Ceramic Implants - Towards a stronger evidence base - Opinion paper

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INTRODUCTION

Commonly lost among personal preferences and scattered clinical results, ceramic implants have been commonly regarded as a therapeutic solution “of last recourse”, “holistic only” or “if the patient is allergic” procedures.

While the clinical possibility of mechanical breakdown and the phantom of breakage and catastrophic failure has always been present, the aesthetic qualities of ceramic have been widely lauded.

With alumina and other materials were randomly failing in clinical trials, the use of titanium reached new heights during the 90´s and early 2000´s.

The 1981 Toronto conference set the tone for the development of new titanium surfaces, connections, and microgeometries, transforming dental practice and clinical protocols.

In a quest to dominate the titanium dental implant market, it was an era of ambitious organizations such as NobelBioCare™, Straumann®, Astratech®, Dentsply Sirona, Biomet 3i ® among others.

Survival curves shot up to 98% and osseointegration time was cut in half (88/89 % for the machined Branemark implant).

The “Titanium train” had left the station, more of a TGV than a steam locomotive with brand and market share (and demand from clinics) ruling out any possibility of the use of an alternative biomaterial.

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THE TURNAROUND AND THE CLINICAL NEED

Although survival rates were high and osseointegration taken to the limit, rough surface titanium retrospective studies showed that at five years (with the early onset after three), biological problems begin to appear. The "bullet proof therapy"had found its nemesis in peri-implant diseases.[1] The onset of peri-implant diseases of the machined implant (10 or plus years) was in some cases, cut by half (Figure 1).[2]

The increase in having to redo work and implant loss pushed implant companies, academics and academies to seek other alternatives.

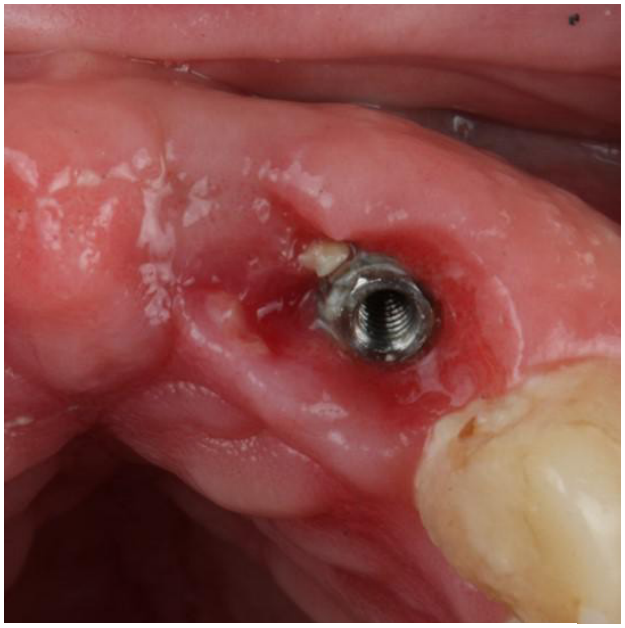

Figure 1. Peri-implant Infection of a titanium implant

DAWN

While promising, the early age of ceramic implants resided in specialist opinion and scattered clinical evidence in Germany and Switzerland.

Professor Sandhaus was one of the first researchers to develop ceramics as a biomaterial for dental implants with several books published on the subject.[3]

He was also strongly involved with Prof. Vasconcelos Tavares and Lisbon University to develop alumina and zirconia oxide benchmarking and animal research, which culminated in his Lisbon University 1994 PhD thesis.

Lisbon, Lausanne and Paris have been linked with ceramic research in what is known as the early "first generation" of ceramic use for dental implant solutions. The path for zirconia dioxide to make way for dental implantology was laid in those years.

But the question remained: was there an alternative to titanium dioxide that could ameliorate peri-implant problems and provide the same osseointegration properties?

Research during this period was showing and proving that the key was for inflammatory cascade to initiate and eventually osseointegrate any material capable of forming a passivation layer.[4,5,6]

Titanium (TiO_2) and zirconia dioxide (ZrO_2) and even gold (AuO_2) have this property and had proven reports of successfully healing in the human body.[7]

Based on the preclinical works of Sandahus, the first prototypes for oral rehabilitation were made only in a one-piece configuration[3], as mastering of a two-piece implant was impossible to achieve at that time due to the lack of machinery and technology.

The 2010´s to 2020´s marked a different attitude from all "players" within the ceramic implant's industry. Low to medium level implant companies stopped working with ceramics and premium implant brands took over in the creation, manufacture and sales of the product.

