

Retrospective Observational Study of MSDI Dental Implants

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1. Introduction

The performance in terms of predictability and efficiency of modern implant systems has reached considerably high levels in recent years. Biomechanical studies, surface treatments, the evolution of the implant-prosthetic connection system and also the advent of digital diagnostic and design procedures, have marked the advent of the most modern development phase of implant systems.

More and more attention is given to the mechanical and aesthetic performance of the implant fixture and of the fixture-abutment-prosthetic restoration complex. The CAE (Computer Aided Engineering) digital systems have made it possible to evaluate the dynamics of the load transfer from the prosthetic restoration to the connection, to the implant and finally to the peri-implant alveolar bone support - this has seen a marked improvement in the resistance to mechanical load of the implant-abutment complex, and a greater biocompatibility of the same mechanical load optimized for the bone structure of the recipient site. A thorough and deep-rooted attention to the problem of the implant site and the clinician's approach to both bone and gingival reconstructive surgical techniques, have then contributed to the improvement of aesthetic performance, also in response to an increase in the patient's expectations.

We started from a sample of 200 MSDI implants to carry out a multicenter retrospective observational study based on the recording of different parameters both intraoperative and technical prosthetic. The aim is to provide a sample as representative as possible of the applicability of the MSDI Alef Spiral implant system to the Implant-Prosthetic rehabilitation clinical practice. The implants were placed in two separate operational realities by three Implant surgeons who recorded the primary stability data of integration and usability of both analogical and digital prosthetic systems trying to return a picture as detailed and objective as possible.

The representative results of the first group of 54 implants inserted gave us data corresponding to a good success rating and a reproducibility of the proposed surgical protocol. The first contact with this implant

method showed both implant and prosthetic performances that seemed to us in line with those normally expected from a product of a good technical level.

Conflict of interest disclosure: MSDI provided the executors of this study, free of charge, with everything necessary for the clinical work performed. The operators did not receive any monetary compensation for the work performed. This report constitutes, having ascertained the usability of the implant material for the European legislation and particularly for the Italian one, a report free from contractual constraints and responding to the actual clinical conditions encountered. Publication in national or international scientific media is not authorized; this work constitutes a document for internal company use only.



Alef implant by MSDI

2. Material and Method

General organizational criteria:

We have established, in agreement with the MSDI, a sample of 200 implants to be inserted and loaded by restoration, on a sample of patients heterogeneous by age, sex and site to be rehabilitated. This report concerns the first stock of 54 implants performed from January 2021 to date. We have selected three clinicians who operate in two distinct Clinics, one located

in Northern Italy (Milan) and one in the South (Trapani). A precise number of implants to be performed by each of the three clinicians was not established, but a random distribution was chosen among the operators, dictated by their surgical needs.

Recruitment of patients:

the need for implant-prosthetic treatment was freely subject to the recruitment criteria of each of the three operators, meaning the choice of the implant site, number of implants, surgical technique used (deferred implants towards immediate post-extraction implants) and the timing of waiting for integration, once the implants have been inserted. This was to make the sampling as heterogeneous as possible and responsive to the technical needs of a sample that was representative of the average Italian clinician. The decision on the local exclusion inclusion criteria linked to architectural deficits or not of the site where the implant-prosthetic treatment is located was also left to the clinician. We believe that even this criterion can ultimately provide a more heterogeneous sample representative of a normal clinical reality.

Exclusion criteria:

we have established absolute exclusion criteria, valid for each of the three clinicians, almost exclusively concerning general health conditions, rather than local ones of dental competence. These include

- 1) insulin resistant decompensated diabetes mellitus.
- 2) current therapies with bisphosphonates for osteoporosis problems. It should be considered that patients with a positive history of bisphosphonate therapy performed with a minimum of 4 years prior to the implant therapy performed were recruited.
- 3) alcoholism / marked chronic smoking.
- 4) patients on immunosuppressive therapy.
- 5) patients with a history of anticancer chemiotherapy performed in the three years prior to recruitment.
- 6) declared drug addiction.

Approach to the method:

before starting the use of the systems, we extensively studied the dedicated information materials provided by the company certifying the technical characteristics, illustrating the suggested application protocols. We have also checked the commercial and distribution licenses of the product in Italy on the basis of the documents provided by the company itself.

Investigation criteria:

once the usability of the implant product proposed to us by the manufacturer has been ascertained, we have drawn up a data acquisition card relating to each individual operated patient. This form provides for the registration of patient details, operated site and implant coordinates, ISQ for insertion and prosthetics, integration time and primary stability scoring and integration coefficient reached at the end of the established period. We have compiled a format for each implant inserted, in order to have an indication, even if provisional, precise and meeting the real criteria. The data were recorded in order of chronological execution of the implant placement intervention.

