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Full-Arch Implant-Prosthetic Rehabilitation in Patients Affected by Hypertension: A Randomized Clinical Trial at 7 Years Follow-Up

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Abstract: The aim of this clinical study was to investigate and compare implant survival rates, marginal bone loss, and surgical and prosthetic complications of healthy patients and subjects affected by hypertension receiving full-arch implant-prosthetic rehabilitation. From January 2016 to November 2016, patients affected by total edentulism of one or both arches or severe impairment of residual teeth who needed full-arch implant-prosthetic rehabilitation and who had the absence of any systemic diseases or the presence of hypertension as a single pathology were randomly selected. According to the inclusion criteria, 39 patients were enrolled for this study. The sample was divided into two groups: A total of 18 patients were included in Group A (healthy patients), and 21 patients were included in Group B (patients affected by hypertension). No statistically significant difference in implant survival rates, marginal bone loss, and prosthetic complications were observed between Group A and Group B. Except for variable bleeding, the results of the Pearson's chi-square test and z-test at a 99% confidence level suggest that there is no statistically significant difference in clinical complications between the groups. Within the limitations of this study, full-arch implant-prosthetic rehabilitation could be a feasible option for treating patients with hypertension, provided that hypertension is compensated and controlled.

Keywords: hypertension; dental implants; immediate loading; systemic diseases

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1. Introduction

Hypertension, also known as high blood pressure, is a medical condition in which the force of blood against the walls of the arteries is consistently too high [1].

Blood pressure is measured in millimetres of mercury (mm Hg) and is expressed as two numbers: systolic pressure (the top number) and diastolic pressure (the bottom number). Normal blood pressure is typically approximately 120/80 mm Hg, while high blood pressure is defined as systolic pressure equal to or greater than 130 mm Hg or diastolic pressure equal to or greater than 80 mm Hg over an extended period [2–4].

Hypertension may affect blood vessels and other organs over time, resulting in a higher risk of heart attack, stroke, kidney impairment, and other medical disorders [5–7].

The risk factors for developing hypertension include age, family history, obesity, lack of physical activity, smoking, and a diet high in salt and saturated fat [8].

The treatment for hypertension may involve lifestyle changes, such as diet and exercise, as well as medications to lower blood pressure. Specifically, renin-angiotensin system (RAS) inhibitors, such as angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), work by inhibiting or blocking certain components of the RAS

pathway, which helps regulate blood pressure, although the specific impact on dental implant stability remains unclear and could be associated with potential effects on bone metabolism and wound healing [9].

Considering the increasing average age associated with a higher incidence of systemic diseases, hypertension seems to be an emerging important factor in the management of totally edentulous patients undergoing implant-prosthetic rehabilitation [10–12].

While there is no direct link between hypertension and dental implants, it is important for individuals with hypertension to take certain precautions before undergoing implant surgery. This is because high blood pressure can increase the risk of bleeding during and after surgery, which can affect the success of the procedure and the healing process [13,14].

In addition, several drugs applied as treatment, such as beta blockers, could cause dry mouth, which can increase the risk of dental implant failure [15,16].

Dry mouth can also increase the risk of developing gum disease and tooth decay, which can further compromise the success of dental implants [17].

Therefore, before undergoing dental implant surgery, it is important for individuals with hypertension to have their blood pressure under control. They should work closely with their healthcare provider to manage their blood pressure and ensure that it is at a safe level for surgery [18,19].

In addition, individuals with hypertension may need to avoid certain medications, such as aspirin or other blood thinners, prior to surgery to minimize the risk of bleeding [20,21].

The aim of this clinical study was to estimate and compare implant survival rates, marginal bone loss, and surgical and prosthetic complications of healthy patients and hypertensive subjects receiving full-arch implant-prosthetic rehabilitation.

2. Materials and Methods

2.1. Patient Selection

From January 2016 to November 2016, patients were randomly selected for this clinical study, which was conducted at the Department of Dentistry, San Raffaele Hospital, Milan, Italy.

All procedures executed in this study involving human participants were in accordance with institutional and/or national research committee ethical standards and the 1964 Declaration of Helsinki and its subsequent amendments or comparable ethical standards. The ethics committee approval number is CE/INT/10/2015.

