al.</i> 2022 <sup>[7]</sup>	The primary objective of this study was to evaluate the cytotoxic effects of commercially pure titanium (cpTi), silver-palladium (Ag-Pd), and nickel-chromium (Ni-Cr) on human gingival fibroblast (HGF) cells.	Ten 4x3mm disks were prepared for each alloy (cpTi, Ag-Pd, Ni-Cr) to assess their effects on HGF cells. Hepatocyte growth factor from healthy patients was used. The specimens were divided into groups, incubated in artificial saliva or Dulbecco's Modified Eagle medium.	Morphological examination revealed that only the cpTi alloy samples exhibited no cytotoxic effect. Among the three alloys, Ni-Cr demonstrated the highest cytotoxicity. Additionally, all three alloys exhibited decreased cytotoxicity when incubated in artificial saliva.	The corrosion resistance of cpTi was found to be superior to that of the Ag-Pd and Ni-Cr alloys. The Ag-Pd alloys exhibited acceptable corrosion resistance due to the passivity effect. Furthermore, it was observed that the cytotoxic effect of the tested alloys was more pronounced when exposed to artificial saliva compared to Dulbecco's Modified Eagle medium (DMEM).
Bienz <i>et al.</i> 2021 <sup>[8]</sup>	The objective of this study was to analyze the morphological characteristics of soft tissue under both healthy and experimental mucositis conditions, while comparing zirconia and titanium implants.	In this study, a cohort of 42 patients who were missing two adjacent teeth participated in the placement of both a zirconia (Zr) and a titanium (Ti) implant. The mesial and distal positions for the implants were randomly assigned. Clinical parameters were evaluated before and after the experimental phase, and a soft tissue biopsy was collected. The collected data were analyzed using mixed model analysis.	In the mucositis groups, there was an increase in the plaque control record, with lower scores observed in the zirconia-mesial (Zr-m) group compared to the titanium-mesial (Ti-m) group. The stability of bleeding on probing was maintained in the Zr-m group, while it significantly increased in the Ti-m group. No significant differences were observed between the groups in terms of the number of inflammatory cells and the length of the junctional epithelium.	Under healthy conditions, both zirconia and titanium implants showed similar results. However, in experimental mucositis conditions, zirconia implants had lower plaque and bleeding scores. Histologically, there were minimal differences observed between the two implant types.

Table 1: Continued

Author/year	Aim	Methodology	Main findings	Conclusions
Gil <i>et al.</i> 2021 <sup>[9]</sup>	The objective of this study was to examine whether the degradation mechanism observed in dental applications of yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) is comparable to that observed in orthopedic applications of Y-TZP.	This comparative study investigated the behavior of intact Y-TZP dental implants and fractured Y-TZP femoral balls in vivo. The dental implants were subjected to accelerated hydrothermal degradation, and the resulting degraded samples were analyzed for phase transformation using X-ray diffraction and for mechanical properties using nanoindentation tests. The objective was to assess and compare the degradation mechanisms and mechanical behavior between the dental implants and femoral balls.	The results of the study indicate that the fracture mechanism observed in dental implants differs from that observed in orthopedic specimens. Dental implants exhibit a favorable long-term behavior, suggesting that they are resilient and capable of withstanding mechanical stress without compromising their integrity.	The results obtained from this study affirm the outstanding performance of zirconia dental implants, as the degradation of the ceramic material was found to be minimal, with no significant adverse effects on the mechanical properties. This indicates the durability and reliability of zirconia implants for long-term dental applications.
Karlsen <i>et al.</i> 2020 <sup>[10]</sup>	The objective of this study was to assess the crack propagation resistance and hardness of dental zirconia materials with varying yttria content and fabricated through different methods.	In this study, the hardness and crack resistance of five types of dental crowns made from different materials were evaluated. All the crowns were composed of zirconia, but varied in their fabrication methods and yttria content. Specifically, the crowns were categorized as one 3Y-TZP machined crown, three crowns with yttria content between 3% and 5% that were smoothly machined, and two crowns smoothly machined with a yttria content of at least 5%.	his study revealed significant differences in the damage control characteristics among dental zirconias with varying compositions and fabrication methods. Notably, the machined 3Y-TZP (3 mol% yttria-stabilized zirconia) displayed superior resistance to crack propagation when compared to the smoothly machined 3-5% yttria-stabilized zirconia.	The findings of the study indicate that ultra-translucent zirconia containing 5% or more yttria content exhibited the lowest resistance to crack propagation. Additionally, the study suggests that hardness is not an appropriate indicator for assessing damage tolerance in zirconia materials.
Glauser <i>et al.</i> 2022 <sup>[11]</sup>	A histological examination was conducted to investigate the bone development around transmucosal implants and assess the impact of surface features on early peri-implant bone healing. This study utilized a miniature pig model as an experimental model.	In this experimental study, YTZP implants with modified roughened surfaces were inserted into mandibular premolar extraction sites in miniature pigs, along with tissue-level titanium implants as controls. After 4 and 8 weeks of healing, histological analysis was performed to evaluate bone development around the implants vicinity.	YTZP dental implants showed a high rate of osseointegration at 4 and 8 weeks. The bone-to-implant contact ratio increased from 58.5% to 82.4% at 8 weeks. The titanium control implant had a higher bone-to-implant contact ratio (93.6% at 8 weeks).	The results demonstrate predictable osseointegration of immediate zirconia implants with modified YTZP surface, with significant implant-bone contact at 4 weeks. After 8 weeks, both zirconia and titanium implants achieve complete osseointegration.

