CLINICAL DOCUMENT

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Clinical evidence

11 years of clinical application of VITANE implants (1989-2000), in hospitals and in private offices.

Outline:

ABSTRACT

The Vitane screwed implant (which is part of a wide implant system) is a cylindrical – conical implant threaded in commercially pure Titanium. It has been regularly used since 1989, until today, first in university-hospital (CHRU of Lille) and then in private clinical offices (implant Clinic of Rouen), then commercially used since 1991, in mixed places by more than 110 clinical implant practitioners in France and Europe.

An ergonomic and potable surgery set, easily sterilized, allows an easy and aseptic implant placement.

More than 4 500 implants have been placed on a mixed population of patients without one, several, or no teeth at all, which allowed a satisfying prosthetic rehabilitation. A statistic study done in 1997 on one part of the implants (2 517) placed by one practitioner showed the following results:

The majority of patients candidates for the implantology, are women (about 75 %). But in the presented study, 62 % of the patients have an average age of 56.5 years, and a good general health condition.
The average number of placed implants is 3.55 per patient. The rate of general success is 94.7 % between 1990 and 1993 for 107 patients who had surgery. The rate is 98.8% from 1993 to this day for 603 patients. The evaluation of the success rate has been done according to subjective criteria established by the designer of the system (see the following results).

Numerous modifications and improvements have been done from the surgery and prosthetic point of view. These improvements affect the surgery instruments and the prosthetic accessories.

The screwed Titanium implant turned out to be a clinically reliable implant, adapted for a big number of cases of partial or total edentation, with or without a prior bone reconstitution, meeting all the scientific and clinical contemporary criteria. Its configuration and its dimensional diversity (diameter: 2.6mm, 3.6mm, 4.3mm and 4.6mm) have been particularly interesting, since it is the only system which can be used in a predictable way in bones with low thickness or where the needed mechanical stress is minimum (ex: upper lateral incisors and all the lower incisors).

Review

The Vitane implant is born of the collaboration between a manufacturer of orthopedic material SOFAMOR and the head of the oral implantology and maxillo-facial department of LILLE II University: the professor CHANAVAZ. The project took shape in the years 1986 to 1989.
The project was finished in 1989, in the same year, the first Vitane implants were placed. During the project, the system was submitted to several tests and evaluations:

- Mechanical, static and dynamic tests on a series of implants with their SERCOVAM prosthetics (1)
- Study of the biocompatibility of the commercially pure micro blasted titanium (2)
- Animal experimentation on Beagle race dogs at the research institute of Calot (3)

PRESENTATION OF THE VITANE SYSTEM

The Vitane system is an instrumentation designed for oral and maxillo-facial surgery.
It is equipped with screwed cylindrical implants, with 4 possible diameters (∅ 2.6, ∅ 3.6, ∅4.3, ∅4.6) and there are 6 lengths for each diameter (8 to 18 mm every 2 mm).
An original surgery set and a prosthetic set are delivered with these implants.

The implants are delivered sterile in triple packaging, according to the requirements of the current community legislation.
The Vitane screwed implant is a threaded cylindrical implant in commercially pure titanium. This metal meets the requirements of the norm ISO 5832-2 shade 1 or according to the American norm ASTM F67 grade 4. These 2 norms are equivalent.

In its permucosa part or prosthetic neck, it is cylidro-conical, with a polished cervical and cylindrical part. In its apical segment, the threaded faces are slashed by longitudinal grooves. At the height of the beginning of these grooves, a diametric transversal hole covers the diameter in both sides of the implant. The apex of the implant is hemispheric.

The surgery set is made three instrument groups:

The preparation instruments of the bone wells (6 pilot drills for the profound drilling of the well, 10 borers to enlarge the hole diameter, 4 drills for the preparation of the cylindro-conic entering hole and 8 screw taps).
Instruments for the geometry control of bone wells and instruments (6 parallelism gauges, 4 profile gauges for the cylindro-conic hole and a small plaque for the verification of the lengths of each pilot drill).

The instruments for the placement of implants, some of them are manual and some of them are to be put on a contra-angle (screwdriver, turn- implant and several extensions: manuals and for motors of different lengths).

All the instruments of the box are put on a tray, and fixed on it with elements like cups or silicon strips.
This fixation allows the possibility of transport and manipulations of the box or of the tray in the surgical unit.
The configuration of the box allows three methods of sterilization available in hospitals:

1 - Steam sterilization
2- Ethylene oxide gas sterilization
3- Dry sterilization

The prosthetic kit has been created to meet all the contemporary requirements: functional, aesthetic of implant-supported prosthetic rehabilitations, fixed, trans-screwed, sealed, and clipsed (barre, O Ring etc).

The prosthetic kit is made of elements for impression taking and of prosthetic pieces. In the impression taking system, we find a trans-screwed system and a system to be screwed directly in the implant. 4 implant analogues make the work possible outside the mouth (plaster model).

