*Section A-Research paper*

# Stability of patient-specific root-analogue implants and conventional root-form implants for treating non-restorable single-rooted maxillary teeth:a randomized clinical trial

**Amr Mohamed Ahmed Ibrahim[1], Essam Adel Aziz [2], Mostafa Helmy mostafa[3]**

[1] Assistant Lecturer in Prosthodontics department, faculty of Dentistry, Cairo University, Egypt.
**Email:** amr.seleimy@dentistry.cu.edu.eg

[2] Professor of prosthodontics department, faculty of Dentistry, Cairo University, Egypt.

**Email:** essam.aziz@dentistry.cu.edu.eg

[3] Assistant Professor in Prosthodontics department, faculty of Dentistry, Cairo University, Egypt.

**Email:** essam.aziz@dentistry.cu.edu.eg
**Corresponding Author**
**Amr Mohamed Ahmed Ibrahim**
**Email:** amr.seleimy@dentistry.cu.edu.eg

**Abstract:**

**Objectives:** the aim of this study is to assess the difference between patient specific root analog implant and conventional root form implant in terms of implant stability. **Materials and methods:** 24 males patients with badly decayed non-restorable anterior tooth were treated with immediate implant placement. Patients were randomly assigned to one of two groups. They were either treated by placing milled titanium immediate root analogue implant or placing conventional root form implant to replace single tooth in anterior maxillary area. Implant stability was measured using periotest for both approaches at the day of surgery then after 3 and 6 months later. **Results:** after 6 months there was no statistical difference in implant stability on comparing Root Analogue implant (RAI) and Conventional root form. However, there was statistically significant difference between the stability at implant placement and after 3 and 6 months in both groups. **Conclusion**: Replacing badly decayed teeth with a Root Analogue implant can be used as an alternative to conventional immediate root form implant.

**Keywords**: RAI, root analogue implant, immediate implant, single tooth restoration, conventional root titanium implant, root-form implant.

## Introduction

Root form dental implants are a highly reliable treatment option for rehabilitating patients who are partially or fully edentulous in different clinical scenarios. It provides a prosthetic solution with predictable outcome and desirable results with considerable survival and success rates (Mangano et al., 2011).

Branemark et al., was the first to introduce the idea of dental implants after he described the process of osseointegration. This treatment option was discussed more than 50 years ago (Brånemark et al., 1969). From this point and along the years, researches were always concerned with how to achieve osseointegration using different implant designs and materials. Along the years of treatment with dental implants, the concern was always how to have an implant with a configuration that would enhance osseointegration on the macro topographic level. Lately, the focus of the researches in the dental field started to be directed towards how to fabricate an implant with adequate osseo inductive potential and how would the implant surface would provide solely the osseointegration rather than the mechanical means of retention.

Immediate implants were introduced several years ago. They can be defined as a procedure of placing dental implants directly after extraction of the affected teeth. Furthermore, the immediate implant has shown massive improvement in providing a treatment option for our patients with a noticeable less treatment time and decreased number of surgical interventions. This approach led to having patients that are highly satisfied and psychological accepting the treatment. On considering the treatment on financial basis, it provides more cost-effective treatment. On another level, using the tooth as a guidance for the placement of the implant would provide a more favorable implant orientation and less anticipated bone resorption at the site of extraction when compared to conventional treatment approach. On the level of the soft tissue contour and pink esthetics, immediate implant achieves better esthetics (Koh et al., 2010).

Primary Stability is considered a major aspect that is used to ensure implant success. If any mobility was found during or after the healing phase, the implant is then considered failed. It is considered an implant failure if mobility is detected after implantation (Barewal et al., 2012). After extraction, placement of implants in fresh sockets normally affects primary implant stability. This happens due to the difference between the dimension of the root form implant and the extraction socket. As after implant installation, a gap (called jumping gap) may occur between the implant and the extraction socket necessitating the use of guided bone regeneration to prevent

down growth of connective tissue or epithelium in between the implant and the socket (Figliuzzi et al., 2012).

