

New concepts in computer-guided implantology

Part I: Thread timing and implant phase

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Fig. 1a



Fig. 1b



Fig. 1c



Fig. 1d

Fig. 1a_ Components of the bottle-neck device.

Fig. 1b_ Embedded sleeve.

Fig. 1c_ Osteotomic sleeve.

Fig. 1d_ Modified extender to fit the osteotomy sleeve—any hand-free surgical kit will work.

Fig. 1e_ Bottle-neck.

Fig. 1f_ Bottle-neck created.

Fig. 1g_ Bottle-neck created.

Fig. 1h_ Bottle-neck created.

Fig. 1i_ Assembly while being screwed.

_Abstract

In recent years, there has been growing interest in guided implantology. A digital work-up is certainly a great benefit for clinicians to better understand their patients' bone morphology and density and consequently to correctly plan implant positions, and to have their hands guided during implant placement by means of a surgical guide. There are many systems on the market today and many authors have studied post-operative CT scans and planning scans by means of superimposition, in seeking to understand the secret to achieving the perfect correspondence and the best system, but this perfect accuracy has not yet been found and there appears to be a missing link between planning and the actual implant position. I have developed a device (Den-

tal Implant Positioning System, International PCT IT 2009 000192, WO 2010/125593 A1; patent pending) that respects the implant spiral movement when being screwed in accordance with mathematical criteria. The same criteria are also important in theorising limits and achieving accuracy using computer-guided implantology. This article presents two cases that were treated using this device.

_Introduction

Accuracy in guided implantology is an issue. The ability to perform implant placement both safely and correctly, in order to load a pre-surgical CAD/CAM bar or cementable metal final framework prosthesis and to digitise the entire procedure, is widely researched. Accuracy

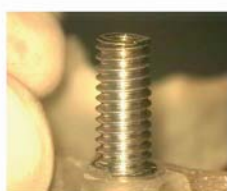


Fig. 1e



Fig. 1f



Fig. 1g



Fig. 1h



Fig. 1i

is a value also in a classical II-stage protocol and respecting hard and soft tissues for long-term implant site stability.

There is an ongoing debate amongst clinicians regarding which is the best available system. Verduyssen summarises this debate.¹ The article reviews only some of the published articles on this topic. All of these articles emphasise the error margins and that they can be considered clinically more or less acceptable, and determine accuracy in implant placement by means of superimposition.

In mathematical terms, "precision" means the repeatability of a measurement, and "accuracy" refers to the correspondence of this measurement to the truth. In our field, accuracy has been considered the correspondence of the placed implant to the planning.

Fortin defines "accuracy" as an ideal, at present somewhat impractical, when considering a definitive prosthesis for immediate loading, with the present systems only offering predictable results (and as such only long-term reinforced provisionals will be available), but does not quantify a threshold.² According to Di Giacomo, at present a post-operative impression appears to be always necessary for immediate loading with a definitive prosthesis.³ Guided implantology is far better than a free-hand approach, however. A guard-rail-like guide is certainly better than nothing.

Many systems are available today, and from a theoretical perspective they have been categorised into semi-active and passive systems. The systems in the first category, whatever the technique used to make the surgical guide (STL or stone surgery), have metal smooth guiding sleeves, which the implant and the implant-driver must pass through, and the second systems, also called navigation systems, do not have any metal sleeves and the surgeon is guided by the monitor. In this category, the surgical handpiece is indexed to spatial markers inside a surgical guide that is inserted into the patient's mouth, but not in the surgical area. These spatial coordinates are viewed by an infra-red system, which transfers data to the computer, allowing the clinician to follow the surgical steps on the monitor. Alarm lights and sounds will warn the clinician of deviations from the desired position.

I propose a new definition of a passive system: a passive system must allow any operators (i.e. it must be operator independent) to achieve the same, repeatable results at an acceptable inaccuracy threshold.⁴ The accepted inaccuracy must allow clinicians to obtain a good metal-to-metal fit without placing tension on the implants. This "to what extent" predictability can determine the reliability of treatment. In fact, in fixed prostheses on natural teeth, passivity (at an acceptable gap) is about 40 to 50 μ in the arch; the same values could be considered acceptable for prostheses on implants. According to this definition, none of the systems on the market has replicable results, and have metal or virtual smooth sleeves. They must thus be considered metal or virtual smooth semi-active systems.

I have developed a new device according to the mathematical concepts of thread timing and implant phase, which can be applied to the implant movement while being screwed, thus allowing clinicians passivity during implant placement. In the future, owing to the predictability of implant placement, the proposed device could be fundamental to achieving the desired goals in computer-guided implantology.

