

Trefoil: A New Solution to Edentulous Mandible

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ABSTRACT

Background: Dental implantology is a term used today to describe anchoring of alloplastic material into the jaws to provide support and retention for prosthetic replacement of teeth that has been lost. To date, overall positive experiences and generation of new knowledge have targeted the immediate future as a time to establish endosteal dental implants as a routinely applied treatment modality in dentistry. As a result of research, advances in implant designs, materials and techniques have led to predictable success in their application, and several types of implants are now available for use in rehabilitation of different clinical problems. Modern dentistry has changed tremendously with implant therapy. For the successful implant therapy, making a proper treatment plan considering both surgical and prosthetic part in mind is the key of success. With the modernization dental implant patients are increasingly demanding immediate restorations. To meet those demands, dental professionals are seeking solutions with fewer surgical steps. Shorter treatment time, high success rate, high patient satisfaction and function on the day of surgery. To meet all these technical demands of dentist and functional demands of patients a newer treatment options for completely edentulous mandible has been introduced. This article describes in detail about trefoil an innovative bioengineering technique made precisely for implant patients with a pre manufactured bar and teeth in a day.

Keywords: Trefoil, passive fit, self-adjusting mechanism, TiUnite, trefoil bar.

INTRODUCTION

Clinical implant dentistry is oriented to low cost treatments using simple protocols that are well supported by scientific data, while providing immediate function through immediate restoration and loading of dental implants. Trefoil system is a concept that fulfills all these functions. This system is been introduced for immediate restoration of dental implants in order to restore patients function and esthetics in a day. Trefoil system is used to rehabilitate and restore edentulous mandible. The trefoil implants CC RP are a part of the trefoil system. Corresponding to the pre-designed bar, three implants are placed in predetermined position (between the mental foramina), with the aid of different standardized templates. The implants are threaded endosseous implants made of

commercially pure grade 4 titanium with a TiUnite surface on the implant body. The implant surface is electrochemically modified by anodic oxidation to increase the thickness of the TiO₂ layer from 17–200 nm in conventional titanium implants to 600–1000 nm. Thus, a porous surface microstructure with pore sizes of about 1.3–2.0 mm, a porosity of roughly 20%, and a moderate degree of surface roughness of $S_a = 1 \mu m$ is generated. Accordingly, this type of implant surface has also been referred to as titanium porous oxide (TPO) or anodized titanium surface implant (ASI). In anodic oxidation, the implant is exposed to an electric circuit with the implant serving as an anode. TiUnite implants have been shown to possess nanoscale surface characteristics. Besides, data from cell experiments suggest that anodic oxidation might be effectively transferred to the implant's neck in order to create

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a tight soft tissue seal. Nanostructured titanium surfaces generated by anodic oxidation have been shown to propagate adhesion, proliferation, and extracellular matrix deposition of human gingival fibroblasts. Sul et al. have shown in a rabbit model that the bone-to-implant contact is slightly greater in implants with anodized surfaces compared to commercially pure titanium implants. Ivanoff et al. reported increased bone-to-implant contact of TiUnite microimplants compared to machined titanium microimplants.

The implant body diameter is 5mm. The implants are available in lengths of 11.5mm and 13 mm with either 4.5 mm or 6mm transmucosal collar. The collar has a smooth machined surface without threads. Trefoil implants are parallel body implant. The three implants of trefoil system are placed between the mental foramen in fully edentulous mandibles in a one-stage surgical technique combined with an immediate function loading protocol, provided sufficient primary stability of one or more implants if not reached, the implants along with the bar may also be used with an early or delayed loading protocol. (parallel body vs tapered implants)

Indications:

- Adequate quantity of bone (minimum height of 13mm for 11.5mm implant and 14.5 mm for 13mm implant, minimum width of 7mm).
- Adequate mouth opening (minimum 40 mm) to accommodate the guided surgery instruments.
- Implant supported prosthesis seated directly on dedicated implants.

Contraindications:

- Patients who are medically unfit for an oral surgical procedure
- Patients who have inadequate volume of residual bone for placing three implants to support the anticipated loads to which the patient will subject the implants (augmentation procedure can be considered).
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypertensive to titanium alloy grade 5 – Ti6Al4V (titanium,

vanadium, aluminium) or diamond like carbon coating (DLC).

- Cases of single –unit, fixed partial dentures and any types of removable restorations.
- Cases of partially edentulous mandible at time of implant insertion.
- Cases of maxillary treatment
- Patients with high expected loading conditions on the framework, e.g. severe bruxism.

Anatomical considerations

Important prerequisites for trefoil implants are:

- Minimum VERTICLE distance 13 mm
- Sufficient distance from mental foramen
- Minimum bony platform width of 7mm.

An extended alveolar crest adjustment has to be prepared with a bone bur distally to the first molar region on both sides to have sufficient space for the Trefoil Bar and acrylic.



