Clinical investigation of a new dental immediate implant system.

(according to ISO 14155:2011)

According to the Medical Devices Directive, both the preparation for clinical trials and marketing of implants require that a risk analysis is performed.

This paper presents the evaluation of a dental implant in the framework of the risk management process carried out for the preparation of a multi-centre clinical trial.

The clinical study aimed to demonstrate the conformity of Axelmed Paradigma with the essential requirements and to evaluate the survival rate and the possibility for the implant to be placed with a torque value between 35 and 50 Ncm in order to allow the possibility to perform, if required, an immediate loading procedure.

Introduction

Several directives regulate the marketing and distribution of medical devices in the European Economic Area. The Medical Devices Directive (MDD), which covers most implants, sets conformity assessment procedures depending on the medical device class type, and requires risk analysis to be performed.

The MDD covers medical devices intended for clinical investigations, dictating the procedure to be followed by the manufacturer and provisions under which the clinical investigations must be conducted. As a result, the EN ISO 14155 harmonised standard has been issued, providing guidance to medical device manufacturers for the conduct of their clinical investigations.

The general aim of this paper is to highlight the importance of performing risk assessments of safety and performance and clinical trials of Axelmed Paradigma using them regularly on patients. We describe the application of the dental implant Axelmed Paradigma in the framework of its development.

Funder	Axelmed s.r.l.
Sponsor	Axelmed s.r.l.
Funding Reference	Guido Ivo Tissi
Chief Investigator	dott. Piero Lazzari
Sponsor Reference	Guido Ivo Tissi

CLINICAL INVESTIGATION MANAGEMENT

CLINICAL INVESTIGATION MANAGEMENT GROUP

The investigation group was composed by clinicians with different surgical skills and the surgical procedures performed in private clinics. The selection of this investigation group was done to simulate the daily routine in order to analyze the implant features in ordinary conditions.

Specifically, the investigation group was composed by six dentists suitably trained about the data collection.

This clinical investigation is conducted in full conformity with the current revision of the Declaration of Helsinki.

PARTICIPANT CONFIDENTIALITY

The clinical investigation staff will ensure that the participants'anonymity is maintained. The participants will be identified only by initials. All documents will be stored securely and only accessible by clinical investigation staff and authorised personnel.

CLINICAL INVESTIGATION MANAGEMENT GROUP

Chief Investigator

Name: Piero Lazzari

Title: Doctor

Signature: 

Date: 16/01/2018

Principal Investigator

Name: Piero Lazzari

Title: Doctor

Signature: 

Date:16/01/2018

Sponsor

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CLINICAL INVESTIGATION SUMMARY

Clinical Investigation title	Analysis of the primary implant stability and the proper osseointegration process of Axemled Paradigm Dental Implant.
Sponsor Reference	Axelmed S.R.L - Guido Ivo Tissi - via della Liberazione, 58 - San Giuliano, Milan - Italy
Clinical Phase	Phase IV
Clinical investigation Design	Observational - Population Study
Number of Participants	29
Follow-up Duration	17 months
Primary Objective	To evaluate the primary stability of Axelmed Paradigma Implant
Secondary Objective	To evaluate the proper osseointegration of Axelmed Paradigm Implant system
Device Name	Paradigma
Manufacturer Name	Axelmed S.R.L.
Principle Intended Use	Tooth replacement

Introduction

Axelmed Paradigma Dental implants are made of titanium alloy and manufactured by Axelmed s.r.l. (Italy). After the milling process the implants are subjected to the surface treatment and to a series of decontamination process through different steps and using different chemical agents. Finally, the implants are packaged, labelled and sterilized. The Axelmed Paradigma implants line acts as anchor for crowns, bridges or prostheses to the bone (both the upper and the lower jaw). They have an internal hexagonal connection, a conical body with two principles thread and are made by titanium Gr. 4 in accordance with the requirement of ISO 5832-2. The Axelmed Paradigma implants are present in 5 different diameters with the same prosthetic connection (look the table at the bottom of the page). The surface of the fixture is machined at the portion of the collar and micro-rough at the level of the body with SAP treatment (sandblasting with Al2O fine-grit, double Acidification, double decontamina- tion with Argon Plasma). The surgical positioning of the implant is at the crestal or subcrestal bone level. It is packaged in a titanium cylinder protected by two sealed sterile tubes and a cover and an healing screw are present in the same packaging. It is sterilized by irradiation with Gamma Ray (min 25kGy) and it is "STERILE" until the expiration date.