Materials and methods

The implants were placed using the bottle-neck-like device, which begins implant rotation before it can touch the bone, thereby avoiding bone interference with implant movement owing to bone density gradients ("bone guidance"). The prototype of the device (Fig. 1a) consists of:

- an internally threaded sleeve ("embedded sleeve", with a "helical gear" feature at its top that is useful during implant placement; Fig. 1b);



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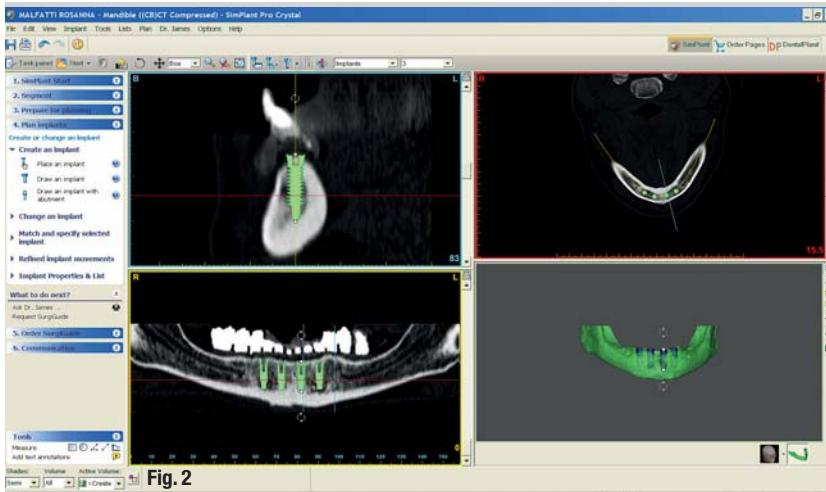


Fig. 2

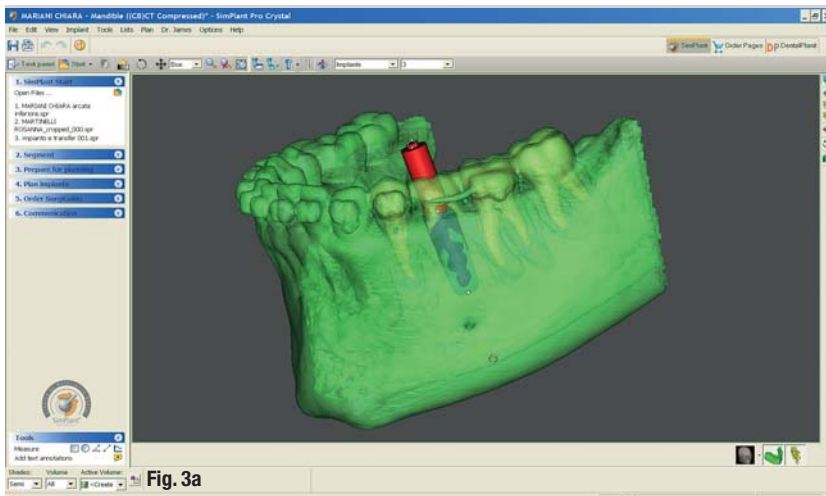


Fig. 3a

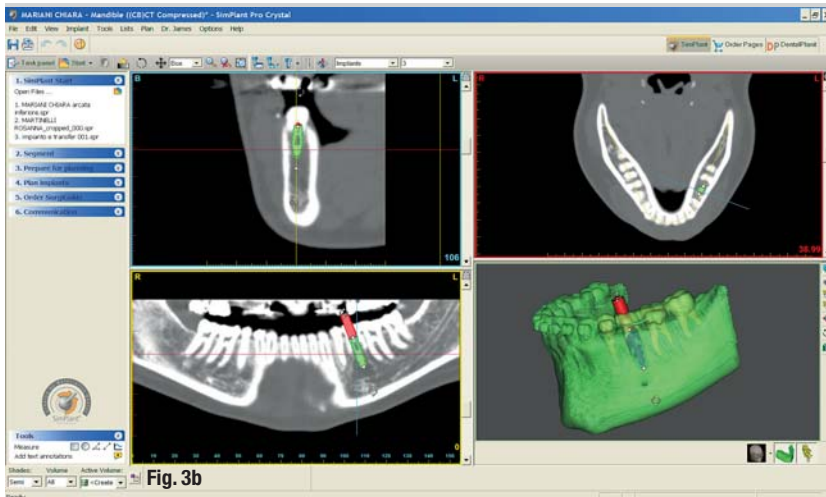


Fig. 3b

Fig. 2 Surgery planning for the STL case.