To overcome this problem a novel approach was proposed where a custom-made root-analogue implant (RAI) is placed immediately into the extraction sockets. More fit is achieved in this scenario due to the precise fit between the implant and the extraction socket as the implant resemblance the extracted root (Hodosh et al., 1969).

Hodosh et al., were the first to propose the use of a custom-made RAI, they placed it in the fresh extraction socket, to reduce the trauma that occurs to the bone and soft tissue. They used polymethylmethacrylate for the fabrication of root analogue implant using either self-cure or heat-cure resin. Using the implant with this material led to soft tissue encapsulation not osseointegration. This fibro integration was considered a failure, that's why other implant materials were proposed to solve this problem (1969).

Another study was conducted using alternative materials and techniques for the fabrication of root analogue implant. It started with laser scanning and machine copying of the extracted tooth then its placement in a subsequent surgery. This approach hasn't reported the all the intended outcomes, so alternative approaches were then proposed later (Pirker et al., 2011).

In last few years, computer aided manufacturing techniques had several uses and applications in the dental field (Traini et al., 2008). Both subtractive and additive techniques were used to fabricate any dental restoration with accurate dimensions and configuration according to the virtual three-dimensional (3D) data (Witek et al., 2012). At the time being for the production of titanium RAI, cone beam computed tomography (CBCT) along with computer-aided designing (CAD) techniques help in providing the data needed for computer aided manufacturing with predictable and precise results (Mangano et al., 2009).

A question now arises, does the new technique will meet the proposed level of implant prognosis in terms of implant stability?

## Materials and Methods:

The present study is a randomized clinical trial. It included 24 male patients with an anterior non-restorable tooth. Patients' age was ranging from 25 to 35 (and an average of 30.33 ±3.36). Patients had an anterior badly decayed non-restorable tooth and all of them received an immediate implant to restore this tooth. Two types of implants were used. The patients were randomly allocated to one of the following groups according to the implant placed; either receive immediate conventional

titanium root form implants or immediate root analogue titanium dental implants. In both groups the implants were loaded by a previously designed temporary restoration.

A thorough preoperative assessment of all patients was carried out including history taking, clinical examination and radiographic examination to confirm that they met the eligibility criteria. Inclusion criteria include placing implants after extraction of badly decayed single rooted tooth or a tooth with fused roots in patients with no systemic condition that would affect implant healing like immunosuppressed or immunocompromised patients and non-heavy smokers (<10/day). Also, any peri-apical or periodontal infection that would render the healing was excluded

A periapical radiograph was done to ensure eligibility and a CBCT Radiograph was then done to evaluate the tooth and surrounding bone condition for implant planning. Furthermore, the DICOM files were transferred to a 3D reconstruction software[1] to prepare and design the virtual root and abutment then exported as STL file to manufacture RAIs. Using the software, it was possible to construct a 3D projection of the maxilla/mandible and segmentation of the residual roots, simulating a "virtual" extraction of the roots (Fig. 1). The virtual root was then designed using another software[2] along with the designed prosthetic abutment and the assembly was then exported as STL file to be milled.

After designing of the root and exporting it, the STL was used for designing of the abutment and the corresponding crown (cement-retained). A temporary restoration was designed either root form implant or RAI. The margin was designed at the level of the cementum-enamel junction (CEJ). It was designed shoulder in shape with a right angle and its inner angle was obtuse with width of 1 mm and then a PMMA crown was designed.

CAD data was transferred to the 5-axis milling machine and the milling was done to fabricate the custom-made RAI with integral abutment, directly from the STL files. The implants were made of Ti-6Al-4V alloy discs. Implants were then acid etched, packed and sterilized with gamma rays (Fig. 1).