In order to use the medical device the operators need to be exclusively a qualified Doctors or a Dentist.

Objectives

Aim of the following clinical investigation is to evaluate the Axelmed Paradigma implant System in order to analyze the possibility for the implants to guarantee a good primary stability in most of cases and to provide a proper osseointegration process. The primary stability is evaluated through the analysis of the torque value obtained during the implant placement procedure.

Materials and methods

The subjects were patients with a pre-existing need for treatment with dental implants who provided written informed consent. The surgeries was performed by different clinicians in their own private clinic.

Inclusion criteria were as follows:

- Provision of informed consent ≥ 21 years;
- In need of one or more single implants;
- Replacing missing or non-restorable teeth in the maxilla and in the mandible;
- Absence of periodontal disease;
- An opposing dentition with teeth, implant, or opposite fixed prosthesis.

Exclusion criteria were as follows:

- Presence of systemic disease affecting the bone healing;
- Jaw fracture;
- Radiotherapy;
- Severe smoking (>20 cigarettes/day)
- Hormonal imbalance;

- Patients with chronic infectious disease;
- Patients receiving immunosuppressive therapy;
- Pregnant women;
- Drug and alcohol addicts;
- Patients with severe periodontal diseases.

Parameters recorded were as follows:
- Patient name
- Surgery date
- Implant site
- Implant dimension
- Mandible or maxilla
- Bone quality
- Torque of implant insertion
- Regenerative procedure
- Material used for regenerative procedure
- Condition of the implant site (healed site or post extraction site)
- Condition of the loading
- Smoking
- Name of the clinician who performed the surgery

The responsible for identifying the participants were the clinician in according to the inclusion/ exclusion criteria.
*(In **Table A** there is a summery of the recorded data)*

Table A

PATIENT NAME	SURGERIES DATE	IMPLANT SITE	IMPLANT DIMENSION	SIDE	BONE QUALITY	TORQUE	REGENE RATIVE	MATERIAL	SITE	LOADING	SM OK E	CLINICIAN
A.M.	28/04/2015	14	3.8x11	Maxilla	III	35	GBR	BioOss + Autologo	Healed	Immediate	SI	Camerucci Daniele
A.M.	28/04/2015	22	3.8x11	Maxilla	III	35			Healed	Immediate	SI	Camerucci Daniele
A.M.	28/04/2015	24	3.8x11	Maxilla	III	40			Healed	Immediate	SI	Camerucci Daniele
A.M.	28/04/2015	12	3.8x11	Maxilla	III	45			Healed	Immediate	SI	Camerucci Daniele
A.M.	28/04/2015	32	3.8x11	Mandible	II	50			Healed	Immediate	SI	Camerucci Daniele
A.M.	28/04/2015	34	3.8x11	Mandible	II	50			Healed	Immediate	SI	Camerucci Daniele
A.M.	28/04/2015	42	3.8x11	Mandible	II	50			Healed	Immediate	SI	Camerucci Daniele
A.M.	28/04/2015	44	3.8x11	Mandible	II	50			Healed	Immediate	SI	Camerucci Daniele
B.M.	04/03/2015	24	3.8x9	Maxilla	III	50			Healed	Transmucosal	NO	Salvatore Terlizzi
B.A.	12/04/2016	14	4.3x11	Maxilla	II	50	GBR	BioOss + BioGide	Post-extra ractive	Immediate	NO	Salvatore Terlizzi
B.L.	1/7/2015	31	4.3x9	Mandible	I	50			Healed	Submerged	NO	Bernardini Luigi
B.L.	1/7/2015	33	4.3x9	Mandible	I	50			Healed	Submerged	NO	Bernardini Luigi