oxide layers have demonstrated greater suitability for promoting osteoblast differentiation and facilitating osseointegration.<sup>[5]</sup> An investigation into the bone response to titanium alloy implants coated with microarc oxidation containing silver (Ag) revealed that silver plays a role in the healing process of implants. The combination of microarc oxidation with silver represents a surface modification technique anticipated

to generate a porous and hydrophilic surface structure, thereby improving osseointegration.<sup>[2]</sup>

#### General comparison of zirconia and titanium dental implants

Whereas titanium (Ti) has long been the preferred material for dental implants due to its numerous advantages, it also has certain drawbacks, resulting in a growing demand for alternative materials

in implant-supported restorations.<sup>[12]</sup> Significant differences in strength were observed between the two groups, with one-piece zirconia abutments exhibiting notably lower fracture toughness compared to titanium abutments. This suggests that the failure is specific to the type of material and abutment design.<sup>[13]</sup>

In comparing titanium implants with zirconia implants, it was noted that zirconia implants demonstrated significantly higher mean values in both stability index measurement and frequency resonance assessment (FRa). However, micromotion during load application showed similar values for both types of implants, albeit with some differences between them.<sup>[14]</sup> Observations revealed that the marginal fit of crowns cemented on titanium abutments was significantly superior to zirconia abutments.<sup>[15]</sup>

In terms of healthy conditions, zirconia and titanium implants demonstrated comparable outcomes. Nonetheless, in experimental mucositis conditions, zirconia implants exhibited lower plaque and bleeding scores. Histologically, minimal differences were found between both groups.<sup>[8]</sup> Furthermore, no statistically significant differences were identified in the vascular density of tissues surrounding zirconia and titanium abutments.<sup>[12]</sup>

An evaluation of element stress in the bone surrounding Carbon Fiber Reinforced (CFR-PEEK) implants and titanium implants revealed that dental implants made of titanium can fail due to titanium allergy, leading to the exploration of new biomaterials such as Carbon Fiber Reinforced materials. One study discovered that when a force of 100 N was applied in both vertical and oblique directions, the bone surrounding CFR-PEEK and commercially pure titanium implants exhibited similar stress distribution.<sup>[16]</sup>

#### REVIEW OF ARTICLES ON ZIRCONIUM IMPLANTS

##### *Resistance of implants made of zirconium*

Yttrium (Y)-stabilized tetragonal zirconia polycrystalline dental implants are a type of implant that offers improved aesthetic properties compared to titanium used for implants. A study examined the degradation mechanism of Y-stabilized tetragonal zirconia in both orthopedic and dental applications. The findings revealed that zirconia femoral balls used in orthopedics exhibited negative results due to premature fracture after implantation. In contrast, zirconium dental implants demonstrated good performance as the ceramic degradation was minimal and did not impact its mechanical properties. Furthermore, the fracture mechanism observed in dental implants differed from that observed in orthopedic specimens.<sup>[9]</sup>

Another study found that zirconia with high translucency, containing 5% or less yttria, demonstrated lower resistance to crack propagation.<sup>[10]</sup> In a comparative study examining the relationship between translucency and biaxial flexural strength of different ceramics, including zirconia, high-strength zirconia, and lithium disilicate, it was observed that high-strength zirconia was the strongest but least translucent, while lithium disilicate was the most translucent but the weakest material. Among the translucent and high-strength zirconia materials, the highly translucent disk (Katana Zirconia UTML) exhibited the highest translucency but was the weakest. Overall, a negative correlation was identified between translucency and biaxial flexural strength.<sup>[17]</sup> Considering suspicions regarding the detrimental effect of zirconia translucency on its physical properties, an *in vitro* study was conducted to evaluate the edge chipping resistance and its relationship to the translucency of different materials, including translucent zirconia, yttria-stabilized tetragonal zirconia polycrystal, and lithium disilicate. The results indicated that as translucency increased, edge chipping resistance decreased.<sup>[18]</sup>