Thus, ceramic based materials for endosteal implants gained a second life (in some circles known as the 2nd generation ceramic implants, although there is no consensus on the matter), in an attempt to find a credible alternative to titanium implants, with advances in available technology allowing companies to aim for more robust macrogeometries and other prosthodontic options. Leading implant companies needed to prove their products, and the new 2020 European Union medical devices regulation and monitorization boosted funds available for pre/clinical investigation.

THE "TRAIN" THEY (CERAMIC IMPLANTS) NEEDED

With the stage set and the clinical demand waiting to be met, evidenced based research took over to finally validate ceramic implants (particularly zirconia dioxide) in the same way as titanium.

In my opinion, the research conducted on ceramic implant must be even more rigorous than that which validated titanium, since clinicians need unequivocal evidence to accept a clinically viable option to titanium implants.

With the "train" leaving the station, major universities from Europe have been the first to establish evidence-based protocols for ceramic implant validation. The pre and clinical results in early outcomes (expressed in systematic reviews) has been similar if not better than titanium in some clinical parameters. Recently validated 5-year data show commercially available ceramic options provide similar outcomes to Titanium for the single unit one-piece implant.

THE ROLE OF THE ASSOCIATIONS

With businesses and universities engaged in ceramic research, The European Society for Ceramic implantology (ESCI) was created in 2018 to bring together and provide a bridge between clinicians and academics, institutions and universities, implant brands and patients.

The ESCI European symposium in Zurich, Switzerland, in 2019 was the first general assembly to approach all stakeholders with the aim of establishing a regulated evidenced based ceramic market.

From company partners to associates, from board of directors to scientific advisory board, discussion was undertaken and votes cast on general guidelines for an experimental methodology, evidenced based market that set ceramic implantology as a safe and reliable option for implant supported rehabilitations.

SEPARATING RHETORIC FROM SCIENCE

At a certain point, Ceramic Implants got caught up in the rhetorical and not so scientifically profitable metal free discussion and the place of zirconium in the periodic table.

This public and common-sense discussion, sometimes shared by clinicians, slowed down the true aim of Ceramic being credited as a biomaterial option for dental implants.

Zirconia dioxide is far from an element and phenomena like phase transformation, fracture toughening, ionic non-metallic bonding and other factors make ceramic implantology a science which is far different from that focused around titanium. Understanding biology, biomechanics and ceramic engineering is key to the success of implant supported rehabilitation.

CLINICAL USES APPROACHES

Ceramic implant therapy resembles titanium, in terms of the drilling protocol, the screw shaped type of implants and connections available.

The one-piece implant was the first to be re-introduced (following the works of early 90s) and hence one of the first to be validated. It is set in one block of zirconia dioxide, with both the implant and abutment fused in one piece. In some companies you must prepare the abutment, while in others you have prefabricated snap-on pieces to click in and out (Figure 2. a, b)

The overall survival rates of commercially available one-piece ceramic implants do not go beyond 5 years.[8,9] Systematic reviews and meta-analysis show 1-year survival rate for commercially available ZrO2 implants (98.3%) and a 2-year survival rate of 97.2%.[10]

Clinical validation of 2-piece implantology is underway and there are already some reports concerning clinical safety.

The development of biomaterial engineering and rapid accuracy of CAD-CAM milling machines and 3D printers, have made it possible to produce a two-piece system (Figure 3 a, b).

In my opinion, two-piece implant protocols are needed, and so we will eventually see implant brands reshape their products to this reality. Ceramic implant dentistry must be simple, faster and less “costly” than what we have now. The integration between titanium surgical cassettes, digital technology and prosthodontic rehabilitation must be compatible and interchangeable, allowing clinicians to change from titanium to ceramic in the blink of an eye.

Either with static guided or dynamic surgery, ceramic implantology must utilize the same tools for implant insertion as titanium (Figure 4).

Injection molding and 3D printing will be the gold standard for ceramic implant production, not only decreasing the cost of manufacture, but also bringing new possibilities for design that even the most advanced milling system cannot achieve. ESCI have just launched a two-piece concept with the conclusion:

“Consequently, based on the currently available scientific data, the two-piece zirconia implant concept can be recommended for clinical application after correct diagnostic evaluation and appropriate patient information.”

A statement signed and approved by leading researchers in the field of ceramic implantology in Europe.