B.L.	1/7/2015	43	4.3x9	Mandible	I	50			Healed	Submerged	NO	Bernardini Luigi
B.K.	04/06/2015	46	5.0x11	Mandible	II	60			Healed	Immediate	NO	Lazzari Piero
B.R.	13/11/2015	25	5.0x13	Maxilla	IV	45			Healed	Immediate	NO	Lazzari Piero
B.R.	13/11/2015	11	4.3x13	Maxilla	IV	50			Healed	Immediate	NO	Lazzari Piero
B.R.	13/11/2015	14	4.3x13	Maxilla	IV	50	GBR	BioOss	Healed	Immediate	NO	Lazzari Piero
B.R.	13/11/2015	15	4.3x13	Maxilla	IV	50	GBR	BioOss	Healed	Immediate	NO	Lazzari Piero
B.R.	13/11/2015	23	4.3x13	Maxilla	IV	50	GBR	BioOss	Healed	Immediate	NO	Lazzari Piero
C.D.	20/01/2015	27	4.3x9	Maxilla	III	40			Healed	Transmucosal	NO	Lazzari Piero
C.V.	28/05/2015	37	5.0X11	Mandible	II	50	GBR	GenOss	Healed	Transmucosal	SI	Lazzari Piero
CA.D.	01/04/2015	32	3.8x11	Mandible	I	43	GBR	Autologo + BioGide	Post-extraction	Submerged	SI	Camerucci Daniele
CA.D.	01/04/2015	33	4.3x11	Mandible	I	50	GBR	Autologo + BioGide	Post-extraction	Submerged	SI	Camerucci Daniele
CA.D.	01/04/2015	42	3.8x11	Mandible	I	50	GBR	Autologo + BioGide	Post-extraction	Submerged	SI	Camerucci Daniele
CA.D.	01/04/2015	43	4.3x11	Mandible	I	56	GBR	Autologo + BioGide	Post-extraction	Submerged	SI	Camerucci Daniele
C.A.	22/01/2015	11	4.3x13	Maxilla	III	50	GBR	GenOss + membrana	Post-extraction	Immediate	SI	Lazzari Piero
F.A.	09/02/2016	24	4.3x13	Maxilla	III	20	Sinus Lift		Healed	Submerged	NO	Lazzari Piero
F.A.	09/02/2016	26	5.0x13	Maxilla	III	30	Sinus Lift		Healed	Submerged	NO	Lazzari Piero
F.B.	06/11/2015	44	4.3x11	Mandible	III	40	GBR	BioOss + BioGide	Healed	Immediate	NO	Lazzari Piero
F.B.	06/11/2015	45	5.0x11	Mandible	III	40	GBR	BioOss + BioGide	Healed	Immediate	NO	Lazzari Piero
F.B.	06/11/2015	47	4.3x11	Mandible	III	40	GBR	BioOss + BioGide	Healed	Immediate	NO	Lazzari Piero
F.B.	06/11/2015	32	3.4x13	Mandible	IV	50	GBR	BioOss + BioGide	Healed	Immediate	NO	Lazzari Piero
F.B.	06/11/2015	42	3.4x13	Mandible	IV	50	GBR	BioOss + BioGide	Healed	Immediate	NO	Lazzari Piero
G.A.	03/11/2015	16	5.0x7	Maxilla	IV	10			Healed	Transmucosal	NO	Lazzari Piero
G.A.	03/11/2015	36	3.4x11	Mandible	II	50			Healed	Transmucosal	NO	Lazzari Piero
G.A.	03/11/2015	46	4.3x11	Mandible	II	50			Healed	Transmucosal	NO	Lazzari Piero
G.Z.	1/7/2015	12	4.3x11	Maxilla	III	45			Healed	Submerged	SI	Bernardini Luigi
G.Z.	1/7/2015	14	4.3x11	Maxilla	III	45	GBR	BioOss + BioGide	Healed	Submerged	SI	Bernardini Luigi
G.Z.	1/7/2015	22	4.3x11	Maxilla	III	45			Healed	Submerged	SI	Bernardini Luigi
G.Z.	1/7/2015	24	4.3x11	Maxilla	III	45			Healed	Submerged	SI	Bernardini Luigi
G.M.	04/03/2016	36	5.0x11	Mandible	II	35			Healed	Transmucosal	NO	Lazzari Piero
L.G.	25/03/2015	22	3.8x11	Maxilla	IV	30	GBR	GenOss + membrana	Post-extraction	Submerged	NO	Terlizzi Salvatore
L.G.	25/03/2015	24	3.8x9	Maxilla	IV	30	GBR	GenOss + membrana	Healed	Submerged	NO	Terlizzi Salvatore
L.G.	25/03/2015	25	3.8x9	Maxilla	IV	30	GBR	GenOss + membrana	Healed	Submerged	NO	Terlizzi Salvatore