Informed consent:

we have developed a format for accepting the informed consent that provides for the provision to the patient of all the information necessary to fully understand the ways in which the rehabilitation would have been carried out, the possible complications related to the insertion of the fixture, the packaging of the prosthetic restoration and how to carry out the follow up. We did not find it necessary to advise patients of the performance of this retrospective study.

Pre-operative diagnostics.

1→Analog method: collection of the patient's requests and expectations // remote and proximate physiological anamnesis to identify potential exclusion criteria // objective intra-oral examination with execution of plaster models of the dental arches // cbct radiological examination of the region to be implanted.

2→ Digital method: collection of patient requests and expectations // remote and proximate physiological anamnesis to identify potential exclusion criteria // intra-oral physical examination // intra-oral scans and digital survey of the inter-arch occlusion // cbct radiological examination of the region to be implanted.

Rehabilitation project

1 → Analog method: evaluation of the implant position on softwares for visualization of cbct exams.

2 → Digital method: prosthetic project on cad software and matching of prosthetic rendering with radiological and intra-oral soft tissue rendering. Evaluation of the architectural

congruence of the prosthetic and periodontal implant.

Implant insertion:

the accepted and used methods for implant insertion are the classic ones. They include:

- a.** Implant insertion in edentulous site // post-extraction implant insertion
- b.** Deferred implant load with deferral times chosen by the clinician in relation to the bone site and bone density found during the packaging of the implant osteotomy site // immediate implant loading at the discretion of the clinician and according to the dictates imposed by international protocols on the subject of ISQ values found at the time of insertion of the fixture. (In this first operational step, no implants loaded immediately after insertion were inserted. The decision comes anyway
- c.** Flapless insertion of the implant fixture // opening of the site by making an appropriate muco- periosteal flap at full thickness
- d.** The creation of the implant insertion site took place in any case using the operating method prescribed by the manufacturer with the steps of the set of drills prescribed and present in the surgical kits provided.
- e.** Once the implant has been inserted in the intended location, the torque and isq values recorded have been recorded. In addition, a radiographic check of the position reached was performed and, in cases considered particular by the clinical performer, intraoperative photos

Period of integration:

variable between three and six months at the discretion of the clinical operator, they are used to integrate the implant into the receiving site. During this interval the patient performed periodic check-up on a monthly basis, checks in which only a local physical examination was performed in order to intercept any problems related to the healing of the surgical wound, to the formation of potentially dangerous infectious pockets for the good integration of the plant itself. During this period, the patient wore a mobile or fixed provisional depending on the need and condition at the entrance. The patient was also subjected to professional control of oral hygiene and plaque retention in order to ensure the most suitable environment for soft tissue healing and implant integration.

Restoration:

the implants were prosthetically loaded at the end of the integration period established a

priori based on the discretion of the clinical operator. The method of prosthetic construction varied according to whether it was analogical or digital strategies and according to the prosthetic connection chosen and the type of prosthetic restoration. In some cases, fixed temporary prosthetic restorations were made. the prosthetic phase began after performing a radiographic check and measuring the implant's ISQ value.

a. Analog method → supra-implant gingivectomy // insertion of healing abutments // impression taking with transfer for open or closed tray // assembly of laboratory model with implant analogues // choice of the most suitable abutment for the case // modelling prosthetic restoration usually cemented or screwed in monolithic ceramic material.

b. Digital method → gingivectomy and insertion of healing abutments // mounting of dedicated scan-body and impression taking with intra-oral scanner. // prosthetic project revision // prosthetic connection and metal free aesthetic anatomy milling.

Follow-up:

patients are monitored every 15 days for the first two months. Then begins a monitoring program at intervals of 3/4 months depending on the clinician's requests.

ASSAYS OF IMPLANTS INTEGRATION



Patient #ITMB2021020



Patient #ITTP2021025

3. Results

Overview:

We report a general summary table of the data collected with an explanatory table [TAB 1 and 1A]. We report the subdivisions by age and sex of the patients treated [TAB 2].

Packaging:

implant packaging has never caused problems during surgery. The grip of the implant after opening the packaging is safe and stable.

Osteotomy:

the creation of the implant site has never given problems. The burs are able to work well without flicker in any bone density.

Implant insertion:

in cases of insertion through very thick and dense cortical bone layers, the tendency of the implant neck to seize in the final stages of deepening in the created site was noted. For this reason, it would be desirable to design a drill dedicated to finishing the intra-cortical section of the hole created. This phenomenon was repeated in two cases of insertion into the mandible in the posterior sectors, precisely in regions 46 and 47.