Fig 1: Prerequisites for placing trefoil implants.

For a correct positioning of the Trefoil Bar and an esthetic outcome, the following factors are important:

Bony platform (c)

- The bony platform (c) should be level and parallel to the maxillary occlusal plane (a).
- The preparation should extend to the first molar region.
- Assess the adequacy of the vertical bone reduction guide, anatomic references, or

measurements of the preoperative vertical dimension.

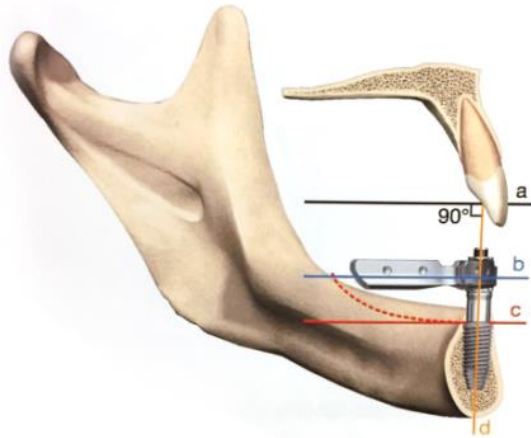


Fig 2: Anatomic guidelines for positioning trefoil bar.

Trefoil bar (b)

- The position of trefoil bar is dependent on implant position (d). The trefoil bar needs to be positioned parallel to the maxillary occlusal plane (a).

Prosthetic considerations

A total height of 22mm for the trefoil prosthesis when the 4.5 mm collar is used and 23.5mm when a 6 mm collar is used.

The occlusion guide trefoil can only be used in combination with the 4.5 mm collar implant. After using the 2mm twist drill in combination with the evaluation template to create the central osteotomy, check that there is sufficient space for the definitive prosthesis.

The trefoil system allows compensation for inherent deviations from the ideal implant position. The pre-manufactured bar, anatomically designed for the natural arch of the mandible, contains adaptive joints that adjust to horizontal, vertical and angular deviations from the planned implant placement. This mechanism is especially designed to work on only three implants and enables the definitive prosthesis to be passively seated.



Fig 3: Adaptive joints showing passive fit of the bar.

Many studies throughout the scientific literature reveal that, in the past, cast bars and some pre-manufactured prosthetics experienced unfavourable levels of implant and prosthetic failures. Historically, there have been many approaches to achieve passive fit. This includes cutting prosthetics bars and piecing them back together intraorally. From an engineering perspective, this approach could affect the integrity of the prosthetic superstructure. Alternatively, the development of CAD/CAM individualized solutions has made great strides to address the issue of passive fit. However, individualized bars are still subject to deviations in implant placement and they can be expensive for many patients due to the need for multiple clinical visits and the use of provisional prosthesis while the definitive solution is manufactured. By contrast, with the Trefoil system- a definitive solution that fits like a custom solution can be delivered by a dental team on the day of surgery.

This is evidenced by a recent in vitro study conducted at Saarland university in which the Trefoil Bar was directly compared to both traditional cast bars and CAD/CAM customized bars. In this study, five replicates of each comparison framework were seated on three NobelParallel CC Tissue Collar RP 5.0 × 13mm implants placed in resin models representing edentulous jaws using the Trefoil surgical guides and templates. Strain gauges were mounted to each system and recorded the strain development at all three implant sites when the clinical screws were tightened to 35Ncm.

The results indicated that cast bars show significantly higher levels of misfit and more uneven distributions of strain compared to other comparison groups (graph picture). The trefoil and

CAD/CAM bars each had a low level of misfit and more even distribution of strain. The two systems were not statistically different from each other.

Trefoil bar

This is a pre-manufactured bar, anatomically designed for the natural arch of the mandible. It contains adaptive joints that adjust to horizontal, vertical and angular deviations from the planned implant placement. This mechanism is specifically designed to work on three implants and enables the definitive prosthesis to be passively seated.

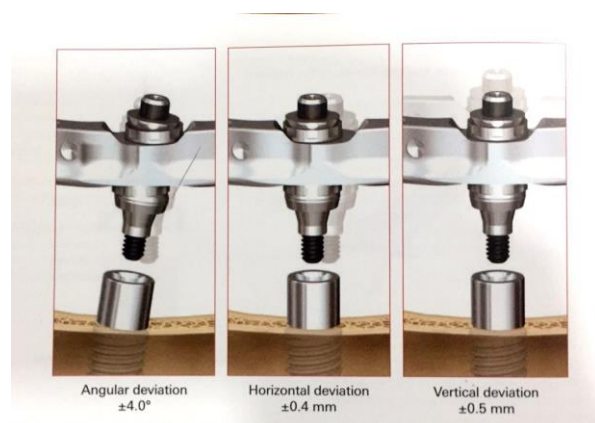


Fig 4: Adaptive joints that adjust horizontal ,vertical and angular deviations.