Fig. 3a Surgery planning for the stone case.

Fig. 3b Surgery planning for the stone case.

- an externally threaded sleeve ("osteotomy sleeve"), which has to be inserted into the embedded sleeve and serves as a regular sleeve for the osteotomy drills (because it is internally smooth; Fig. 1c);
- a modified extender for drills (Fig. 1d);
- an externally threaded sleeve, longer than the osteotomy sleeve, that acts as a "bottle-neck" and is screwed into it (Fig. 1e); and
- the "bottle-plug", which is screwed onto the bottle-neck (Figs. 1f-h).

For the osteotomy, I used a regular surgical kit, not a dedicated one to precision, just modifying a plain extender to fit any osteotomy surgical kits (general and not guided surgical kits). The extender should match up with the sleeve before the drill touches the bone. The prototype was realised with no endo-stop features in the extender; only lines indicate depth.

The bottom end of the bottle-plug is provided with a helical gear (to match up with the corresponding embedded sleeve's helical gear; Fig. 1i). The bottle-plug in the prototype device consists of two components, the cylindrical screwed part and the lid, and they are fastened together with a joint. The lid is integrated into the implant mounting component; thus, while the bottle-plug is being screwed onto the neck, the implant mount is entering inside the bottle-neck, forcing the implant downwards. The implant mount has a hollow to allow for an implant fastening screw (the same as used to fix implants and abutments, just longer, to allow for minimal screwdriver length, when it is necessary to unfasten the components at the end). The mount also has a gauge for a wrench at its top (but it can work for a hand-piece driver as well). Once implant placement has been carried out, the mount can be unscrewed from the implant and vertically unfastened from the bottle-plug. At this point, the surgical guide can be removed easily, with no risk of hex undercuts.

The device must resist the vertical dislodging torque created when screwing the implant into the bone. A screwed bottle-neck performs well for this purpose and the lid must be fastened to the vertical part of the bottle-plug. A sleeve to be screwed on the bottle-plug bottom can be realised. SimPlant Pro Crystal (Materialise Dental) was used only to plan the implant position (Figs. 2-3a & b), but instead of using a surgical guide, a STL digital cast with analogue implant holes for placing analogues was used in the first case reported (Fig. 4). A plain stone model with a (presumably) correct analogue position was used for the second case reported (Fig. 5). In both cases, the analogues were fastened to the device, screwed to it, and then the device was secured to a bite-like thing (using plain relining resin for the provisionals) to obtain a surgical guide (no surgical guide fixation to the bone was considered; Fig. 6).

No guided tapping drill was used. This is something that should be considered, especially in high density bone. It could imitate the implant, with acuminate threads and narrow body, to be screwed to the bottle-plug, or a bottle-plug dedicated to the tapping step, with the tapping part integral to the bottle-plug itself.

In both clinical cases, the device was assembled chairside to allow for minimal vertical clearance (Figs. 7a-d). A resin for baseplate was then used to create jigs to check accuracy between the models and the mouth.



Fig. 4



Fig. 5



Fig. 6

_Results

The case results were satisfactory. The device was easy to use (Figs. 8a & b) and jig correspondence between the abutments screwed on the analogue models and the clinical implant positions was obtained.

For the STL case, four abutments were modelled on the STL model, the resin jig was created directly in the mouth, and then its correspondence to the same abutments was checked on the STL model (Figs. 9a-c). For the stone case, a transfer was screwed onto the analogue, the resin jig was created, and then its correspondence was clinically checked (Figs. 10a & b).

_Discussion

The present systems do not offer sufficient and reliable accuracy because they do not consider the concepts of thread timing and implant phase. Their weak point is the smooth sleeve (whether metal or virtual), which does not have any control over the mechanics of a screw, which an implant is. Shooting a bullet makes sense, but shooting a screw does NOT.

Smooth sleeve-dependent inaccuracy

The first element to be considered is the gap between the implant mount and the sleeve. A twisting implant apex is the natural effect. When the implant is guided by a smooth sleeve, the position in the arch will be correct only if the implant mount does not ever touch the sleeve during the process, but when the dentist is working there will always be contact, which will result in an error in B-L and M-V position. This is what I call the "position paradox effect" of a guiding smooth sleeve (similar to a guard-rail).