[1] Mimics, Materialise HQ, Leuven, Belgium
[2] Exocad Matera, Darmstadt, Germany

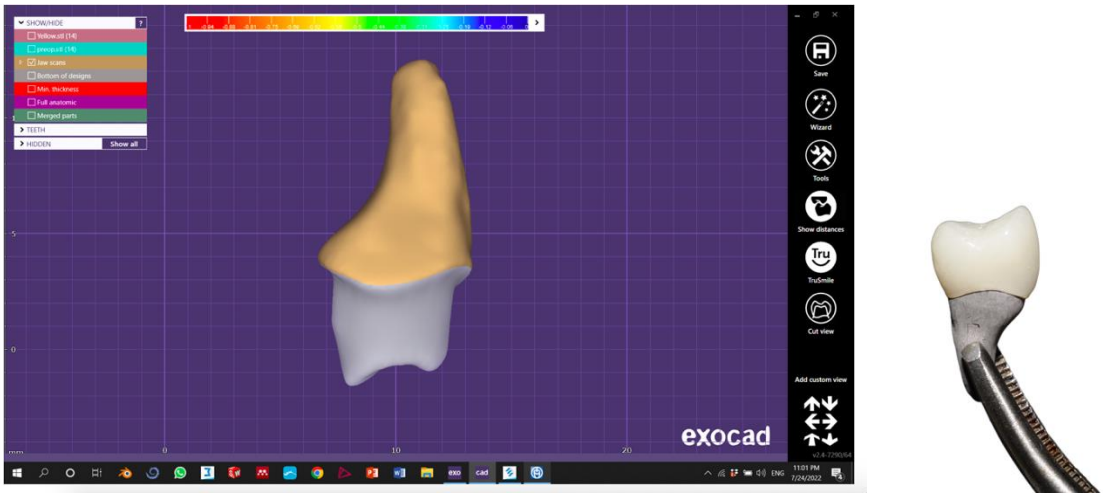


Figure 1: virtual RAI and milled one with temporary restoration

## Surgical procedures:

Tooth extraction protocol is the same for both groups. Local anesthesia Septocaine[3] was administrated and extraction was done atraumatically using periotomes with minimal expansion of bone around the root. Followed by the use of straight apexo then root forceps. It is crucial to extract tooth without violating the labial plate of bone, leaving it intact. Curettage and irrigation of the socket was done to ensure that all granulation tissues are removed and the socket was inspected to ensure integrity (Fig. 2).

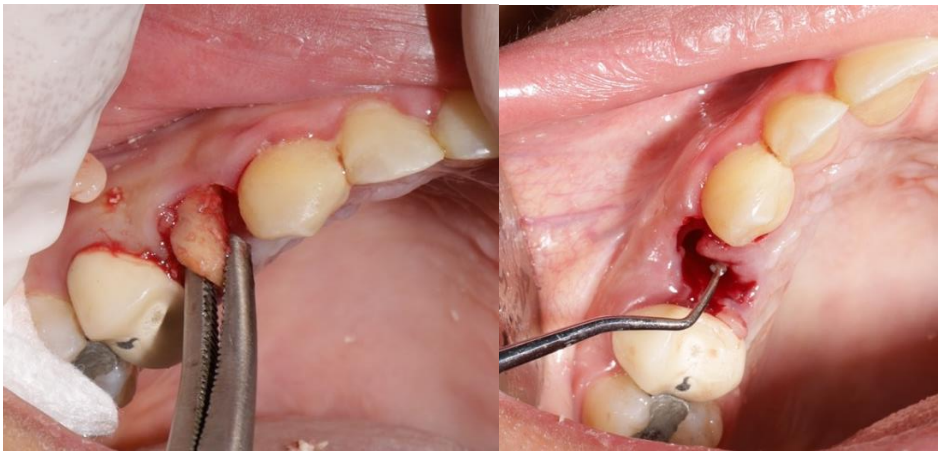

Figure 2: tooth extraction and socket inspection

The osteotomy preparation of the conventional root form implant group was done as usual. Starting with a point drill to locate the point of drilling then the pilot drill was used to prepare the full depth osteotomy following the notch done by the point drill in a palataly based direction. Then sequential drilling was done after confirming the direction with a paralleling pin to place an implant of 12mm diameter