Trefoil bar consist of following components:

A. Try-in Screw Trefoil: It is used in the dental lab to fasten the trefoil Bar to the round abutment trefoil, passing through the screw disc trefoil and bar discs trefoil.

B. Screw Disc Trefoil: Used as a compensation component for angulations. It has a spherical bearing surface in contact with the bar disc trefoil and a flat surface to support the head of the clinical and try-in screw trefoil.

C/D. Bar Disc Trefoil: It has one flat bearing surface and one spherical bearing surface. The spherical bearing surface is in contact either with the screw Disc trefoil (above the Trefoil Bar) or with the round abutment Trefoil (below the trefoil Bar). The flat bearing surface is in contact with the Trefoil Bar.

E. Trefoil Bar: It is a horseshoe shaped titanium framework.

F. Round Abutment Trefoil: It has flat surface with a conical connection to engage with the implant and a spherical bearing surface in contact with the Bar Disc Trefoil.

G. Lab Screw Trefoil: It has a 10mm long head, used to fasten the Trefoil bar to the implant replica passing through the Screw disc trefoil, Bar Discs Trefoil and the Round Abutment Trefoil. It is used for laboratory steps.

H. Clinical Screw Trefoil: Screw with a diamond-like carbon (DLC) coating to fasten the Trefoil Bar to the implants, passing through the screw Disc Trefoil, Bar discs Trefoil and Round Abutment Trefoil.

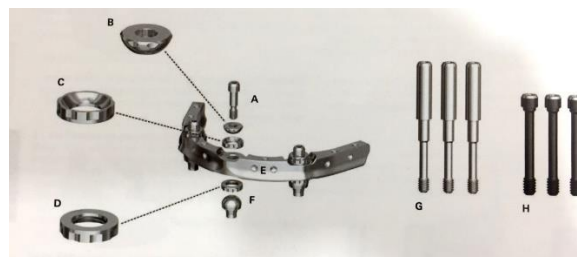


Fig 5: Components of trefoil bar.

Clinical procedure for trefoil implants.

The drilling protocol for trefoil implant follows the principal of guided surgery, where pre-manufactured templates for drills and implants are used for precise implant placement which are predetermined pertaining to trefoil system.

The drill system for Trefoil implant CC RP 5.0 × 13 + 4.5 mm in medium and dense bone follows a sequence:

1. Preparation of the bony platform until the alveolar crest has a minimum width of 7mm and a minimum ridge height of 13 mm extending to first molar region. After bone flattening a guide template and a guide drill is used to identify and mark the implant site.
2. Occlusal guide trefoil is used to verify the minimum vertical height 22mm for the definitive prosthesis. It also verifies bone reduction in relation to maxillary occlusal space and correct position and angulation of the central implant, which is to be placed first.

3. Positioning template is used thereafter to place the central implant only. Guide pins are used in the distal osteotomies for stabilization of the template.
4. Once the central implant is in place a V-template is used to place the two distal implants. V-template is fixed with the help of temporary screws. The templates for the preparation of distal osteotomies are engaged with two guide pins in distal positions to V-template for correct alignment of the V-template. Stabilizing screws are used into the bone for fixation of V-template.
5. The guide pins are removed and the distal sites are prepared through the template according to the drill protocol to appropriate depth with regards to the implant length and collar height. Drill sequence is dependent on the bone density and implant diameter. After all the three implants are in place the V template is removed from the position.
6. The implant position verification is done with the try-in bar trefoil. It allows to verify if the three implants are aligned and placed within the compensation range, and if the bar is in the correct position in relation to the mandible and the opposing dentition.
7. If any of the round abutments are not seated completely to the implant platform, one or more implants could be outside of the compensation range. In such cases, the misaligned implant needs to be removed and repositioned following the drill protocol. Alternatively, a nobel procera implant bar may be considered as a solution.
8. Verification index is fabricated with two transfer abutments on the distal implants and a temporary abutment non-engaging CC RP on the central implant. The abutments are connected with the resin. Once the resin is set verification index is removed and Soft tissue closure is done.

DISCUSSION

The misfit in removable complete dentures can cause soreness and patient discomfort, and is a consequence of severe bone resorption/atrophy of

the jaws, with a direct impact upon patient quality of life. The magnitude of these changes is important for decision-making and comprehensive treatment planning, and has a considerable impact on tooth replacement therapy, particularly when implant-supported restorations are planned.

The trefoil treatment concept arises as an attempt to allow treatment with affordable time and cost through immediate implant-supported restorations, providing relatively straightforward and predictable treatment in edentulous mandible patients. The outcome is favorable in terms of quality of life, when compared with the traditional 3-6 months during which the fixtures are protected from premature loading, requiring second surgery to expose them and connect the transmucosal components, and increasing the time and cost of treatment, as well as patient morbidity.