Since the sleeve has a top and a bottom plane, this paradox effect is reproduced in both these two planes, and an axis deviation is a natural consequence (what I call the "axis paradox effect of a smooth sleeve"). The gap affects position and axis: these parameters go hand in hand. Depending on the gap entity, it is possible to calculate the implant apex twisting entity, using simple proportionality (Fig. 11a). At a 20 mm depth from the top of the sleeve (approximately 13 mm below the ridge),

the linear deviation will be 0.8 mm (1.6 mm on the diameter that is the possible implant apex twisting entity). Trigonometry is an easy way to calculate the deviation angle of the implant axis (sine/cosine and tan/cot rules). If the gap is 0.1 mm (0.2 on the diameter), the axis deviation will be a deviation of 2° 20' (Figs. 11b-d).

Tapered implants can engage bone at an even greater angle, particularly if the driver is conical at its first part. Consequently, it will work only at the end of the implant placement phase. According to the previous considerations, I suggest that it does not work efficiently. This cone-shaped driver limits too large an insertion torque because it may be damaging; however, the larger the axis deviation, the greater the torque perceived by the operator, who will be given an inaccurate sense of implant stability.

Fig. 4 Analogues in the STL model.
Fig. 5 Surgical guide created for stone surgery.
Fig. 6 Surgical guide created for stone surgery.

Fig. 7a Assembly.
Fig. 7b Assembly.
Fig. 7c Assembly in the stone-based surgical guide.
Fig. 7d Assembly in the STL-based surgical guide.
Fig. 8a Surgical guide in the mouth.
Fig. 8b Surgical guide in the mouth, showing the helical gear in particular.



Fig. 7a



Fig. 7b



Fig. 7c



Fig. 7d



Fig. 8a

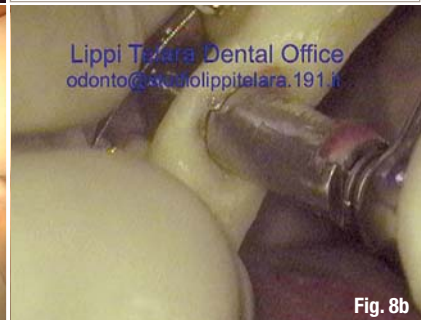


Fig. 8b



Fig. 9a



Fig. 9b



Fig. 9c

Fig. 9a_Jig created in the mouth for the STL case.

Fig. 9b_Jig created in the mouth for the STL case.

Fig. 9c_Jig verified against the model in the STL case.

The good results reported in publications could have been affected by right-handed operators in isotropic D2 and D3 bone or by working in sites in which cortical plates can directionally address implant placement. Excellent results reported could have been affected by working in low-density bone, where the marketed system allows for a good axis and depth, but the drills created a truncated cone volume devitalised area (depending on the drill blades' cutting power and operator's hand force), because the low-density trabeculae would be drilled 360° around. The hex would be missed anyway. The second matter to be considered is bone guidance. Depth and anti-rotational feature orientation depend on bone morphology and density.

When the implant has started its rotation inside the bone, it is not possible to change the threading pattern: while screwing the implant, the platform will move increasingly deeper downwards to the bone. Since it is possible to index a hex to a peripheral point along the circumference and a point along the same circumference can be indexed to the implant thread, the need to change the platform depth and hex orientation and control the threading pattern (implant phase) will be indicated. Any painted notch to index the hex and the sleeve is misleading information and naïve, as it is approximate, that is, no implant phase, and dependent on notch size, point of view (parallax) and operator's visual acuity.

Fig. 10a_Jig created on the stone model in the stone case.

Fig. 10b_Jig verified in the mouth in the stone case.

Once the implant has started its rotation, it is not possible to correct the position by redirecting the implant, as the apex is inserted into the bone and will act as a fulcrum. Even if the operator redirects the implant

axis, the implant body will remain displaced in position (B-L and M-D). Moreover, the redirection would be done by sight, which is dependent on the operator's visual acuity and a parallax error is a possibility.

The axis deviation introduces another concept: bone response in terms of bone density and bone anisotropy. As a matter of fact, on the other side of the surgical guide, when the implant touches the bone, with a smooth sleeve it is impossible to predict when it starts being screwed. The moment the implant starts rotating depends on the bone friction, depending on the density (HU), and the progression of the osteotomy and the implant insertion will be dependent on the HU gradient (anisotropy), which describes how rapidly the density changes per unit of length along the three spatial coordinates inside the bone. Unless we use a device able to force implants in a precise position (referred to as the surgical guide) along a path engineered according to a particular mechanics, the bone will determine the implant threading pattern (bone density for initial screwing, whether or not a crestal bone drill has been used) and bone density gradient, or anisotropy for the subsequent axis.