[3] Septocaine, Articaine with epinephrine 1:100000, Septodont, Canada.

and 3.5 mm width. The implant was placed 2 mm beyond the bone level (Fig. 3) and the prefabricated PMMA milled temporary abutment and restoration were then placed. The temporary restoration is kept out of occlusion in both centric and eccentric movements (Fig. 4).

In the Root analogue implant group, the implant is tapped in place till full seating to confirm adequate primary stability (Fig. 3). A radiograph is done to confirm seating (Fig. 4). Implant stability is then measured using periotest[4] and the temporary restoration is then cemented. The final restoration was then fabricated after the 3 months of healing.

Implant stability was measured at baseline and after 3, 6 months of healing using the periotest.

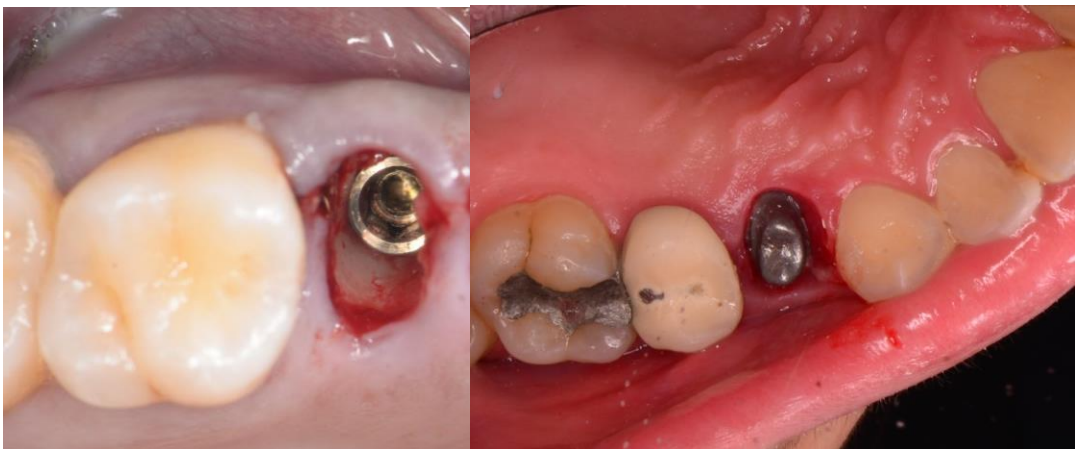

Figure 3: The implants in place

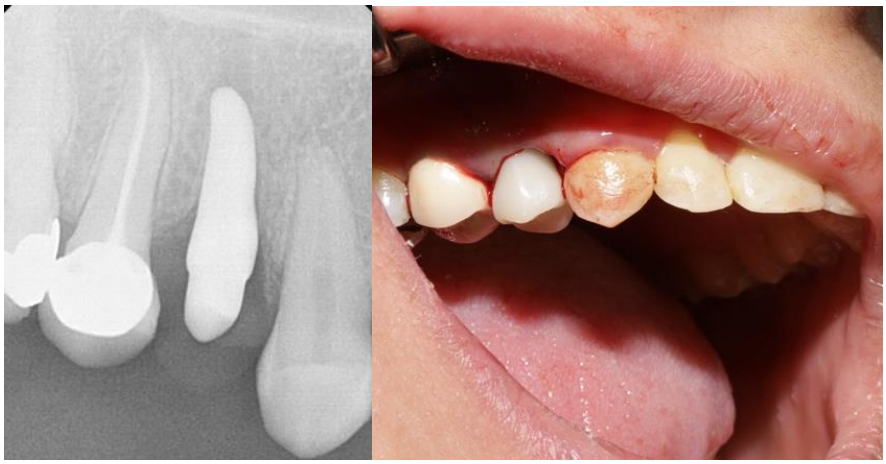

Figure 4: radiograph to ensure implant seating followed by temporization

Sample size calculation

This power analysis used implant stability at baseline, after three and six months as the primary outcome. Based upon the results of Basa et al (2004), the mean and