Prof. André Chen, Prof. Jérôme Chevalier Prof. Jens Fischer Prof. Michael, Gahlert Prof. Ralf Kohal Dr. Frank Maier, MSc, Prof. Mutlu Özcan Prof. Michael Payer Prof. Corrado Piconi PD Dr. Stefan Röhling Dr. Jens Tartsch Prof. Werner Zechner (alphabetical)

In my opinion two-piece systems will evolve for slimmer connections (much resembling the titanium counterpart) allowing for clinical flexibility without losing mechanical properties (Figure 5 a, b).

New dopant agents such as Ceria and Magnesium will boost the widespread use of yttria.

They will also shift from a supracrestal approach to a sub-crestal (bone level) approach, and this change will lead to a need for the development and refining of prosthodontic components.

The tendency for interfaces and metallic connections between

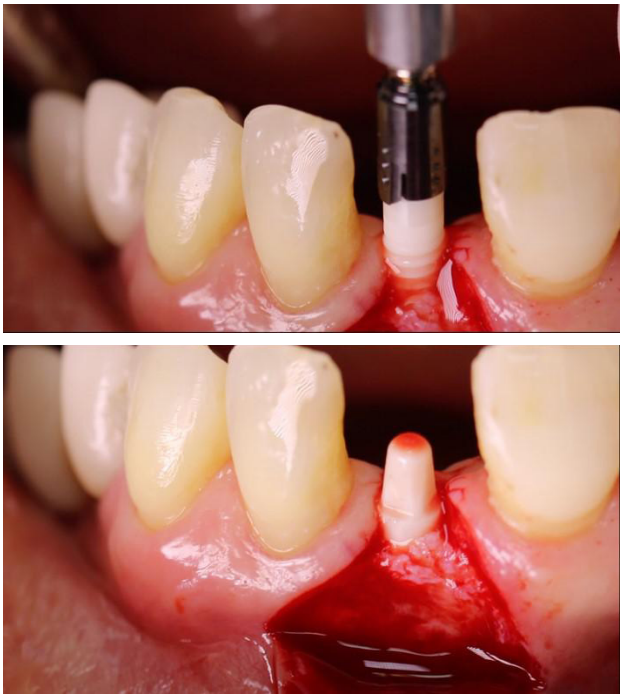

Figure 2 a, b. The One-piece Zirconia Dioxide implant with snap-on prosthodontic parts for cemented restorations

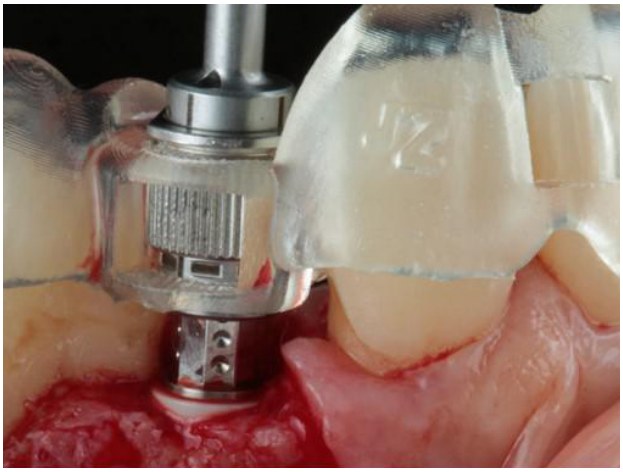

Figure 4. Fully digital workflow for two-piece ceramic implant. Static fully guided with digital drilling protocol.