M.ML.	29/10/2014	34	4.3x11	Mandible	II	35			Healed	Submerged	NO	Lazzari Piero
M.ML.	29/10/2014	32	3.4x13	Mandible	I	40			Healed	Submerged	NO	Lazzari Piero
M.ML.	29/10/2014	42	3.4x13	Mandible	I	40			Healed	Submerged	NO	Lazzari Piero
M.ML.	29/10/2014	44	4.3x11	Mandible	II	40			Healed	Submerged	NO	Lazzari Piero
M.ML.	29/10/2014	46	4.3x9	Mandible	II	40			Healed	Submerged	NO	Lazzari Piero
M.ML.	29/10/2014	36	4.3x9	Mandible	II	45			Healed	Submerged	NO	Lazzari Piero
M.B.	27/02/2015	44	3.8x11	Mandible	II	50	GBR	BioOss	Healed	Transmucosal	NO	Casella Davide
M.B.	27/02/2015	45	4.3x9	Mandible	II	70	GBR	BioOss	Healed	Transmucosal	NO	Casella Davide
R.R.	24/06/2015	36	5.6x11	Mandible	II	35	GBR	BioOss	Healed	Transmucosal	NO	Lazzari Piero
SF.R.	16/04/2015	46	4.3x11	Mandible	II	40			Healed	Transmucosal	NO	Lazzari Piero
SF.R.	16/04/2015	17	4.3x11	Maxilla	II	60			Healed	Submerged	NO	Lazzari Piero
S.R.	18/11/2015	33	4.3x13	Mandible	III	50	GBR	BioOss	Post-extraction	Transmucosal	NO	Lazzari Piero
S.R.	18/11/2015	43	4.3x13	Mandible	III	50	GBR	BioOss	Post-extraction	Transmucosal	NO	Lazzari Piero
S.M.	19/11/2015	45	4.3x11	Mandible	II	50	GBR	BioOss	Post-extraction	Immediate	SI	Lazzari Piero
S.M.	01/03/2015	25	3.8x11	Maxilla	II	20			Healed	Transmucosal	SI	Seidita Maurizio
S.M.	01/03/2015	26	4.3x11	Maxilla	II	20			Healed	Transmucosal	SI	Seidita Maurizio
S.M.	01/03/2015	15	3.8x11	Maxilla	II	50			Healed	Transmucosal	SI	Seidita Maurizio
S.M.	01/03/2015	16	4.3x11	Maxilla	II	50			Healed	Transmucosal	SI	Seidita Maurizio
S.C.	03/12/2014	26	5.0x9	Maxilla	I	40			Healed	Immediate	SI	Lazzari Piero
S.C.	03/12/2014	22	4.3x11	Maxilla	I	45			Healed	Immediate	SI	Lazzari Piero
S.C.	03/12/2014	24	4.3x13	Maxilla	I	45			Healed	Immediate	SI	Lazzari Piero
S.C.	03/12/2014	12	4.3x11	Maxilla	I	50			Post-extraction	Immediate	SI	Lazzari Piero
S.C.	03/12/2014	14	4.3x13	Maxilla	I	50			Post-extraction	Immediate	SI	Lazzari Piero
S.C.	03/12/2014	24	5.0x9	Maxilla	I	50			Healed	Immediate	SI	Lazzari Piero
S.E.	10/11/2015	32	4.3x11	Mandible	I	20			Healed	Transmucosal	NO	Lazzari Piero
S.E.	10/11/2015	42	4.3x11	Mandible	I	20			Healed	Transmucosal	NO	Lazzari Piero
S.E.	10/11/2015	34	4.3x11	Mandible	I	20			Healed	Transmucosal	NO	Lazzari Piero
S.E.	10/11/2015	44	4.3x11	Mandible	I	20			Healed	Transmucosal	NO	Lazzari Piero
S.E.	10/11/2015	12	4.3x9	Maxilla	IV	50			Healed	Submerged	NO	Lazzari Piero
S.E.	10/11/2015	14	4.3x9	Maxilla	IV	50			Healed	Submerged	NO	Lazzari Piero
S.E.	10/11/2015	22	4.3x9	Maxilla	IV	50			Healed	Submerged	NO	Lazzari Piero
S.E.	10/11/2015	24	4.3x9	Maxilla	IV	50			Healed	Submerged	NO	Lazzari Piero