Surgical kit:

simple in the layout, intuitive, it contains everything necessary for the packaging of the implant site, the insertion of the implant and for the subsequent prosthetic phases.

Performance:

we report the results of primary stability recorded after insertion by evaluating the torque value used for insertion, and of integration evaluated based on the

measurement of the ISQ value at the time of assembly of the prosthesis [TAB 3]

Failures:

We have a documented case of failure. In the first, placement of the implant in the post-extraction 45 seat of the tooth root with evident apical rarefaction of 10mm in diameter. The extraction was followed by a deep grooming of the rarefaction area which was followed by the insertion of the implant as per the summary table. Another implant was placed in 46. The control after 4 months of waiting revealed painless and stable fibro-integration of the implant 45 and perfect integration of the implant 46.

Digital prosthetic procedures:

The digital method did not show any problems of any kind. The production mathematics of the components are well distributed on the national territory and easily supplied by the manufacturing company in case they are requested. We have designed and produced custom abutments that are well coupled with the corresponding implant without experiencing unscrewing or engagement problems.

Analog prosthetic procedures:

the analogical components supplied did not show any malfunctions. The way of fixing the transfers to the implant and to the implant replica is very practical. The prosthetic abutments show a firm and precise engagement. We did not register any unscrewing, once screwed with the torque value prescribed by the manufacturer.

Table 1 - Monitoring of dental implants

Operator	Patient	Sex	Age	Code	Lot number	IMPL sizes	IMPL site	Ccontrol	T=0 ISQ	T=end ISQ	Success score	TOT Implants
IT-01-BL	DR. A.	FEM	75	ITMB2021 001A	30467	4.2 x 10	44	90DYS	54	60	PS.3-I.2	1
				ITMB2021 001B	30468	4.2 x 11.5	45	90DYS	73	79	PS.3-I.3	1
IT-02-MR	F.R.	FEM	76	IT01A2021 002	31552	3.75 x 11.5	13	90DYS	70	73	PS.3-I.3	1
IT-03-BL	DS. L.	MAL	50	IT01A2021 003	30839	4.2 x 11.5	45	90DYS	57	62	PS.3-I.3	1
IT-01-BL	B.S.	FEM	49	ITMB2021 004	30351	3.3 x 11.5	22	90DYS	433	67	PS.3-I.3	1
IT-01-BL	B.M.	MAL	55	ITMB2021 005	29599	3.5 x 13	25	90DYS	65	68	PS.3-I.3	1
IT-02-MR	C.D.	MAL	60	ITMB2021 006A	31552	3.75 x 11.5	36	90DYS	60	71	PS.3-I.3	1