[4] Medizintechnik Gulden e.K., Germany

standard deviation (SD) for control group were –3.2 ± 0.7. The minimal clinically significant difference was -4 PTV according to expert opinion. Using alpha (α) level of (5%), β level of 0.8 (Power = 80%); the effect size for independent samples t-test (d) was 0.736 and the minimum estimated sample size was 12 implants per group. Sample size calculation was performed using PS Power and Sample Size Calculations Version 3.

Statistical Analysis

Data were then explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. As the data showed parametric distribution so Independent-t test was used to compare between both groups. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM[5] SPSS[6] Statistics Version 20 for Windows.

**Results:**

All patients completed the follow up period with no dropouts and no implant failure. Implant stability was found to be comparable in both groups with no statistically significant difference along different follow-up periods (p=0.333). There was no statistically significant difference between baseline and after 3 months of follow-up with higher values in the control group. in the follow up of 3 to 6 months there was also no significant difference with higher values in the control group. lastly the significance difference was found in the comparison comparing baseline with the 6 months follow-up with comparable results in both groups (Table 1 and figure 7).

**Table (1):** Mean and standard deviation of implant stability in both groups at different intervals:

| Interval | Control | | Intervention | | Difference (Independent t test) | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | MD | SEM | 95% CI | | P value |
| | M | SD | M | SD | | | L | U | |
| Baseline – 3 months | -1.42 | 1.88 | -1.92 | 1.00 | 0.50 | 0.61 | -0.77 | 1.77 | 0.425 |
| 3 months -6 months | -1.75 | 1.76 | -1.33 | 1.07 | 0.42 | 0.60 | -1.65 | 0.82 | 0.492 |
| Baseline - 6 months | -3.17 | 1.53 | -3.25 | 1.48 | 0.08 | 0.61 | -1.19 | 1.36 | 0.893 |

M: mean SD: standard deviation MD: Mean difference

P: probability level which is significant at $P \leq 0.05$

[5] IBM Corporation, NY, USA.

[6] SPSS, Inc., an IBM Company.