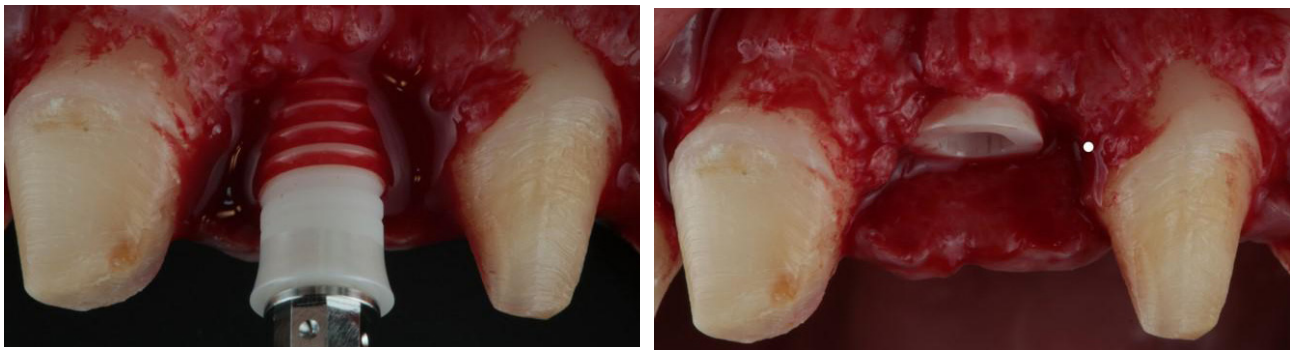

Figure 3 a, b. The new two-piece implant systems with an internal connection and a two-millimeter polished collar in a supracrestal (tissue level) position with separate screw-retained portfolio for prosthodontic rehabilitation

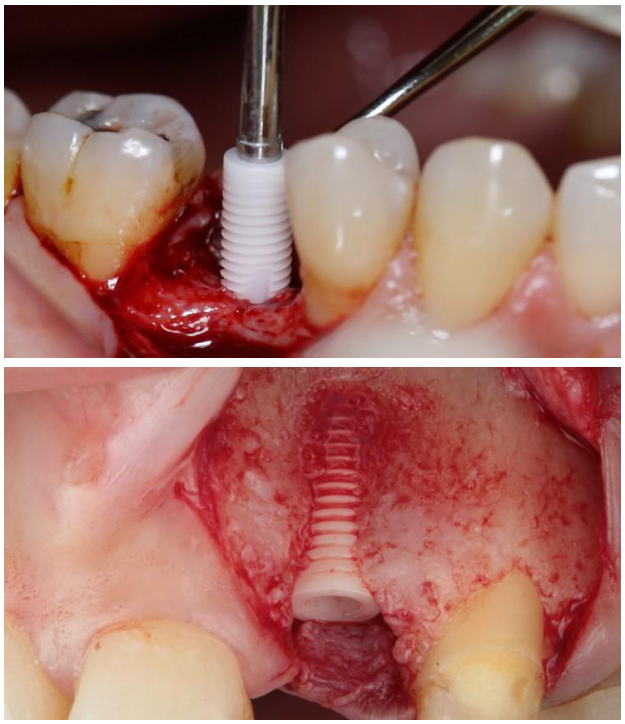

Figure 5 a, b. Example of a prototype two-piece 3.5 mm diameter ceramic implant with a conical internal connection for a subcrestal approach

crown and implants will always be there, particularly for CAD-CAM prostheses and the use of digital platforms for creation and production, but it is also true that zirconia dioxide abutments are needed for ceramic implantology, and the use of the zirconia-zirconia complex must be predictable for daily use (Figure 6 a, b). In cases of titanium or metal hypersensitivity, ceramic implants are regarded as predictable and a fair alternative, but the key factor is regarded as being in its soft tissue response. Although with no sound evidence of better results, linear soft tissue measurements are at least equal to titanium.[11] In some clinical parameters, ceramic may behave better in terms of a faster maturation of peri-implant epithelial and connective tissue,[12] a significant Jemt papilla index in peri-implant papilla formation[13] and improved attachment to the gingival tissue.[14]

Following the idea of lowering inflammation and foreign body reaction, ceramic implantology shifted to non-metal prosthodontic components from the day of surgery up to final crown insertion (Figure 7)

Peek and ceramic material are current clinical realities in prefabricated, lab milled, and soon in 3D printing.

Clinical validation of partial rehabilitation is underway and started with simple 3 unit bridges. Clinically this option has been shown to have similar results to that of titanium (Figure 8 a, b).

Short implants will also be accruing an evidence base in the next years with, the first randomized clinical trials set for late 2022, early 2023.