The prosthetic systems are the followings:

The right screwed post-implants (2 heights)
The right post trans-screwed and leaned at 10°, 17°and 25° (2 heights)
The telescopic system (2 heights)
The calcinable trans-screwed system (2 heights)
Finally the O Ring based system (2 heights)

Placing tools are provided with these pieces (screwdriver and turn-post)

OPERATIVE TECHNIQUE

The technique is similar to the majority of the systems in the market.

But there are 6 particularities, which distinguish this technique from the others:

1 The presence of threadings on the implant confers to the implant the characteristics of self-tapping systems at the level of the maxillar in general and with patients with a low bone density. For this reason, the threading phase has not been systematically realized. Moreover, the hemispheric shape of the implant apex greatly facilitates the insertion of implants in patients.

2 The hemispheric shape of the implant allows us to place the implant more profoundly in the maxillar sub-sinusal osteotomy trench by lifting the sinusal floor in a non-traumatic way, as long as the antral mucosa has not been perforated. The voluntary penetration of 1 to 3 mm in the antral space is done by simple energetic manual screwing which causes a little breaking of the bone floor without tearing the mucosa.

The remade floor repairs itself adequately after 4 to 5 weeks, which makes it possible to win some bone thickness. The same behaviour is seen during the placement of implants at the level of the distal segment of the atrophied mandible where the insufficient thickness of the bone leaves the inferior alveolar nerve exposed to the manoeuvres of drilling and tapping

In both cases, the system allows the meticulous preparation of the osteotomy trench with the indicated drilling instruments for implants with a length immediately inferior within the respect of the integrity of fragile anatomy zones. A final implant with a length immediately superior is inserted in the trench and screwed till the end. Then, it is progressively screwed in meticulously and firmly beyond the limit of preparation until the ideal position.

3- The cylindrical -conic shape of the “ prosthetic neck ”is particularly favourable to the getting of a primary increased stability of the implant if the osteotomy turns out to be non homogenous or if the quality of the bone is not “cortical” enough. The crestal compression caused by the conic part provides this stability. In fact, it is thanks to this conicity that these Vitane implants with diameters going from 4.3 mm to 4.6 mm have been used successfully in cases of immediate implantation after the extraction of damaged roots.

4 -1 the Vitane implant of 2.6 mm diameter, shows, as predicted, its application limits. But, when this same implant, is placed as a replacement of lateral incisors of the maxillar or of the four mandibular incisors, it is reliable and of great help. Its small diameter is perfectly compatible with the functional and aesthetic considerations of these sectors.

4-2 the implant 2.6 mm is a relay implant of great usefulness in multi-implanted patients, with whom the placement of one or two supplementary implants in low bone volume zones promotes long term success of these prosthesis. This particularity is not found in other systems.

4-3 Finally, in the making of epitheses or maxillofacial prosthesis in patients with low periphery bone thickness after an initial therapeutic resection, implants of 2.6 mm and from 8 mm to 10 mm of diameter have been very useful. In fact, the performance limits of these small implants are not exceeded by the stress required by maxillo-facial prosthesis.

PROSTHETIC TECHNIQUES

The prosthetic realization on Vitane implants demands components and common characteristics with other systems. But, there is one interesting particularity:

The transfixed transfer of impressions adapted to four implants diameters is manufactured in titanium TA6V. This arrangement ensures not only the initial impression taking and its pouring, but also it can be cut and drilled in order to be used as a definitive transfixed final stump.

This is an advantage of great importance in order to eliminate the complications linked to the absence of parallelism, which does not exceed 15° between several implants in the same sector.

Within the framework of the prosthetic rehabilitation of Vitane implants, all the conceptions have been envisaged successfully. From the realization of implant-supported overdentures in totally edentulous patients to the realization of complete bridges sealed or trans-screwed, the prosthetic components have proved their functionality and reliability.

Moreover, the dismantling of broken stumps shows the same technical aspects than for other systems without compromising the sustainability of implants as such.

CLINICAL APPLICATIONS (1990-2000)

The first Vitane implants have been placed as soon as June 1990, simultaneously in the Maxillofacial surgery unit of LILLE hospital (CHRU) and in the Implant Clinic of Rouen. Many other practitioners have also used the Vitane system as soon as 1991.

The general clinical use has been accelerated as soon as March 1991. In October 1993, about 110 French and foreign practitioners were regularly using the system.

An independent study done by a practitioner within his activity in a hospital and in his private office made possible the counting of several data. (4)

Moreover, a study of 2517 placed implants, have counted the following data:

Repartition according to criteria:

Number of treated cases: 710 patients

Number of placed implants: 2517 implants

Sex:

Women in menopause 36 %

Women with no menopause 26 %

Men 38 %

Age:

Women 49 years old spread from 31 to 79
Men 58 years old spread from 40 to 82

Health condition:

The reference criteria are based on the classification of the American Society of Anaesthesiology, ASA1, ASA2, ASA3, and ASA4.