In a preclinical investigation, the fracture toughness of zirconia dental implants was evaluated following thermomechanical cycling in a chewing simulator. The findings revealed that the average fracture toughness of zirconia implants met the accepted clinical limits. However, certain implants exhibited fractures at relatively low loads, and some experienced failure during cyclic loading, indicating a potential risk in clinical use. Furthermore, it was concluded that the preparation of the implant head had a significant impact on the fracture toughness of the implants.<sup>[3]</sup>

##### *Osseointegration of zirconia implants*

The objective of this study was to investigate the early bone formation around transmucosal implants and evaluate the impact of surface characteristics on the initial healing of peri-implant bone. To achieve this, a miniature pig model was employed, and histological observations were performed. The study employed polycrystalline tetragonal zirconia dental implants stabilized with YTZP (Yttria-Stabilized Tetragonal Zirconia Polycrystal) and compared them to Titanium control implants. The findings indicate that after 4 weeks, the immediate zirconia implants with a modified YTZP surface exhibited favorable osseointegration and a high level of bone-to-implant contact.<sup>[11]</sup> Another study conducted on miniature pigs produced similar results in terms of direct bone contact between zirconia and titanium surface structures. Histomorphometric measurements of bone-implant contact indicated

slightly better results for the titanium implant surface, although no statistically significant difference was found between these materials.<sup>[5]</sup> Microcomputed tomography analysis of zirconia implants in miniature pigs yielded results consistent with the previous study, further supporting the findings.<sup>[19]</sup>

## DISCUSSION

In terms of morphological and histological comparisons, the study revealed that both mucositis groups showed a significant plaque control record. Notably, the Zirconia-mucositis (Zr-m) group had significantly lower scores compared to the Titanium-mucositis (Ti-m) group.<sup>[8]</sup> Furthermore, there were statistically significant differences in strength between the two groups, with the fracture toughness of one-piece zirconia abutments being significantly lower than that of titanium abutments.<sup>[13]</sup> Additionally, the study found that the marginal fit of crowns cemented on titanium abutments was significantly better than that of zirconia crowns.<sup>[15]</sup> On the other hand, the cpTi alloy showed no cytotoxic effect, and bone consolidation of the titanium implant occurred predominantly on the exposed bone surfaces rather than the implant surface.<sup>[7]</sup>

In terms of the strength of yttria-stabilized tetragonal zirconia, a comparison between orthopedic and dental applications revealed that its use in orthopedics resulted in premature fractures, while dental implants made with this material performed well. This is attributed to the limited ceramic degradation observed in dental implants, which does not affect their mechanical properties, unlike in orthopedic applications. Therefore, yttria-stabilized tetragonal zirconia is considered suitable for dental implants but not necessarily for orthopedic applications that require higher load resistance.<sup>[9]</sup>

Some studies have indicated concerns regarding the strength of zirconia implants. Under relatively low forces, zirconia implants have been observed to fracture during strength tests conducted on artificial mouth models, raising concerns about their clinical use.<sup>[3]</sup> The risk of chipping and cracking is also associated with the translucency of zirconia implants, as a negative correlation has been found between translucency and biaxial bending strength, as well as edge chipping resistance.<sup>[10,17,18]</sup>

Regarding osseointegration, the reviewed studies consistently demonstrate that zirconium implants exhibit optimal osseointegration comparable to titanium implants.<sup>[5,11,19-21]</sup>

The limitations of this study include time constraints and personal issues, as well as potential selection bias due to using only the PubMed database. Other limitations stem from the heterogeneity of the included studies in terms of methodology and population, making it challenging to synthesize the results. Additionally, limitations related to the social context and communication difficulties between authors were encountered, and external influences affected the research, leading to its premature termination.

The main strengths of this review article are the comprehensive and critical examination of the available literature, the clear and organized synthesis of relevant information, the identification of emerging trends and patterns, the assessment of research quality and limitations, and the provision of informed recommendations and suggestions for future research and practical application in the field.

## CONCLUSIONS

Within the scope and limitations of this narrative review, after reviewing the available literature, it can be concluded that both titanium and zirconium are suitable materials for dental implants at present, as they have similar advantages and disadvantages. The differences between the two materials are not very significant, so the final choice will depend on the needs and preferences of the patient and the dental professional.

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## CONFLICTS OF INTEREST

There are no conflicts of interest.

## AUTHORS' CONTRIBUTION

Concept: JC, AD, DAT, AMD, FMT; Design: FMT, JC, AD, DAT; Definition of Intellectual content: JC, AD, DAT, AMD, JBO, FEC, FMT; Investigation: JC, AD, DAT, AMD, JBO, FEC, FMT; Manuscript writing: JC, AD, DAT, JBO, AMD, FEC, FMT.

## ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

Not applicable.

## PATIENT DECLARATION OF CONSENT

Not applicable.

## DATA AVAILABILITY STATEMENT

Not applicable.

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