T.I.	2/12/2014	16	5.0x9	Maxilla	III	35	Summer		Healed	Submerged	NO	Lazzari Piero
Z.A.	5/04/2015	27		Maxilla	IV	20			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	17		Maxilla	III	35			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	22		Maxilla	III	35			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	12		Maxilla	III	40			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	14		Maxilla	III	40			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	16		Maxilla	III	40			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	24		Maxilla	III	40			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	26		Maxilla	III	40			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	15		Maxilla	III	45			Post-extraction	Immediate	SI	Lazzari Piero
Z.A.	5/04/2015	25		Maxilla	III	45			Post-extraction	Immediate	SI	Lazzari Piero
P.A.	7/7/2016	12		Maxilla	II	40			Healed	Immediate	No	Lazzari Piero
P.A.	7/7/2016	14		Maxilla	II	35			Healed	Immediate	No	Lazzari Piero
P.A.	7/7/2016	22		Maxilla	II	35			Healed	Immediate	No	Lazzari Piero
P.A.	7/7/2016	24		Maxilla	II	45			Healed	Immediate	No	Lazzari Piero
P.A.	7/7/2016	16		Maxilla	II	40			Healed	Immediate	No	Lazzari Piero
P.A.	7/7/2016	26		Maxilla	II	35			Healed	Immediate	No	Lazzari Piero