Accepting inaccuracy, manufacturers and researchers have created depth-control systems in the hope of offering certainty about this parameter at least, but the gap will be responsible for not only position and axis deviations, but also depth errors. In fact, the implant mount endo-stop will match up with the sleeve at an angle. The first contact will be beyond the desired depth, and keeping on screwing the implant will create a great torque with surgical guide deformation and tension on the bone.

The complete contact will correspond to a deeper implant position than desired. The correct depth may be halfway (maybe operator dependent and determined using the naked eye). Depth error, axis deviation and translation in crestal position in the axial deviation direction will be the results (Figs. 12a-e).

The likelihood of ideally positioning two implants is one out of seven billion and 500 million possibilities (just a few million less, if it is any comfort to us). And this eval-



Fig. 10a



Fig. 10b

uation comes from a 0.1 mm mean deviation and 1° deviation, which implies insufficient inaccuracy. Fancy what the chances would be of achieving acceptable accuracy.

Thread timing and implant phase

From a mathematical perspective, it is possible to describe all implant spatial coordinates concentrated on the platform, where we can summarise everything, and calculate its trajectory to create kind of a spiral path, through which it is possible to start and stop an implant platform along all the parameters, thus being able to truly speak of implant-guided prosthodontics.

The idea is based on the following: when screwing a coca-cola plug onto the bottle-neck, the final position will always be the same (Figs. 13a & b). Once two final positions have been found, two threads will be inside the plug; once three final positions have been found, three threads will be present on the plug. The label written on the plug can be considered to be a hex (or a trilobe). So the hex, that is the platform, can easily be reproduced in its position because the thread pattern and hex are indexed to each other. This means that if we can control the threading pattern, we can consequently control the platform position too.

According to this consideration, all the parameters that define the platform position can be controlled. The parameters are the position in the arch (B-L and M-D), the axis, the depth and the anti-rotational feature (classically, a hex) orientation.

The mechanical engineering of a screw is quite different from that of a bullet (smooth sleeve) and was defined by Archimedes (applications of an endless screw are still in use today, like the meat mincer) and by Euler (Swiss mathematician, who died in St Petersburg more than two centuries ago). In particular, Euler pointed out that the movement of a circle (in our field, the implant platform) can be described with mathematical formulas: a point along the circumference (in our field the perimetric projection of a part of the hex) can be projected along a plane orthogonal to the direction of the circle movement itself (in our field, the progression of the platform while the implant is being screwed in multiplanar reconstructions). The projection will describe a sine wave (in our field, the sine wave period can be identified with the implant thread pitch). With this in mind, I developed the device discussed in this article, which controls the threading pattern. In mechanical engineering, this is called thread timing, and the hex position can be defined as hex timing. For both of them we can speak of phase control (i.e. we can speak of the phase of the implant, both for the thread and the hex). Along this spiral track, the implant can be theoretically and actually screwed and unscrewed as many times as we desire (back and forth), and it will always be possible to know

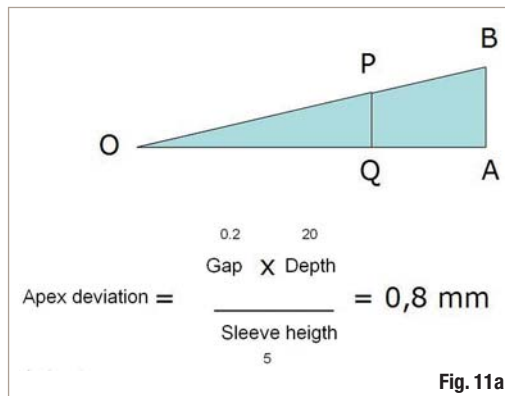


Fig. 11a_Mathematical proportion to calculate the linear radial apex deviation.

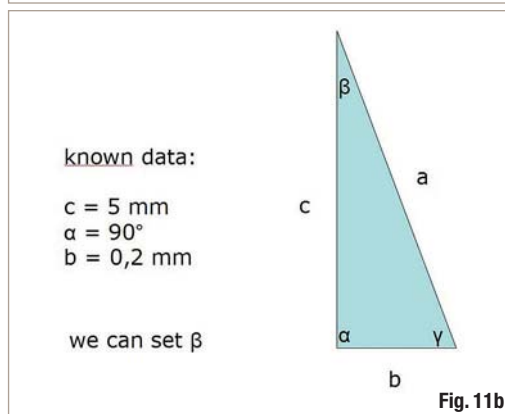


Fig. 11b_Calculation of the trigonometric angle deviation.