2.1.1. Inclusion Criteria

The eligibility criteria were the following: patients with total edentulism of one or both arches or severe impairment of the residual dentition who needed complete implant-prosthetic rehabilitation of the upper or lower arch or both and absence of systemic diseases or presence of hypertension as a single disorder.

2.1.2. Exclusion Criteria

Exclusion criteria were smokers, presence of systemic diseases other than hypertension, uncompensated hypertension, bisphosphonates therapy, individuals who had received radiotherapy to the head and neck region within the last year, severe malocclusion, severe parafunction, and patients who could not comply with the recommended oral hygiene maintenance regimen including professional dental cleanings and home care instructions. Patients who had not complied with monitoring checks and hygiene maintenance sessions provided for in the follow-up protocol adopted at the Department of Dentistry, IRCCS San Raffaele Hospital, Milan, Italy were also excluded.

2.2. Implant-Prosthetic Rehabilitation

2.2.1. Pre-surgical Protocol

Before surgery, the diagnosis was made according to clinical and radiographic examinations. Two types of radiographic investigation were performed—panoramic radiography and cone beam computed tomography (CBCT)—to identify the residual bone height and width [22]. The study sample was divided into two groups based on the absence or presence of hypertension with blood tests being conducted approximately one month before surgery to assess the patients' general health and identify any signs of uncontrolled hypertension [23].

2.2.2. Implant-Prosthetic Protocol

The surgical procedure involved the administration of antibiotic prophylaxis (2 g amoxicillin 1 h before surgery or 1 g clarithromycin in the case of penicillin allergy) only for hypertensive patients [24]. Anaesthesia was induced by local infiltration of opticaine 120 solution with adrenaline 1:80,000 (AstraZeneca, Milan, Italy). A full-thickness flap was performed through a crestal and vertical medial and distal release incision. The exposed bone crest was then regularised with a straight handpiece and bone forceps. The midline, sinus region, and mental nerve were identified as reference sites for implant placement according to the height of the residual bone viewed with CBCT [25–27]. Six straight implants or two straight implants and two implants angled mesially and distally were then placed using a lanceolate drill and a ø 2.00 pilot drill.

The implant site was overprepared vertically and underprepared transversely to promote primary mechanical stability, and the insertion torque varied between 30 and 40 N-cm before final implant placement.

The implant fixtures used belonged to the K and TT line (Winsix, Biosafin, Ancona, Italy). More details are described in Table 1.

Table 1. Details concerning the dental implants employed in this study.

Dental Implant Details	K Line	TT Line
Generalities and connection	The Kappa line of dental implants features three different implant collars, all sharing the same implant body and internal hexagonal connection.	The TT line of dental implants consists of a single implant body designed to maximize implant stability and support early or immediate loading. The TT line offers two variations: TTi with an internal hex and TTx with an external hex.
Macromorphology	The Kappa implants have a variable coil geometry that gradually transitions from square to triangular shape. The coils are also designed with varying depths to promote vertical micro-expansion and progressive horizontal expansion. These design features aim to facilitate bone deposition and the formation of coagulum during the implant insertion process.	The TT implants have double-threaded, double-principled coils. This design facilitates easy implant insertion with fewer turns required. The groove present in the lower part of the loop helps decompress the bone by dissipating forces and aids in the deposition of blood clot. It also increases the implant surface area, promoting the formation of new cells for enhanced osseointegration.

Table 1. *Cont.*

Dental Implant Details	K Line	TT Line
Implant Body	The K-implant within the Kappa line has a cylindrical shape with a truncated conical body. It features a self-filtering coil with differentiated depth and thickness, allowing for modulation of primary stability during surgery. This design helps optimize the implant's stability during the initial healing phase.	The apex of the TT implants is conical and slightly undersized by 1.3 to 1.8 in relation to the implant diameter. This tapered design allows for an osteotomic effect, making it easier to insert the implants at an angle even in cases where there is limited bone availability.
Crestal Module	The crestal module of the Kappa implants has a height of 0.3 mm and is equipped with microgrooves. These microgrooves contribute to enhanced bone stability in the coronal (upper) area of the implant. Additionally, the apex of the implant has a hemispherical shape along with wide and deep sulcuses, which can aid in supporting bone growth and stability.	The TTi implant within the TT line has a cylindrical shape with a conical apex. It features a polished truncated conical collar with a height of 0.7 mm and an angle of 3°. This collar design helps facilitate a smooth transition between the implant and the abutment.