There have been multiple concepts in order to restore the failing full mouth restorations and or edentulous patients, like "All on 6" "All on 4" which have been introduced for immediate fixed solutions. These concept have been cost effective than traditional full mouth implant restorations as they avoid bone grafting procedures as well as multiple surgical procedures to receive more number of implants. The all on 6 and all on 4 procedure is used to replace entire upper and lower set of teeth. This allows implantation of six implants and four implants respectively. Whereas, the trefoil procedure deals with only lower rehabilitation with implants. In this system three implants are implanted in the lower jaw. The major advantage of trefoil system is that it comes with a pre-manufactured passive fit bar that can be used to immediately load the implants and have final fixed restoration. The all on 6 and all on 4 implant procedure lacks this advantage. They have to be restored with a conventional manner as done for the traditional implant procedures. Trefoil pre-manufactured bar is an ingenious fixation mechanism for treating mandible. The pre-manufactured bar, anatomically designed for the natural arch of the mandible, contains adaptive joints that adjust to compensate for horizontal, vertical and angular deviations from the ideal implant position. Each mechanism has five self-adjusting joints that help correct the position of pre-manufactured bar, enabling passive fit of the

definitive prosthesis. This system also avoids multiple surgical and lab procedures like all other implant procedures (all on 6 and all on 4 and all other conventional procedures) as everything is standardized. These preformed templates help to reduce surgical time for the patient reducing patients anxiety and discomfort. In the past, replacing an entire set of teeth would typically require many more implants, could include jaw bone grafting, and would need about 6 months of healing before patient would have been ready for the crowns or dentures. With the “All On” approach, there is less healing since there are less implants, and temporary dentures can usually be installed at the same time until your permanent dentures are ready (typically within 3 months). But Trefoil concept is a one day fixed teeth solution procedure as the major component is already pre-manufactured plus it's a guided surgically procedure which is also graftless. This makes the trefoil concept easy to be performed and less traumatic and time consuming for the patient. The choice of one concept over another depends firstly on the patient and secondly on the dentist. It is completely case dependent as to what concept to be followed. In many cases, the patient doesn't need such an extensive reconstruction, so an All-on-4 or trefoil may be more appropriate depending on the patients condition. Also, the location of the missing teeth, the situation of the remaining teeth, and the general health situation of the patient might affect which type of reconstruction is more appropriate for the patient.

CONCLUSION

The ability to immediately deliver a final fixed solution reduces chair time for the patient and clinician as well as laboratory time compared to treatments requiring a provisional prosthesis. This time- and potential cost-saving solution combined with successful clinical outcomes and high satisfaction introduces an important new treatment protocol for edentulous or soon-to-be edentulous mandible.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

REFERENCES

1. Emami E et al. Implant-assisted complete prostheses. *Periodontol* 2000. 2014 Oct; 66(1):119-31. doi: 10.1111/prd.12041.
2. Chung S, McCullagh A, Irinakis T. Immediate loading in the maxillary arch: evidence-based guidelines to improve success rates: a review. *J Oral Implantol* 2011;37:610-621 <https://www.ncbi.nlm.nih.gov/pubmed/22004059>
3. Romanos G, Froum S, Hery C, Cho SC, Tarnow D. Survival rate of immediately vs delayed loaded implants: analysis of the current literature. *J Oral Implantol* 2010;36(4):315-24. <https://www.ncbi.nlm.nih.gov/pubmed/20735268>.
4. Carretta R, Geisendorf M, Spinnler A, Heuberger P, Higuchi KW, Brunski JB. A Novel Prefabricated Final Fixed Solution for the Edentulous Mandible. *J Dent Res* 96(Spec Iss A):3348, 2017 (www.iadr.org).
5. Higuchi K. et al. An adaptive prefabricated full-arch framework on three implants in the mandible- preliminary results. Oral poster presentation accepted to be presented at the 26th Annual Scientific Meeting of the European Association for Osseointegration. Saturday 7th October, 2017. IFEMA Feria de Madrid, Spain.
6. Karl, M. and Albrektsson, T. Clinical performance of dental implants with a moderately rough (TiUnite) surface: A meta-analysis of prospective clinical studies, *Int J Oral Maxillofac Implants*. 2017 Jul/Aug;32(4):717-734. doi: 10.11607/jomi.5699.]
7. Clinicaltrials.gov. The TREFOIL concept 5-year clinical investigation (NCT02940353). <https://clinicaltrials.gov/ct2/show/NCT02940353>. Accessed June 22, 2017.
8. Allen PF, McMillan AS. A longitudinal study of quality of life outcomes in older adults requesting implant prostheses and complete removable dentures. *Clin Oral Implants Res*. 2003 Apr;14(2):173-9.