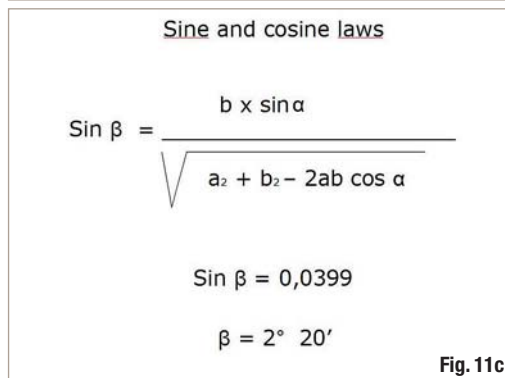


Fig. 11c_Calculation of the trigonometric angle deviation (sine/cosine rule).

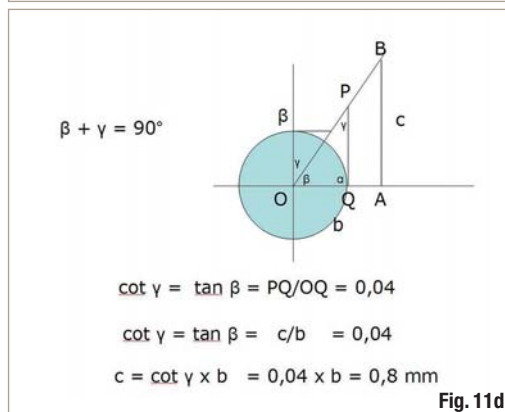
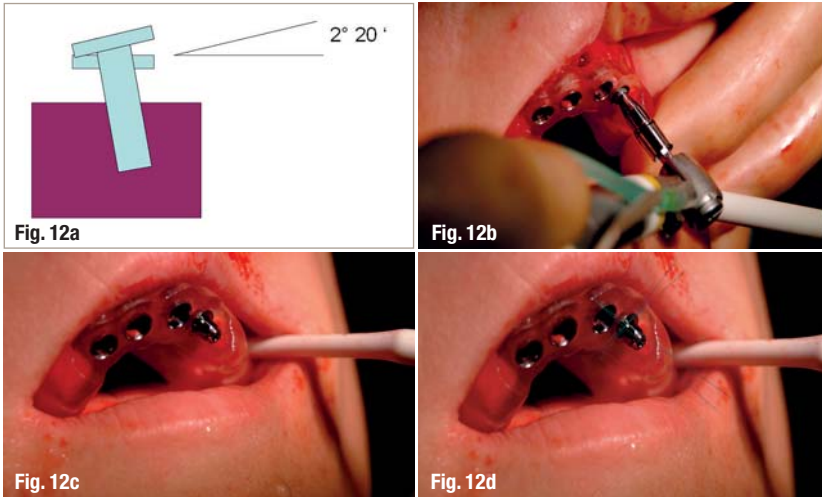


Fig. 11d_Calculation of the trigonometric angle deviation (tan/cot rule).

the hex position at the end of the spiral path (final analogue and implant position; Figs. 14a–c). As a spiral circular motion is transformed into a pure translation, a threaded device will respect also position and axis. The information needed to correctly (position and axis, anti-rotational feature and depth) place an implant is in its



tion deviation (in the arch this will signify a possible 2/100 mm deviation), no axial deviation, depth and anti-rotational feature correspondence. This discrepancy is within the limits that allow the clinician to make a pre-made final prosthesis and allows for presumably optimal long-term tissue stability.

Some of the systems available also consider hex orientation position, but in order to seat the implant correctly with regard to the anti-rotational feature, an extra rotation may be needed. Speaking of "correctly", at which angle resolution? If the feature described is in the shape of two points (painted or alike) to be vertically aligned, what is the point dimension? What is the eye resolution? Is it possibly a parallax error? Extra-rotation is an implicit admission of inaccuracy: the depth will not be respected as well, and the implant platform depth may be a little above or below the desired position (it depends on the degree to which the operator is out of phase, more or less than 180°). It is easy to realise that, unless all this has been calculated, all attempts to find the anti-rotational feature position and depth are only guesswork—a waste of time! Thread timing and implant phase have not been respected. Forget any notches on the implant mount and smooth sleeves, if anti-rotational feature orientation is the goal. Notches are history in digital guided implantology.