Flap adaptation and suturing (Vicryl; Ethicon, Johnson & Johnson, New Brunswick, NJ, USA) were then performed, and titanium cylinders were screwed onto the abutments. A provisional all-acrylic resin prosthesis was then drilled at the abutments to take pick-up impressions (Per-madyne, ESPE, Seefeld, Germany). Intraoral radiographs were taken to assess the correct positioning of the implant, and antibiotic and analgesic therapies were prescribed (1 g amoxi-cillin/500 mg clatritromycin every 12 h for six days and ibuprofen 600 mg as needed up to a maximum of three times a day or Tachipirin 1000 mg as needed at the patient's choice). Mouth rinses with a solution containing chlorhexidine digluconate (0.20%) twice a day for 10 days have been recommended [28–30].

A screw-retained provisional denture composed of metal-reinforced acrylic with a maximum of 12 teeth and without a cantilever was delivered approximately 3 h after surgery, and the screw access holes were covered with temporary resin (Fermit, Ivoclar Vivadent, Naturno, Bolzano, Italy). Four months later, the provisional prosthesis was replaced with an implant-supported definitive prosthesis composed of acrylic resin with a titanium framework and fitted with a distal cantilever. The screw access holes were covered with acrylic resin (Fermit, Ivoclar Vivadent Naturno, Bolzano, Italy), and the occlusion was checked with articulating paper (Bausch, Nashua, NH, USA).

2.3. Follow-Up

Follow-up visits were carried out 1 week after surgery, at 3 and 6 months, and then once a year for the following 7 years. Professional oral hygiene appointments were carried out every 4 months after the surgical-prosthetic procedure.

These follow-up visits were important to assess the success of the implant-supported prostheses and identify any potential issues that needed to be addressed. The 1-week visit allowed the dental team to evaluate the healing process and monitor the patient's post-operative condition. The 3- and 6-month visits assessed the stability and osseointegration of the implants, and any necessary adjustments to the prostheses were made. The yearly visits provided a long-term evaluation of the implant-supported prostheses, ensuring their longevity and function. The professional oral hygiene sessions every 4 months

were necessary to maintain the health of the patient's peri-implant tissues and prevent peri-implantitis, a common complication of dental implants [31,32].

2.4. Clinical Outcomes

2.4.1. Implant Survival Rate

To compare the implant survival rate between healthy patients and patients with hypertension, the study involved placing dental implants in both groups of patients and then following them up for seven years. The number of implant failures or losses was recorded, and the implant survival rate was calculated for each group.

2.4.2. Marginal Bone Loss

The patients underwent regular follow-up visits at specific intervals (3, 6, 12 months, and every year) after the placement of the dental implants. This periodicity allows for monitoring changes in bone levels over time.

Intraoral radiographs were taken during each follow-up visit. These radiographs provide detailed images of the implant and surrounding bone structures.

The DIGORA 2.5 software was utilized for the analysis of the radiographs. Before measuring bone levels, the software was calibrated for each image using the known diameter of the implant fixture at the most coronal side of the implant neck. Calibration ensures accurate and consistent measurements.

The linear distance between the most coronal point of the bone–implant contact and the coronal margin of the implant neck was measured on both the mesial (toward the midline) and distal (away from the midline) sides of the implant. This measurement was performed to the nearest 0.01 mm. The average distance for each implant was then calculated.

By measuring the bone level at each follow-up visit, the changes in bone level over time can be tracked. These measurements provide information about bone remodelling and stability around the dental implants.

At the group level, the average changes in the bone level for individual implants were calculated and statistically compared. This analysis allows for evaluating the overall trend of the bone level changes and comparing the results with established success criteria for implant therapy.

2.4.3. Clinical Complications

Possible clinical complications, such as post-surgical swelling, pain while taking analgesic drugs, and bleeding and/or wound infection, were recorded during the follow-ups.