				ITMB2021 006B	31393	4.2 x 10	37	90DYS	37	37	PS1-I.1	1
IT-01-BL	C.V.	MAL	55	ITTP20210 07	30489	5.0 x 10	47	90DYS	55	65	PS3-I.3	1
IT-03-BL	DS.A.	MAL	65	ITMB2021 008A	30468	4.2 x 11.5	43	90DYS	58	63	PS3-I.2	1
				ITMB2021 008B	29985	6.0 x 6.0	45	90DYS	58	64	PS3-I.2	1
				ITMB2021 008C	30489	5.0 x 10	46	90DYS	57	64	PS3-I.2	1
IT-01-BL	T.D.	MAL	57	ITMB2021 009A	30842	5.0 x 11.5	16	90DYS	72	73	PS3-I.3	1
				ITMB2021 009B	29745	5.0 x 8	46	90DYS	75	86	PS3-I.3	1
IT-03-BL	G.F.	MAL	65	ITMB2021 010A	29985	6.0 x 6.0	27	90DYS	58	70	PS3-I.3	1
				ITMB2021 011B	30489	5.0 x 10.0	36	90DYS	83	85	PS3-I.3	1
				ITMB2021 011C	30489	5.0 x 10.0	37	90DYS	57	80	PS3-I.3	1
IT-03-BL	P.C.	FEM	52	ITMB2021 012	31393	4.2 x 10	35	90DYS	58	82	PS.3-I.3	1
IT-03-BL	Z.D.	FEM	47	ITMB2021 013	29985	6.0 x 6.0	27	-	19	-	FAILED	1
IT-03-BL	DM.L.	FEM	46	ITMB2021 014	30465	3.75 x 10	47	90DYS	57	64	PS.3-I.2	1
IT-03-BL	T.A.	FEM	35	ITMB2021 015	31099	3.75 x 10	35	90DYS	58	76	PS.3-I.3	1
IT-03-BL	T.G.	FEM	70	ITMB2021 016A	31099	3.75 x 10	15	180DYS	57	-	PS.3	1
				ITMB2021 016B	30490	4.2 x 8.0	16	180DYS	56	-	PS.3	1
				ITMB2021 016C	30842	5.0 x 10.5	17	180DYS	56	-	PS.3	1
				ITMB2021 016D	30468	4.2 x 11.5	45	180DYS	56	-	PS.3	1
				ITMB2021 016E	30842	5.0 x 11.5	47	180DYS	56	-	PS.3	1
IT-03-BL	R.S.	FEM	44	ITMB2021 017	30351	3.3 x 11.5	24	90DYS	40	63	PS.2-I.2	1
IT-02-MR	G.D.	FEM	68	ITMB2021 018	30351	3.3 x 11.5	68	90DYS	70	74	PS.3-I.3	1
IT-03-BL	N.G.	MAL	68	ITMB2021 018A	3486	3.75 x 13	12	120DYS	73	-	PS.3	1
				ITMB2021 018B	31552	3.75 x 11.5	14	120DYS	77	-	PS.3	1
				ITMB2021 018C	30839	4.2 x 11.5	16	120DYS	70	-	PS.3	1
				ITMB2021 018D	30466	3.75 x 13	32	90DYS	81	-	PS.3	1
				ITMB2021 018E	30466	3.75 x 13	34	90DYS	57	-	PS.3	1
				ITMB2021 018F	30842	5.0 x 11.5	36	90DYS	57	-	PS.3	1
IT-03-BL	M.P.	MAL	60	ITMB2021 019	30352	4.2 x 13	21	180DYS	58	-	PS.3	1
IT-01-BL	B.B	FEM	55	ITMB2021 020	29745	5.0 x 8.0	37	90DYS	70	75	PS.3-I.3	1

Operator	Patient	Sex	Age	Code	Lot number	IMPL sizes	IMPL site	Ccontrol	T=0 ISQ	T=end ISQ	Success score	TOT Implants
IT-01-BL	K.A	FEM	41	ITMB2021021	29599	3.3 x 13	21	90DYS	63	69	PS.3-I.3	1
IT-03-BL	T.C	FEM	47	ITMB2021022A	30466	3.75 X 13	15	120DYS	70	75	PS.3-I.3	1
				ITMB2021022B	30352	4.2 X 13	46	180DYS	80		PS.3	1
				ITMB2021022C	30468	4.2 X 11.5	47	180DYS	80		PS.3	1
IT-02-MR	C.B	MAL	57	ITMB2022023A	31552	3.75 X 11.5	12	120DYS	50	-	PS3	1
				ITMB2021023B	31099	3.75 X 10	14	120DYS	45	-	PS.2	1
IT-03-BL	C.D.	MAL	64	ITMB2021024A	30466	3.75 X 13	32	180DYS	53	55	PS.3-I.3	1
				ITMB2021024B	30466	3.75 X 13	34	180DYS	70	70	PS.3-I.3	1
				ITMB2021024C	30466	3.75 X 13	42	180DYS	69	69	PS.3-I.3	1
				ITMB2021024D	30466	3.75 X 13	44	180DYS	79	74	PS.3-I.3	1
IT-01-BL	DV.S.	FEM	70	ITTP2021025A	31099	3.75 X 10	44	120DYS	60	64	PS.3-I.2	1
				ITTP2021025B	30467	4.2 X 10	45	120DYS	65	67	PS.3-I.3	1
				ITTP2021025C	31393	4.2 X 10	46	120DYS	64	68	PS.3-I.2	1
				ITTP2021025D	29745	5.0 X 8.0	47	120DYS	68	68	PS.3-I.3	1
				ITTP2021025E	31552	3.75 X 11.5	43	120DYS	60	65	PS.3-I.3	1
IT-01-BL	M.M	MAL	27	ITTP2021026	31393	4.2 X 10	46	120DYS	60	65	PS.3-I.3	1
IT-01-BL	A.M.	FEM	42	ITTP2021027	29599	3.3 X 13	42	90DYS	86	90	PS.3-I.3	1