Once we have set a threading pattern, it is possible to set the stop point simply making a helical gear (a helical gear is realised by contouring the thread along its 360° run; a vertical step will be present once we have gone 360° all round) both in the bottle-neck plug and in the embedded sleeve (the coordinating feature inside the surgical guide), so that a vertical stop is realised in the device. When the two vertical parts match up, we can be certain that the hex is just where we have engineered it to be.

The device pitch must have the same implant pitch because differences will lead to bone stripping. In fact, a difference in implant and mount insertion speed (i.e. the distance covered in depth every 360°) and a different wave period (i.e. thread pitch), will lead to something different from an out of phase working device; it will lead to bone stripping. In particular, a longer mounting period will force the implant downwards into the bone, with consequent vertical bone stripping, whereas a shorter mounting period will force the implant to rotate horizontally, with consequent horizontal bone stripping. Self-tapping implants should show better torque control.

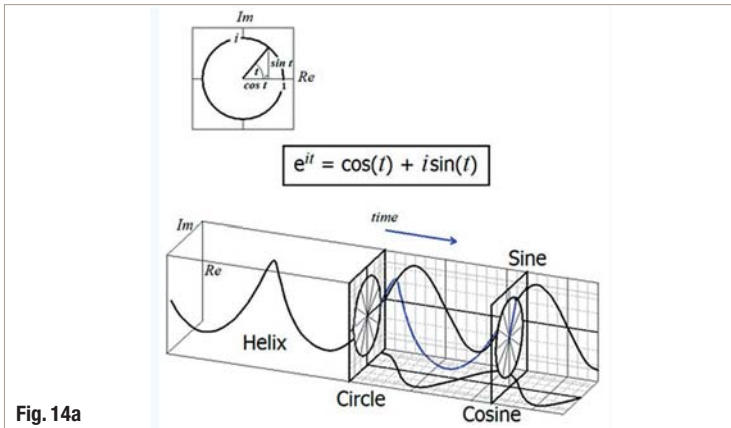
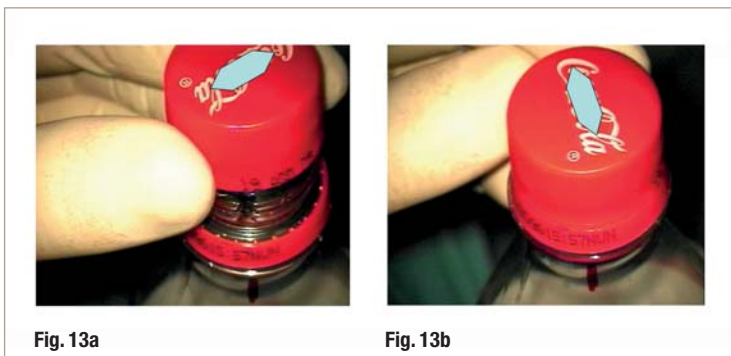
Rigidity

The device must be secured to the surgical guide to resist the rotational torque and vertical torque always present during the implant rotation inside the bone.

Fig. 12a Missed implant position parameters in the depth-control systems owing to congruent triangle considerations (implant axis deviation and endo-stop angle).
Fig. 12b Missed implant position parameters in the depth-control systems owing to congruent triangle considerations (implant axis deviation and endo-stop angle).

platform and inside its threads. By creating in the surgical guide a track along which the implant is screwed before its contact with the bone, it is logically possible to start and stop the implant with a final seating with all the parameters always reproduced. We can thus decide when to stop the implant during its fall along this spiral track. The final position will always be the same, that is repeatable, and operator independent. The device meets my earlier definition of a passive system.

The maximum precision possible will be what manufacturers can effectively offer (a 1/100 mm is expected to be realistic), which corresponds to the actual implant placement. With a threaded system, there is no axial deviation. Therefore, there will only be a 1/100 mm posi-



Components and undercuts

In the prototype device, a driver for a ratchet was used. It was completely redundant because the ratchet can cooperate directly with a plug-top feature for a ratchet at its top; thus, the driver is something that can be eliminated. Once the assembly has been fixed to the embedded sleeve, the plug can be screwed with the fingers, at least until sufficient torque is found, when a ratchet can be used.