2.4.4. Prosthetic Complications

Possible prosthetic complications, such as provisional prosthesis fracture, provisional screw loosening (abutment), provisional screw loosening (prosthesis), and/or chipping of the veneering material (final prosthesis), were recorded during the patients' visits [33,34].

2.5. Statistical Analysis

The researchers used Python 3.8.5 and several statistical packages (math, SciPy, and pandas) to perform statistical analyses on the recorded data. The specific tests employed depended on the sample distribution, variance, and experimental setup and included independent-samples parametric *t*-tests, Pearson's chi-square tests, and z-tests.

The researchers applied a significance level of $p < 0.05$ to determine whether the differences between the groups were statistically significant. The data were analysed at an aggregate level, which means they examined overall patterns and trends in the data rather than individual data points.

To examine the differences in implant survival rates and complications between Group A and Group B, the researchers used Pearson's chi-square tests and z-tests. To compare the marginal bone loss between the two groups over time, they used Pearson's chi-square tests and Student's *t*-tests.

Overall, the researchers employed a variety of statistical techniques to analyse the data and draw conclusions about the differences between Group A and Group B. The use of statistical tests helps to ensure that the observed differences are not due to chance but rather reflect real differences between the groups.

The null hypothesis was that there were statistically significant differences between the groups compared.

3. Results

Based on the inclusion and exclusion criteria, 39 patients (23 females, 16 males) were enrolled for this study. The mean age was 69 years (range: 56–82). The sample was divided into two groups: A total of 18 patients were included in Group A (healthy patients), and 21 patients were included in Group B (patients affected by hypertension).

Depending on the degree of bone atrophy in the posterior region, the patients received a full-arch rehabilitation (of one or both arches) with six axial implants or, if the residual posterior bone height was insufficient, an All-on-Four rehabilitation with the placement of a total of 228 dental implants (Tables 2–4).

Table 2. Number of patients in each group classified according to the need for rehabilitation of the maxilla, mandible, or both jaws.

	Group A	**Group B**
	18	21
Need of maxilla rehabilitation	6	6
Need of mandible rehabilitation	8	9
Need of rehabilitation of both arches	4	7

Table 3. Kind and site of implant-prosthetic rehabilitations: Group A.

	Maxilla	**Mandible**
Six straight implants	4	3
All-on-Four	6	9

Table 4. Kind and site of implant-prosthetic rehabilitations: Group B.

	Maxilla	**Mandible**
Six straight implants	2	3
All-on-Four	11	13

In Group A, fixed rehabilitations supported by six axial implants were performed in four cases in the maxilla and three cases in the mandible for a total of 42 implants.

The All-on-Four protocol was applied in six cases in the maxilla and nine in the mandible for a total of 60 implants. The total number of implants placed in the healthy patients was 102.

In Group B, fixed rehabilitations supported by six axial implants were performed in two cases in the upper jaw and three cases in the lower jaw for a total of 30 implants.

The All-on-Four protocol was applied in 11 cases in the maxilla and 13 in the mandible for a total of 96 implants. The total number of implants placed in the patients with hypertension was 126.

3.1. Implant Survival Rate

In the healthy patients, the recorded implant survival rate was 95.09% with a total loss of five implants. In the patients with hypertension, eight implants were lost, resulting in an implant survival rate of 93.65% (Table 5).

Table 5. Number of implants lost for each group and implant survival rate according to early and late failure.

	N° Implants	Early Failure	Late Failure	Implant Survival Rate
Group A	102	3	2	95.09%
Group B	126	5	3	93.65%.

Based on the information provided, it appears that there was no statistically significant difference in implant survival rates between Group A and Group B. This means that the null hypothesis, which states that there is no significant difference between the two groups, cannot be rejected at a 95% confidence level.

In other words, the data do not provide strong evidence to suggest that the implant survival rates in Group A are different from those in Group B.

3.2. Marginal Bone Loss

Marginal bone loss was summarised from the measurements obtained during the follow-up and averaged for each group (Table 6).

Table 6. Average marginal bone loss for each group during the follow-up.

