ABSTRACT

Scientific Research for Better Results

Years 1995 - 2016

Follow up at 10 Years

Winsix® Implant System

Follow up at 5 Years

Just on 4® Technique
The research activity conducted by BIOSAFIN has always been based on a severe application in the three fields of scientific evidence:

- **In vitro tests**: serve the basic studies of the materials and of new technologies, by means of well described experimental models in cell cultures or direct analysis of the materials (e.g. SEM, molecular analysis, others...);

- **In vivo tests on animal models**: serve the initial clinical applications of new medical devices, by simulating the patient’s oral microenvironment. Animal models with biological characteristics as close as possible to those of humans are used, both anatomically and genetically;

- **Clinical evidences**: clinical application of experimental procedures on a growing number of patients, according to the *clinical trials* criteria, in order to obtain reliable and *evidence based* results.

Throughout the 20 years of research on WINSIX® Implant System, covering all its aspects and applications, all the variables have been implemented, in particular:

- numerous in vitro studies have been conducted using the scanning electron microscope (SEM) to study the implants surfaces and the bone tissue cells in contact with them. Molecular biology studies have followed;

- publication of studies and researches on peer-reviewed and impact factor reviews, and in reviews widespread in dental offices;

- studies and researches are showed and discussed in scientific congresses and poster sessions.

The evolutive path followed by WINSIX® System, that can be read in the over 300 publications, is a substantial contribution to the scientific-technological progress of oral implantology.
WINSIX® PILOT CENTER

WINSIX® PILOT CENTER is based in San Raffaele Dental Clinic of Milan; here the many Research and Development activities of the implant devices take place.

The Dentistry Department at San Raffaele Hospital in Milan is one of the most important Dentistry Centers in Italy for its workflow and scientific basis. WINSIX® Implant System has been in collaboration with the Center for many years, during which, many new devices and innovative surgical techniques have been developed, in coherence with the scientific concept of Translational Research.

The most recent innovations of WINSIX®, highly appreciated from clinicians all around the world, were born from the effective and synergic collaboration among researchers, clinicians and industry, their experiences and exchange of ideas.

Professionals with a high standard of experience and scientific standing contribute to the activities of WINSIX® PILOT CENTER, being point of reference for different clinical environments, be it private offices or hospitals.

ACRIS - Cultural Association of Dental Implant Research San Raffaele - was founded in 2011 to give shape and new perspectives to what de facto has been existing for years: a Scientific Team with renowned experience and skills widely appreciated by the dental world on a national and international level.

ACRIS is a no-profit association born to give concrete answers to the continuous requests of cooperation coming from different subjects to the University Vita-Salute San Raffaele and to the Dentistry Operating Unit at San Raffaele Hospital, both located in Milan. This means to be able to offer real support to the industry to develop research projects and to the dental profession with continuing education programs on the most actual topics. 

Info on activities: www.acrisr.org

Prof. Enrico Gherlone is specialised in Odontostomatologia and is Chair Professor in Dental Disease at the University Vita-Salute San Raffaele in Milan. He is highly involved in several fields, such as Educational, Editorial and political-professional. In any of this field he puts a lot of positive efforts, dedication and energy for the development of Dentistry, according to present times.

AN INTERNATIONAL REFERENCE CENTER

Italian dentistry is reckoned by the international scientific community as a reference point in terms of scientific progress, clinical practice and solutions that may conjugate functionality and aesthetics. WINSIX® PILOT CENTER welcomes and trains users of the implant system coming from foreign Countries. In a highly qualified and of maximum availability context, they have the opportunity to enrich their cultural background, in a fast and efficient way.
FOLLOW UP AT 10 YEARS
WINSIX® IMPLANT SYSTEM

10 YEARS RETROSPECTIVE ANALYSIS OF THE RESULTS OF IMPLANT-PROSTHESIS TREATMENTS CARRIED OUT WITH WINSIX® IMPLANT SYSTEM.
DECEMBER 2005 DECEMBER 2015.

Authors: Dentistry Operative Unit – University Vita-Salute San Raffaele of Milan, Dir. Prof Enrico Gherlone

Materials & Methods. 3,651 implants positioned in 1,696 patients were evaluated, between December 2005 and December 2015 at Dentistry Complex Operating Units of I.R.C.C.S. San Raffaele Hospital in Milan. Out of these implants, 3,027 were placed in 1,587 patients that regularly attend the maintenance care program at the Oral and Prevention Hygiene Centre at the Dentistry U.O.C. (Graph 1).

The remaining patients did not subscribe the maintenance care program. In patients undergoing the maintenance program it was possible to collect, for each implant, the clinical parameters needed to evaluate the health status of the implant site: probing pocket depths (PPD), bleeding on probing (BoP), x-ray evidence of peri-implant bone resorption and mobility.

Data analysis. Out of 3,651 implants, 1,97% failed, equal to 72 units placed in 69 patients, showing a failure incidence rate in line with the results reported in the literature. (Graph 2).