When multiple implants have been planned, in case of divergent implants, hex undercuts could prevent the surgical guide from releasing itself from the bone, once the implants have been placed. In order to resolve this, the device, at least the mounting part, must be removed from the surgical guide. The device is thus divided in two components and the lid, which is integral to the driver, can be unscrewed, leaving the surgical guide along with all the other components still fastened to it, but disengaged from the implants, freely and easily removable. For single implant placement, the lid is not necessary, because there are no hex undercuts. In this case, a bottle-plug with one component will be sufficient.

Crest module

The implant crest module morphology does not affect this guiding device because the bottle-neck's internal diameter is just a little wider than the implant diameter at any point (platform or below the platform). By the way, additional threads in the crest module are not important either because, mathematically speaking, they are harmonic waves of the implant period (thread pitch).

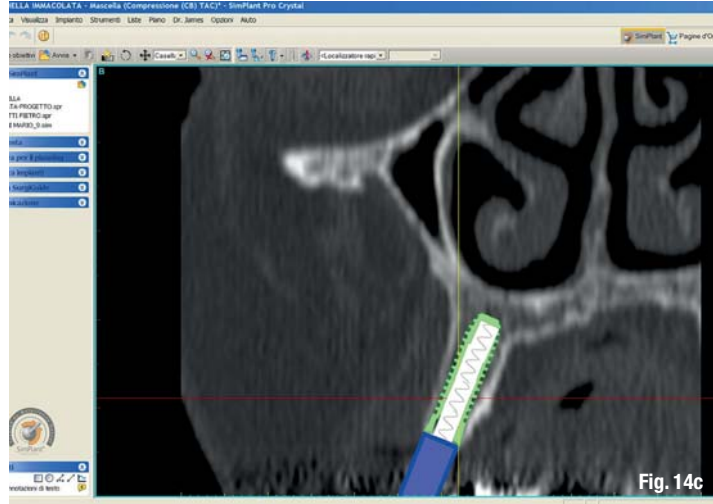
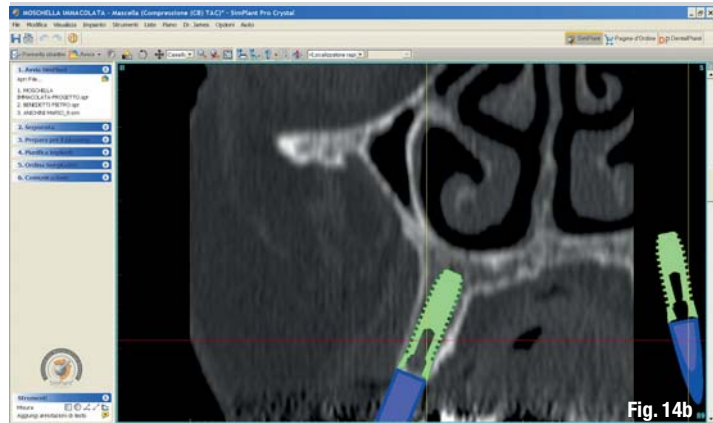


Master cast

The helical gear can easily be oriented vestibularly in the threaded guiding device before pouring the master model.

Vertical clearance

To make the correct surgical guide, the helical gear must be engineered in the planning at a multiple pitch distance from the bone, just equalling the implant length (the implant must start rotating before it touches the bone to avoid bone guidance). For instance, the dis-



tance will be 9 or 10 mm for 9 or 10 mm long implants with a 1 mm pitch, and the distance will be a multiple of 0.75 for a 0.75 mm pitch (9 mm will correspond to 12 implant revolutions and 10.5 mm to 14 revolutions). The average mouth opening values should be considered. In case of tapered implants, a short distance can be considered because the implant apex can enter the osteotomy hole without being engaged. To reduce vertical clearance, the device can be pre-assembled, thus obtaining a working length even shorter than that of the present systems (Fig. 15). A shorter vertical clearance is possible also with trans-mucosal implants because the platform results are more superficial.

Editorial note: A list of references is available from the publisher.

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- Fig. 12c_** Missed implant position parameters in the depth-control systems owing to congruent triangle considerations (implant axis deviation and endo-stop angle).
- Fig. 12d_** Missed implant position parameters in the depth-control systems owing to congruent triangle considerations (implant axis deviation and endo-stop angle).
- Fig. 13a_** Coca-cola screw plug analogy.
- Fig. 13b_** Coca-cola screw plug analogy.
- Fig. 14a_** Euler's formula.
- Fig. 14b_** Euler's formula in applied mathematics.
- Fig. 14c_** Euler's formula in applied mathematics.
- Fig. 15_** Vertical clearance paragon.

First published: Dent. Implantol. 8, p. 374-382 (2004), Spitta Verlag