	Group A	Group B
6 months (mm)	0.57 ± 0.52	0.63 ± 0.54
1 year (mm)	0.99 ± 0.82	0.91 ± 0.65
2 years (mm)	0.84 ± 0.73	0.83 ± 0.74
3 years (mm)	0.86 ± 0.79	0.90 ± 0.86
4 years (mm)	1.00 ± 0.90	1.01 ± 1.00
5 years (mm)	1.02 ± 0.94	1.04 ± 0.77
6 years (mm)	1.03 ± 1.01	1.11 ± 0.67
7 years (mm)	1.04 ± 0.94	1.12 ± 0.77

No statistically significant differences in marginal bone loss were observed between Group A and Group B in any of the follow-up assessments ($p > 0.05$). The differences between the two groups at a 95% confidence level do not appear to be sufficiently significant to reject the null hypothesis, and it must be assumed that the two groups are not statistically different.

3.3. Clinical Complications

Concerning clinical complications (Table 7), post-surgical swelling was observed in three cases in Group A and in five cases in Group B. All patients stated that post-surgical pain was almost absent as they were sufficiently managed with analgesics. Post-surgical haemorrhage was mainly observed in the patients with hypertension, never in the group consisting of the healthy subjects. Wound infection was observed only in one patient affected by hypertension.

Table 7. Clinical complications classified by groups.

Clinical Complications	Group A	Group B
Edema	3	5
Pain	0	0
Bleeding	1	8
Wound infection	0	1

Except for the bleeding variable, the differences between the two groups at a 95% confidence level do not appear to be significant enough to reject the null hypothesis. The results of Pearson's chi-square test and z-test at a 99% confidence level suggest that there is no statistically significant difference in clinical complications between the groups.

3.4. Prosthetic Complications

Fracture of the provisional prosthesis was recorded in one case in Group A and two cases in Group B; loosening of the provisional screw (abutment) was recorded in two cases in Group A and two cases in Group B; loosening of the provisional screw (prosthesis) occurred in one case for each group. No loosening of the lining material (final prosthesis) was reported during the follow-up. The obtained results are summarised in Table 8.

Table 8. Prosthetic complications classified by groups.

Prosthetic Complications	Group A	Group B
Provisional prosthesis fracture	1	2
Provisional screw loosening (abutment)	2	2
Provisional screw loosening (prosthetic)	1	1
Detachment of the veneering material (final prosthesis)	0	0

No statistically significant differences were observed in prosthetic complications (fracture of the provisional prosthesis, loosening of the provisional screw (abutment), loosening of the provisional screw (prosthesis), and detachment of the lining material (final prosthesis)) between Group A and Group B ($p > 0.05$). The differences between the two groups at a 95% confidence level do not appear to be sufficiently significant to reject the null hypothesis, and the two groups should be considered statistically not different.

4. Discussion

Patients selected for this research paper underwent clinical, radiographic, and blood examinations before surgery to identify any signs of uncontrolled hypertension. Uncompensated systemic diseases could interfere with implant osseointegration processes, implant survival rates, and the possible development of intra- and postoperative complications [34].

In this clinical study, it was possible to identify high implant survival rates in both patient Groups A and B. Thus, we are able to state that there is no statistically significant difference on implant survival between a patient with hypertension and a healthy patient. However, it should be remembered that statistical significance does not necessarily mean clinical significance. The number of participants in each group, the duration of the study, and the specific characteristics of the implants used should also be taken into account in order to interpret the data correctly.

In contrast to our study, Singh R. et al., in their 10-year retrospective study of 826 patients with placement of 1420 implants, identified the main risk factors of implant failures including hypertension. Precisely, they stated that implant failures could be traced to cigarette smoking in 37 percent of cases, hypertension in 20.8 percent, diabetes in 20.3 percent, and cardiovascular disease in 18.7 percent. While in the group of healthy patients, failures were approximately 4.37% [35].

In the retrospective cohort study by Wu X. et al., 728 patients and 1499 implants were evaluated by dividing patients into two different groups: hypertensive drug users and non-hypertensive drug users. In their study, they investigated the possible association between antihypertensive medication and the survival rate of dental implants, stating that only 0.6 percent of implants had failed in patients taking antihypertensive medication, while 4.1 percent of implants had failed in the non-users' group, thus suggesting that antihypertensive drugs may prove to be a positive factor in the process of osseointegration of implant fixtures [36].