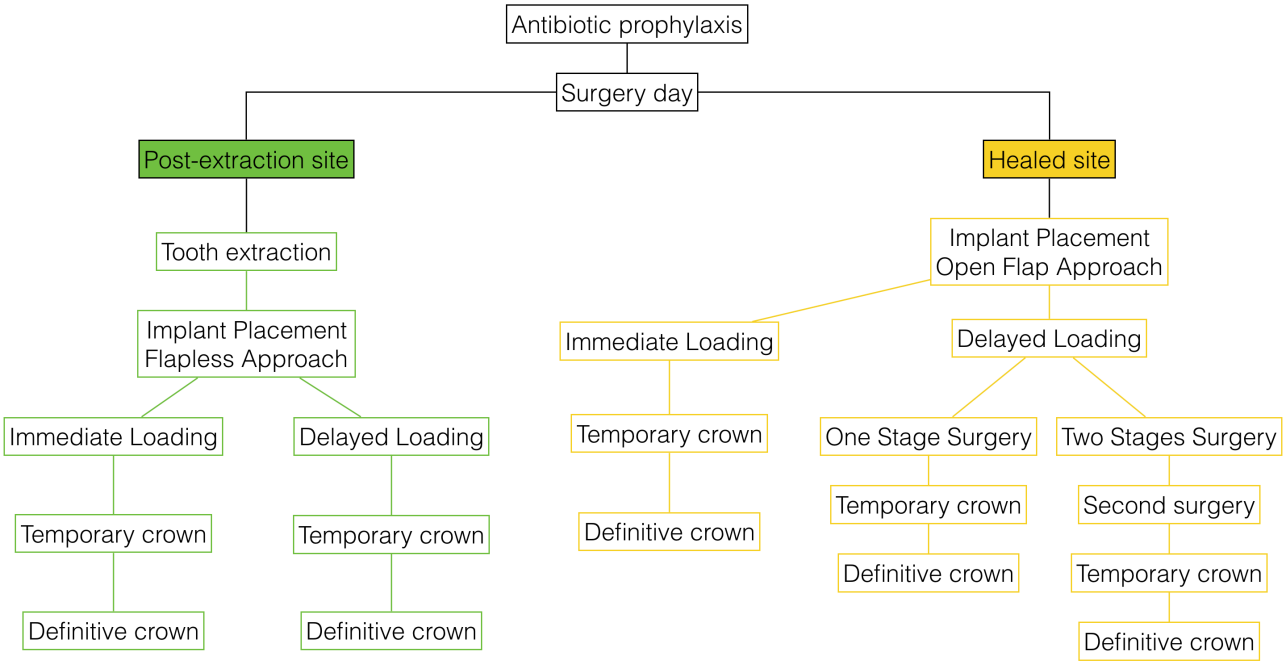
Consenting Participants

The participant must personally sign and date the latest approved version of the informed consent form before any clinical investigation specific procedures are performed.
Written and verbal versions of the participant information and Informed consent will be presented to the participants detailing no less than: the exact nature of the clinical investigation; the implications and constraints of the clinical investigation plan; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the clinical investigation at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the informed consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participants. The original signed form will be retained at the clinical investigation site.

CLINICAL INVESTIGATION

Obtaining a good primary stability is one of the main objectives during a dental implant placement procedure and the specific geometries for each Axelmed Paradigma diameter were developed to satisfy this requirement. The present report aims at analyzing this feature in different clinical conditions.
29 patients received consecutively a total of 93 Axelmed Paradigm by different operators.
The clinical protocol is summarized in the following scheme.



One day prior to surgery, the patients received prophylactic antibiotic therapy:

Amoxicillina
orally starting 1 day before procedure

For patients who cannot use oral medications

Clindamicina 300 mg
orally starting 1 day before procedure

They also continued the treatment after the procedure, taking 2 capsules daily for 6 days. After surgery, a Chlorhexidine mouthwash was prescribed for twice-daily use for 15 days. Ibuprofen (600 mg, 2 times daily) was prescribed if necessary because of post-operative pain. All patients were treated under local anesthesia using articaine with adrenaline.

Post extraction site

A "**flapless**" approach was chosen for the procedure. Tooth extractions were performed with elevators to help minimize trauma. Great care was taken to maintain the integrity of the buccal bone wall. After extraction, the socket was carefully curetted; subsequently, the implant bed was prepared according to the following procedure. The implant site was prepared using Axelmed drills,

following the palatal bony walls and always placed ≥ 3 mm beyond the root apex. Copious irrigation with saline was done during the surgical procedure. The coronal margin of the implant was located 2 mm below the buccal level of the bone crest. Grafting materials was placed into the peri-implant gap without the use of barriers membranes.