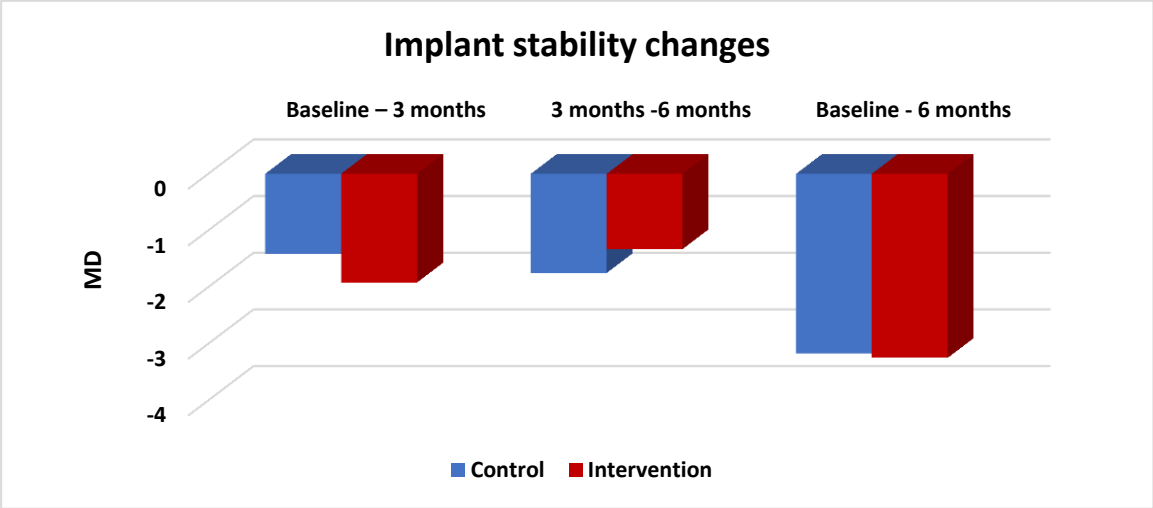


Figure 7: bar chart showing implant stability changes in both groups at different study intervals.

## Discussion:

The current study was conducted to evaluate the performance of conventional titanium root form implant and titanium root analogue implant placed immediately after tooth extraction to restore an anterior badly decayed tooth. The comparison with such settings was not proposed yet in other studies to the best of the authors' knowledge, however studies evaluating the performance of RAI was found in the literature. In this study it was witnessed that immediately placed titanium RAI would provide comparable results to immediately placed conventional titanium root form implant regarding plant stability.

Immediate implant placement and loading is a viable treatment option that offered several advantages. It reduces the treatment time, with less surgical steps and most importantly it preserves the bone contour, decreases its resorption and maintains the gingival tissues contour which enhances pink esthetics especially the form of the interdental papilla. In addition to its psychological impact where it becomes more favorable for some patients to skip the period of healing following the regular approach (Schropp & Isidor, 2008).

However, immediate implant placement has several drawbacks, the main one is the difficulty to obtain adequate primary stability due to difference between the size of the implant and the size of the socket. This discrepancy affects the primary stability and it was advocated by different authors when to fill the jumping gap to enhance this situation and when you should not. This led to the emergence of the idea of Root Analogue Implant which fits precisely to the socket (Chen et al., 2005).

From another prespective, RAI eliminates the problem of microleakage that occurs at the implant abutment interface this problem was encountered by the use of one-piece dental implant. However, still abutment modification should be done intra-orally which is an unfavorable procedure to the patient. This problem is overcome by the RAI as it is predesigned and readily fabricated to receive the restoration instantly (Böse et al., 2020).

The results of this study were mainly concerned with implant stability from the initial placement then along the healing phase up till 6 months of follow up. The clinical outcome was evaluated using the perio test. All factors that should be considered to avoid any interference during the healing period were considered.

The implant stability after three months in the intervention group showed statistically significant difference between baseline and after 3 months with mean and standard deviation of -1.92 ±1.00. These results were expected as reported by Figliuzzi et al., who reported that the implant was osseointegrated after 3 months and no implants failed (Figliuzzi et al., 2012).

Regarding the 6 months follow up period, the results showed statistically significant when compared to the baseline and to the 3 months follow up. The mean and the standard deviation after 6 months were -1.33 ±1.07, -3.25 +1.58 respectively. The results were favorable and precise indicating good secondary stability.

These results can be explained by the fact that the primary stability is mainly dependent on the mechanical stability that is achieved by the accurate fit between the implant and the socket. Later this stability changes by bone remodeling to biological based stability which is enhanced by micro irregularities and surface treatment of the implant. This secondary stability increases with time providing better values after 6 months compared to 3 months of healing.

## Conclusion:

Within the limitation of the current study, replacing badly decayed non-restorable teeth with a Root Analogue implant is a viable treatment option that shows comparable results to conventional immediate root form implant treatment. This conventional is due to favorable stability outcome and predictable survival that is similar to that of immediate implant. The results may be attributed to the precision of the milling technology, the biocompatibility of the titanium, its osseointegration capability and implant surface treatment.

**References:**

Barewal, R. M., Stanford, C., & Weesner, T. C. (2012). A randomized controlled clinical trial comparing the effects of three loading protocols on dental implant stability. *Int J Oral Maxillofac Implants*, *27*(4), 945-956.