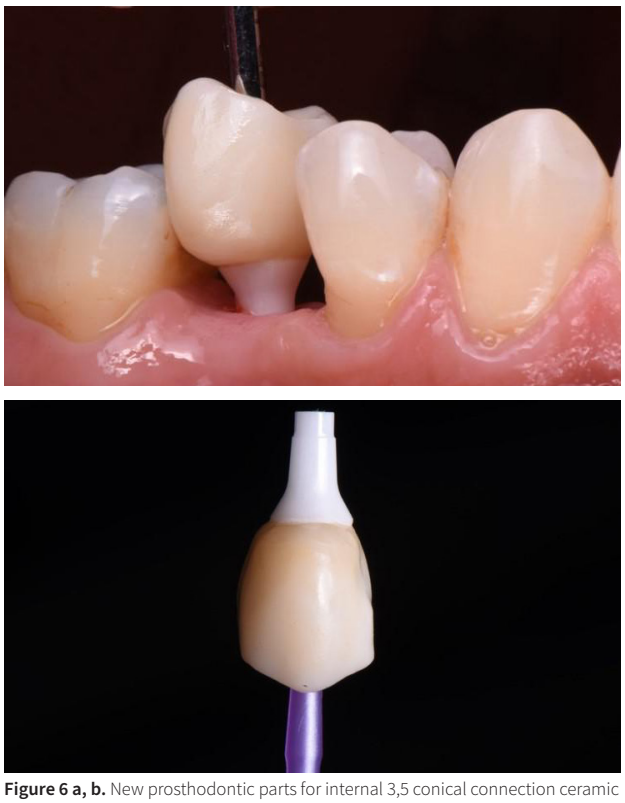

Figure 6 a, b. New prosthodontic parts for internal 3,5 conical connection ceramic implant

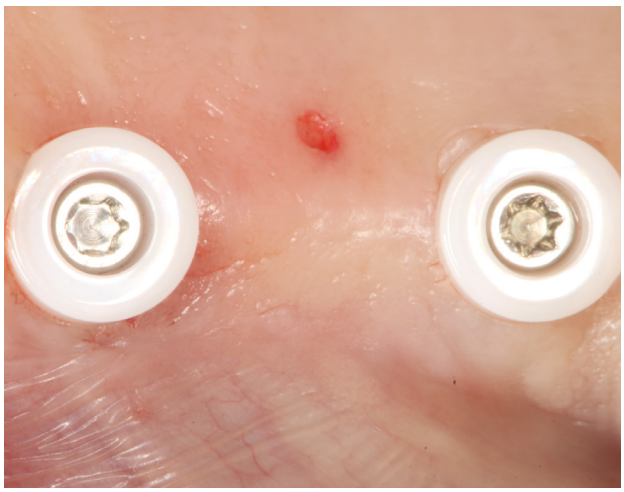

Figure 7. Clinical Situation after 3-month osseointegration period of zirconia dioxide implants with ceramic healing abutments

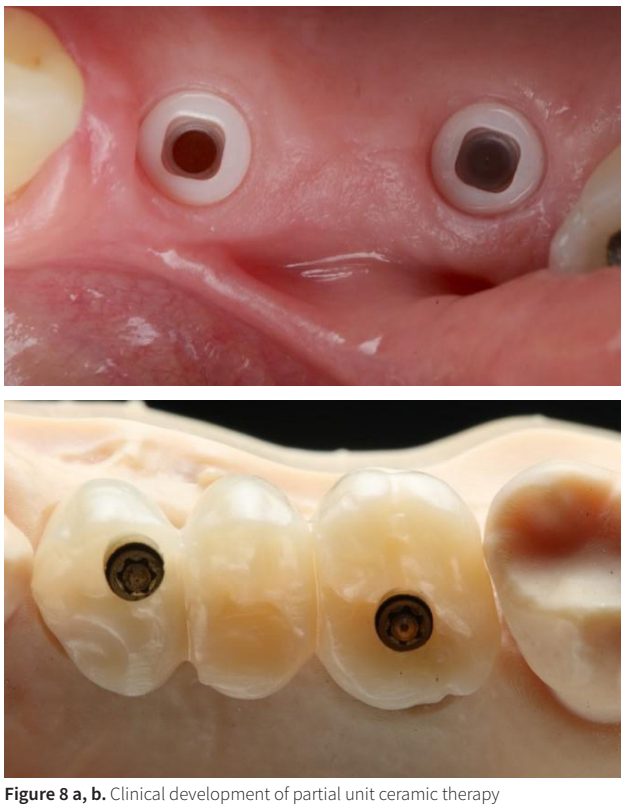

Figure 8 a, b. Clinical development of partial unit ceramic therapy

With all this quest to prove the efficacy of implant protocols, it's the collation of the 10-year data in ceramic implants that will be key to fully validating this therapy. The expected lower incidence of biological peri-implant complications such as periimplantitis and mucositis will be the final arbiters of effectiveness.
If this alternative is unequivocally lower, then there is a possibility that they will become the gold standard for practitioners, but if the results are equal then they will remain as a 2nd line implant option.

THE FUTURE

In my opinion, inflammatory processes and foreign body reaction will be key to unlocking further developments within ceramic materials.
Ceramic will have a place in the dental field, but the real question is if it will become the leading or the supporting actor of implant supported therapy.

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