Healed site

An "**open flap**" approach was chosen for the procedure. An incision was given to reflect the mucoperiosteal flap. The osteotomy was initiated using a pilot drill of 2 mm through the surgical template followed by sequential drilling to prepare the site according to the selected implant size. Copious irrigation with saline was done during the surgical procedure. The implant was inserted with the help of insertion tool and a torque wrench.

At the end of the surgical procedure, on the basis of primary stability, an immediate loading or a delayed loading were performed. Minimum of 35–40 N-cm of torque was considered useful for the immediate loading procedure.

Immediate Loading

Immediately after the end of the surgery an impression trough the "Open tray technique" and using a Polyether material (Impregum - 3M Italia) was made. The day after the temporary crown was delivered to the patient.

Delayed Loading

One stage procedure

An impression trough the "Open tray technique" and using a Polyether material (Impregum - 3M Italia) was made and a temporary crown was delivered 7 days after.

Two stage procedure

12 weeks after the implant placement a second surgery was performed in order to replace the cover screw with an healing cap. A minimally invasive approach was preferred and a short incision was performed in correspondence with the implant site. If possible after the healing abutment placement any suture was applied.

In order to shape a proper transmucosal space and to give to the technician the possibility to create a proper emergence profile, in both cases (Immediate ore Delayed Loading), the temporary crown was removed 8 weeks after the delivery.

Of the 93 implants, 39 (41.9%) were loaded immediately, while the remaining 54 (58,1%) were loaded 10 weeks after the placement. 63 (67.7%) Axelmed Paradigma implants were used in a one-step technique, while the remaining 30 (32.3%) received a two-phase approach.

Torque insertion was evaluated, postoperative Rx were taken at T0 (immediately after surgery), T1 (1 month), T2 (3 months), T3 (1 year) and the follow up was between 4 and 16 months.

2 implants (2.1%) failed, both in the maxilla, both placed immediately after tooth extraction and both treated with an immediate loading protocol where the initial insertion torque was 50 Ncm in presence of a III Class bone quality (Lekholm and Zarb, 1985). 23 implants (24.7%) were placed in post-extraction sockets, while 70 (75.3%) were in healed sites. The 93 Axelmed Paradigma received

an initial torque with its distribution summarized in the bar graph. These values were recorded using the surgical motor Intrasurgery 2.0.
Literature data indicate that it's desirable to reach a minimum value of 35 Ncm to proceed with an immediate loading protocol. However, some authors advise against using very high torque values (above 70 Ncm) to avoid possible necrosis around the implant fixture. The data and the experience in this report indicate the possibility to achieve good levels of primary stability using Axelmed Paradigma dental implants that respect bone tissue biology and surrounding structures.
The implant thread design (trapezoidal with decreasing depth) and the conical shape of the body allowed to achieve a good primary stability. This is the main objective for the clinicians dealing with immediate loading protocol during their activity.
Effectively, this implant design appears to demonstrate in almost 84% of the cases an excellent primary stability with > 35 Ncm torque insertion.

Discussion

Overall survival rates of Paradigma implants of **97.9%** have been reported. Failure rates were higher in the maxilla in patients with metabolic diseases, bones of D4 quality and in smokers.

Esposito et al found a set of factors associated with the failures of oral implants, with excessive surgical trauma together with an impaired healing ability, premature loading and infection as the most common causes of early implant losses. Progressive chronic marginal infection and overload, in conjunction with the host characteristics were the major etiological agents causing late failures.

A scientific literature review, together with the personal experience of the surgeons taking part in the clinical study, led to the identification of the main hazards of implant failure. These were the implant insertion operation (and the associated surgical trauma), patient hygiene (including smoking habits), patient bone quality and the mechanical properties of the implant.

It is certainly important a careful selection of the patient who undergoes to the surgical procedure and it is equally important the quality of the medical devices.

Regarding the last point Axelmed Paradigma, with its survival rate which is in accordance with the best standard of data present in literature, seems to respect the quality standard required to perform the procedure safely and properly.

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