In the present study, it can be stated that there were no statistically significant differences on marginal bone loss between the two groups considered. The literature review by Mombelli A. et al. assessed the impact of systemic disease on the success of implant therapy by going to human studies that included implant rehabilitations, a diagnosis of systemic disease, and at least implant survival. The authors highlight how a single risk factor may not have a significant impact, while a combination of several independent factors could lead to a different outcome [37].

Contrary to our research paper, in the systematic review and meta-analysis by Chappuis V. et al. carried out on a final selection of 17 articles investigating the relationship between systemic drug intake and bone metabolism with the consequent impact on implant failures, it was found, in the article by Brater DC., that antihypertensive drugs can interfere with and inhibit the physiological action of osteoclasts on bone, leading to a blockade of the renin-angiotensin system [38,39].

Seki K. et al., in their retrospective cohort study carried out on 35 patients and a total of 77 implants with a follow-up of 7 years and 1 month, evaluated the influence of antihypertensive drugs on peri-implant clinical parameters by dividing patients into two groups: those taking antihypertensive drugs and those who were healthy. The results obtained from their research paper are in agreement with our study, which is that marginal bone loss in relation to radiographic evaluation in patients on antihypertensive medication was greatly reduced and no implants were lost. The explanation is thus traced back to the influence that antihypertensive drugs may have toward bone metabolism [40].

Similarly, in the study by Fabris ALDS. et al. conducted on 30 patients undergoing rehabilitation with implant fixtures in the posterior mandible, it appears that antihypertensive drugs can prevent catabolic changes in bone turnover, thus preserving alveolar bone quality. The study was carried out by dividing patients into two groups: the first were hypertensive patients taking RAS antagonists, while the second were normotensive patients taking no drug therapy. Bone biopsies and histological analysis were performed to assess trabecular thickness, number of trabeculae, and the total ratio of trabecular bone to porosity, concluding that these factors were similar between the two groups [41].

Post-surgical clinical complications can be found in both healthy and hypertensive populations. As stated in the research papers by Yagiela J.A. et al. and Aubertin MA., more care should be taken in the population with medical complications, especially if they are untreated. In particular, the article by Aubertin MA. reviews the current versus previous guidelines [42,43].

So, it is good to monitor blood pressure in the dental office. Blood pressure monitoring is of paramount importance as stated in Little JW's article, as these patients are at an increased risk of complications, such as stroke and renal and retinal diseases. The risk increases during more stressful dental procedures, such as oral surgery, periodontal surgery, and implant fixture placement. This article reviews recent advances in the dental and medical management of hypertension [44].

Post-surgical bleeding in our research paper was observed in only one case in the group of hypertensive patients. As stated in the study by Nimma V. et al. conducted in 40 patients over 60 years old of whom 20 were normotensive subjects and 20 were hypertensive subjects under drug therapy, bleeding on probing and the presence of inflammation was more frequent in hypertensive patients [45].

No statistically significant differences in prosthetic complications were observed between the two groups examined. Fracture of the provisional denture, loosening of the provisional screw, and detachment of the denture lining material are prosthetic complications that were also found in the study by Kern M. et al., which was a randomized controlled clinical trial with a 2-year follow-up of 158 patients who received at least one implant and were randomly assigned to either the immediate loading group or the delayed loading group with more satisfactory results being obtained in the case of loading three months after implant fixture placement [46].

Medesimal issues were addressed in the retrospective investigation by Francetti L. et al. conducted on 86 patients in which 61 mandibular and 34 maxillary rehabilitations were performed and all with immediate loading within 8 to 48 h after surgery with a follow-up of 16.3 to 112 months of function. They reported a total of 42 prosthetic complications, which were reversible and did not affect the implant survival rate [47].

5. Conclusions

Within the limitations of this study, full-arch implant-prosthetic rehabilitation could be a viable option for treating patients with hypertension, provided that hypertension is compensated and controlled.

In addition, placing the patient within a follow-up course could prevent implant rehabilitation failure, marginal bone loss above physiological ranges, and the occurrence of postoperative complications. Further clinical studies may be needed to confirm and extend the results obtained.

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