The involved patients belong to ASA1 and ASA2:

ASA1: patient with no systemic trouble of general health

ASA2: patient with minor troubles well compensated and responding to the treatment.

The ASA2 class was divided in 2, so that we show 3 criteria named Z (Z1, Z2, Z3):

Z: for health condition
Z1 : patient in perfect health condition (ASA1)
Z2: patients with minor troubles totally compensated by treatment
Z3: patients with minor troubles more or less compensated
No patient with major health troubles, compensated or not, has been implanted.

Operated sectors

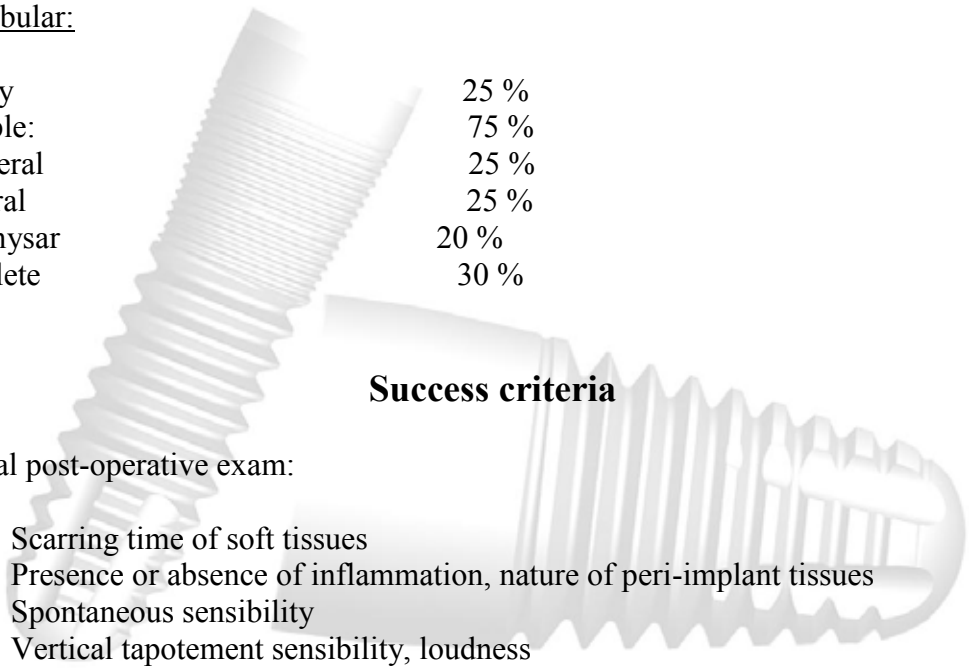
The distribution of surgery cases is the: following:

Maxillar:

Unitary	22%
Multiple:	78 %
Unilateral maxillar	10 %
Bilateral maxillar	50%
Premaxillar	35 %
Complete	5 %

Mandibular:

Unitary	25 %
Multiple:	75 %
Unilateral	25 %
Bilateral	25 %
Symphysar	20 %
Complete	30 %



Success criteria

Clinical post-operative exam:

- Scarring time of soft tissues
- Presence or absence of inflammation, nature of peri-implant tissues
- Spontaneous sensibility
- Vertical tapotement sensibility, loudness
- Lateral movements sensibility, loudness

Radiological exam:

- Rate of periimplant bone resorption
- Presence or not of fibrous tissues

Nature of prosthetic loading

Patients' follow-up

Short term (until 2 months), middle term (2 to 12 months) and long term (more than 12 months).

Success rate

Spontaneous success

Success after minor incidents management

RESULTS AND DISCUSSION

An analysis of (given) results shows a growing rate of success of VITANE implants which can be divided in two periods:

a) 1990-1993 period, we find a general success rate on three years of 94.7%
b) 1990-2000 period, general success rate of 97.1 %
c) Period between 1993 and 2000 with a success rate of 98.8 %

This significant improvement is linked to the technical improvement brought by increasing the periphery thickness of the implant ∅3.6, which was small in its first version and also with the restriction of the use of little implants ∅2.6 in incisors sectors.

Table of general success according to criteria

Success criteria	Rate of general success for 1999 to 2000
1 spontaneous	**97.1 %**
2 after minor incidents management	**98.8 %**

CONCLUSION

The Vitane implant system has all the characteristics of contemporary implant systems in dentistry.
The system shows a big adaptability of dental and unitary rehabilitation, in segments and total, of edentulous patients.
The functional and aesthetic and restorative results have been exceptional and in conformity with the expectations of the designer.
The system is perfectly adapted to the criterion of assumption of responsibility of the European community of edentulous patients and to the health expenses considerations of the community.

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