Basa, S., Varol, A., & Turker, N. (2004). Alternative bone expansion technique for immediate placement of implants in the edentulous posterior mandibular ridge: a clinical report. *Int J Oral Maxillofac Implants*, *19*(4), 554-558.

Brånemark, P. I., Adell, R., Breine, U., Hansson, B. O., Lindström, J., & Ohlsson, A. (1969). Intra-osseous anchorage of dental prostheses. I. Experimental studies. *Scand J Plast Reconstr Surg*, *3*(2), 81-100. https://doi.org/10.3109/02844316909036699

Böse, M. W. H., Hildebrand, D., Beuer, F., Wesemann, C., Schwerdtner, P., Pieralli, S., & Spies, B. C. (2020). Clinical Outcomes of Root-Analogue Implants Restored with Single Crowns or Fixed Dental Prostheses: A Retrospective Case Series. *J Clin Med*, *9*(8). https://doi.org/10.3390/jcm9082346

Chen, S. T., Darby, I. B., Adams, G. G., & Reynolds, E. C. (2005). A prospective clinical study of bone augmentation techniques at immediate implants. *Clin Oral Implants Res*, *16*(2), 176-184. https://doi.org/10.1111/j.1600-0501.2004.01093.x

Figliuzzi, M., Mangano, F., & Mangano, C. (2012). A novel root analogue dental implant using CT scan and CAD/CAM: selective laser melting technology. *Int J Oral Maxillofac Surg*, *41*(7), 858-862. https://doi.org/10.1016/j.ijom.2012.01.014

Hodosh, M., Povar, M., & Shklar, G. (1969). The dental polymer implant concept. *J Prosthet Dent*, *22*(3), 371-380. https://doi.org/10.1016/0022-3913(69)90200-5

Koh, R. U., Rudek, I., & Wang, H. L. (2010). Immediate implant placement: positives and negatives. *Implant Dent*, *19*(2), 98-108. https://doi.org/10.1097/ID.0b013e3181d47eaf

Mangano, C., Mangano, F., Shibli, J. A., Tettamanti, L., Figliuzzi, M., d'Avila, S., . . . Piattelli, A. (2011). Prospective evaluation of 2,549 Morse taper connection implants: 1- to 6-year data. *J Periodontol*, *82*(1), 52-61. https://doi.org/10.1902/jop.2010.100243

Mangano, C., Raspanti, M., Traini, T., Piattelli, A., & Sammons, R. (2009). Stereo imaging and cytocompatibility of a model dental implant surface formed by direct laser fabrication. *J Biomed Mater Res A*, *88*(3), 823-831. https://doi.org/10.1002/jbm.a.32033

Pirker, W., Wiedemann, D., Lidauer, A., & Kocher, A. A. (2011). Immediate, single stage, truly anatomic zirconia implant in lower molar replacement: a case report with 2.5 years follow-up. *Int J Oral Maxillofac Surg*, *40*(2), 212-216. https://doi.org/10.1016/j.ijom.2010.08.003

Schropp, L., & Isidor, F. (2008). Timing of implant placement relative to tooth extraction. *J Oral Rehabil*, *35 Suppl 1*, 33-43. https://doi.org/10.1111/j.1365-2842.2007.01827.x

Traini, T., Mangano, C., Sammons, R., Mangano, F., Macchi, A., & Piattelli, A. (2008). Direct laser metal sintering as a new approach to fabrication of an isoelastic functionally graded material for manufacture of porous titanium dental implants. *Dental materials*, *24*(11), 1525-1533.

Witek, L., Marin, C., Granato, R., Bonfante, E. A., Campos, F., Bisinotto, J., . . . Coelho, P. G. (2012). Characterization and in vivo evaluation of laser sintered dental endosseous implants in dogs. *J Biomed Mater Res B Appl Biomater*, *100*(6), 1566-1573. https://doi.org/10.1002/jbm.b.32725