Table 2- An explanation of the acronyms of Table 1

1. Operator
 - a. IT-01-BL → DR Luca Barbera Md Dmd -Milan Italy
 - b. IT-02-MR → DR Riccardo Mauri Dmd -Milan Italy
 - c. IT-03-BL → DR Lorenzo Bontempelli Dmd -Milan Italy
2. Patient
 - a. Indicated as Surname /Name first identificative letter
3. Sex
 - a. FEM → female
 - b. MAL → male
4. Code
 - a. ITMB2021001A → identifies country where surgery was performed
 - b. ITMB2021002A → region where surgery was performed MB → Milan Metropolitan area TP → trapani- Sicily- Metropolitan Area.
 - c. ITMB2021003A → year of surgery
 - d. ITTP2021004A → Progressive number
 - e. ITMB2021005B → Identification letter in case of multiple implants on same patient
5. Implant site

- a. European dental formula is used to indicate dental implant site
- 6. Control
 - a. Indicated how many days passed between implant positioning and restoration insertion
- 7. T=0 ISQ
 - a. ISQ value registered at time of implant insertion
- 8. T=END ISQ
 - a. ISQ value registered at time of restoration inserted
 - b. An omitted t=end Isq value indicates a not yet finished case
- 9. Success score
 - a. **PS.3-I.3** → indicates Primary Stability Evaluation value in term of insertion torque
 - i. **PS.1** → insertion torque less than 25
 - ii. **PS.2** → insertion torque between 26 and 45
 - iii. **PS.3** → insertion torque over 45
 - b. **PS.3-I.2** → indicates a value of integration based on final ISQ value
 - i. **I.1** → Isq < 40
 - ii. **I.2** → Isq >40 <65
 - iii. **I.3** → Isq >65
 - iv. An omitted I Value indicates a not yet finished case

Table 3 - Implants placed additional info

Number of implants placed	Number of patients	Males	Females	Average age	Single implantation	Multiple implantation
54	28	13	15	53	17	11

Table 4- primary stability and integration

Prime stability 3	Prime stb < 3	Integration 3	Integration < 3
50 OF 54	3 OF 54	28 OF 37	9 OF 37

4. Discussion

Results:

the results obtained did not show particular differences with respect to the implant methods used during the career of the three clinicians enrolled in this study. Given the current numbers, although they are only partial as they represent 25% of the total sample of implants to be inserted, the percentage of failures is around 2% of the total number of cases treated. The data on primary stability and integration obtained from the torque value at the time of insertion and ISQ at the end of the integration were judged satisfactory.

By completing the work on the remaining implants, we will reserve the right to compare the definitive data with those of the international literature.

Surgical technique:

it is of the conventional type, based on the packaging of the alveolar seat with drills of increasing diameter and length. this did not show peculiarities to such an extent as to make it seem scrupulous or not very usable in non-expert hands. The undersigned, deliberately, approached the first surgery without having consulted the operating manual, looking at the surgical kit during the operating session. The first sensation was that of simplicity both in the organization of the kit and in the execution of the surgical osteotomy. The cutters included in the kit have a good cutting efficiency. Very comfortable and reassuring for novice surgeons to have the drills equipped with vertical stops for the different depths provided. This, in practice, also represents a fact of speeding up the surgical work, compared to the techniques in which the drills are equipped

with adapter rings calibrated to different lengths.

Prosthetic techniques:

the analogue method with systems for recording and transporting information on the intra-osseous position of the implant, is the traditional one commonly used by manufacturers; transfer for open or closed technique and implant replication for the laboratory. The transfer system that can be inserted both in the implant and in the Replica, without fixing screw, seemed very useful and usable, providing for stabilization through a non-rotating retention pin. This detail greatly facilitates the positioning of the transfer in situations and positions of the fixture that are not easy to reach. The digital technique was found to be usable and replicable, ensuring positional precision to the prosthetic products. We took the systematics to a digital laboratory to which this systematics was unknown. The collaboration with the manufacturer was quick and easy as regards the supply of parts and digital information necessary for the completion of the design work. We also considered this an important plus. In fact, any Dental Laboratory will be able to perform operations on these impulses with extreme ease and without hitches. The Manufacturer also supplies the so-called Digital Implant Replicas, a detail that allows the laboratory to create physical replicas of the clinical case starting from digital information, a very useful procedure in the case of extensive implant rehabilitation.

5. Conclusion

This first approach to the multicenter retrospective study, object of the current program, was judged absolutely positive in all aspects considered. Simplicity, predictability and accuracy of results are certainly important aspects to judge a modern and usable implant system. The sensations recorded in the operating room make us think of a system suitable for both an expert user and a novice. Certainly, the panorama of Manufacturers now seems to be aimed, in addition to the production and marketing of an implant system, at the provision of a service where the implant product is customized on the individual user and patient, providing digital devices together with the implant and components. for positioning and prosthetics of the inserted fixture.