It was observed that among the 72 failed implants, 19 were placed in smoking patients and 39 in patients already suffering from periodontitis. Limiting the analysis to the patients undergoing the follow-up program, the failure incidence decreases to 1.28%, equal to 39 implants. Among the same patients, 84.2% shows a PPD average data <4mm (10,195 probing sites out of 12,018 in total), obtained by 4 sites for each implant (Graph 3), finally, the average data of O’Leary plaque index (PI) and of bleeding on probing (BoP) in patients under maintenance care were analysed and, in those subjects who faced implant loss, both parameters were definitely higher than that observed in the patients whose peri-implant tissues show healthy conditions. In particular, PI average data in patients whose peri-implant tissues show healthy conditions is 17.2% and BoP is 5.7%. In patients who faced implant failure, the average data are 48.4% and 63.8% respectively (Graph 4).

Conclusions. In search of long term success in implant-supported prosthetic rehabilitations, a maintenance care program adjusted to the patient’s needs and characteristics proves to be an essential factor: it is a useful tool for preventing periodontitis and for precociously intercepting the beginning of inflammatory processes in peri-implant tissues and/ or mechanical problems of the implant-prosthetic system. The reduction of the failure rate observed in patients undergoing the above follow-up program can be considered an element probing the efficacy of such a clinical attitude, even without investigating on the microbiological phenomena that have led to these results.

Graph 1
- Implant in follow up program
- Drop-out

Graph 2
- Successfully survived implants
- Failed implants

Graph 3
- PPD<4 mm
- PPD>4 mm

Graph 4
- PLaque AND BLEEDING INDEX OF PERI-IMPLANT TISSUE CONNECTED TO IMPLANT SUCCESS OR FAILURE
- PI
- BoP
The technique Just on 4®/6® (JO4/6) allows the rehabilitation of the fully edentulous arch with immediate implant-supported full-arch solution, in those patients affected by serious jaws atrophy. The approach is such to guarantee the minimum invasiveness combined to a satisfactory aesthetic result of the screw-retained prosthesis, moreover also the patients’ biological and economic costs are dramatically reduced. The possibility to use the CAB® support bar in the construction of the prosthesis, building it inside the prosthetic device allows the achievement of excellent performances in terms of structure resistance of the prosthesis under the chewing load. The synergic use of JO4/6 and CAB® has so far allowed to achieve extraordinary clinical results, in terms of percentage of success/survival of the implants and prosthesis, encountering Patient’s satisfaction, which in just one treatment session, can be rehabilitated positioning the temporary prosthesis. From December 2010 to December 2015, the systematic use of this technique at the UOC of Dentistry and Oral Surgery of the I.R.C.C.S. in San Raffaele Hospital, allowed to rehabilitate 191 edentulous arches (148 with JO4 and 43 with JO6 for a total of 850 implants) in 159 patients (men 80, women 79), average age of 61 years, 32 of those patients have undergone a rehabilitation of both arches. All rehabilitated patients with the technique JO4/6 have been included in a follow up program of professional hygiene which is based on attending sessions of preventive care every four months, moreover prostheses are dismantled once a year to allow a more professional intervention to peri-implant tissues. The repositioning of new implants can be rehabilitated according to the “all on four” immediate function protocol, according to the professional oral hygiene, the use of air polishing used for the over gum and the peri-implant furrows and the plastic ultrasound scalers whose efficacy has been demonstrated in the total respect of implant-prosthesis materials.

**CONSIDERATIONS**

From the analysis of the data extracted from the clinical records of patients undergone to the rehabilitation with the technique JO4/6, it was possible to establish that the systematic has produced a survival rate of the implants equal to 98.47% (failure 1.53% equal to 13 units). Failure cases have all occurred at an early stage, mostly likely due to the lack of osseointegration, to whom the repositioning of new implants have followed; implants have then achieved all their functionalities. Overall the 191 prosthetic arches, 41 have not been internally reinforced by means of the CAB® bar. Of those, 6 provisional prostheses broke down and were repaired at a later stage. None of the arches armsed by means of the CAB® bar has suffered of fracture. Considering all the data, a prosthetic success of 100% can be stated in those cases performed by means of the CAB® (150 arches) and 85.4% for the screw-retained prosthesis without the bar, in any case, their survival rate is still of 100%. Considering the professional maintenance of patients undergone the rehabilitation JO4/6, none of the implant has been affected by peri-implantitis. Therefore, it is important to highlight the importance of the right prosthetic design which makes easy the domestic cleansing of the prosthetic surface overlooking the osteo-mucosa as well as the most advanced technologies applied to the professional oral hygiene, the use of air polishing used for the over gum and the peri-implant furrows and the plastic ultrasound scalers whose efficacy has been demonstrat-
BioSAF IN is a certified Company:

UNI EN ISO 9001: 2008 which certifies the whole work process at 360° in accordance with quality standards considered optimal to safeguard the User of the product – the Professional Dentist and the final user – the Patient.

UNI CEI EN ISO 13485: 2012 relates specifically to the Quality of the Medical Devices.