

## Special print

# An adaptive prefabricated full-arch framework on three implants in the mandible: preliminary results

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## Original abstract

### Background

Treatment of the edentulous mandible with implant-supported prostheses offers considerable functional and esthetic advantages over traditional removable dentures. Here we introduce preliminary results from a study of an innovative treatment concept that uses a standardized prefabricated framework, fitted with a specialized adaptive mechanism designed to allow passive fit, secured on three strategically placed implants between the mental foramina.

### Aim/hypothesis

The aim of this 5-year international multicenter clinical investigation is to evaluate implant and prosthetic survival of the Trefoil™ treatment concept in the mandible. Preliminary data, including 6-month results for most patients and 1-year outcomes for early recruits, are presented.

### Materials and methods

The study plan called for the recruitment of 90 patients with an edentulous mandible or failing dentition of the mandible. Inclusion criteria required a minimum height of 12–13 mm and width of 6–7 mm of interforaminal bone following initial bone preparation. With the aid of treatment-specific surgical guides and templates, three implants were placed in anatomically predetermined positions between the mental foramina. The prefabricated framework (Trefoil™, Nobel Biocare) was secured onto three conical connection implants after adjusting the compensation mechanism for passive fit. The three implants were loaded with the final prosthesis within 24 hours to maximally 2 weeks after surgery. Follow-up visits

took place 3–4 weeks after prosthesis placement and are scheduled at 6-months, 1-, 2-, 3- and 5-years after prosthetic delivery. Implant survival will be assessed at all visits.

### Results

The study was expanded to include 110 patients (330 implants) when recruitment closed in February 2017. The 22% larger patient recruitment was due to increased patient need at the request of the clinicians. As of March 2017, 45 patients completed the 6-month follow-up visit (mean  $6.6 \pm 3.0$  months, range 1–12 months). Implant survival rate was 98.5% with 5 implant failures reported in 4 patients. In 3 patients, a single implant failed due to non-osseointegration ( $n = 1$ ), pain ( $n = 1$ ), and an infection which started 3 weeks after initial surgery ( $n = 1$ ), respectively. In all 3 cases, the prosthesis has remained in function on 2 implants and patients were advised to switch to a soft diet. Following a healing period, the 3rd implant will be replaced. Prosthetic survival rate was 99.1% with one prosthesis being removed due to both distal implants failing to osseointegrate. The patient was then treated with two non-Trefoil implants and a custom prosthesis on three implants.

### Conclusions and clinical implications

Within the constraints of these preliminary findings, the Trefoil concept demonstrates good early outcomes in terms of prosthetic and implant survival rates. This innovative, adaptive, prefabricated framework supported on 3 implants allows for immediate loading of a final fixed solution for the edentulous mandible. 6-month and up to 1-year outcomes will be reported at the time of presentation.

# An adaptive prefabricated full-arch framework on three implants in the mandible: preliminary results



International, multicenter, prospective study evaluating the implant and prosthetic survival of the Trefoil system in the mandible (ClinicalTrials.gov: NCT02940353)



Interim results of a 5-year study:  
 – 1-year follow-up (40 patients)  
 – 6-month follow-up (94 patients)



110 patients  
 330 Trefoil implants

## Time to teeth<sup>1</sup>

- 76.4% of patients (n = 110) received the final fixed prosthesis within 48 hours.
- Mean time-to-teeth was 2 days 11.5 hours.

## Time to complete surgical and restorative procedures

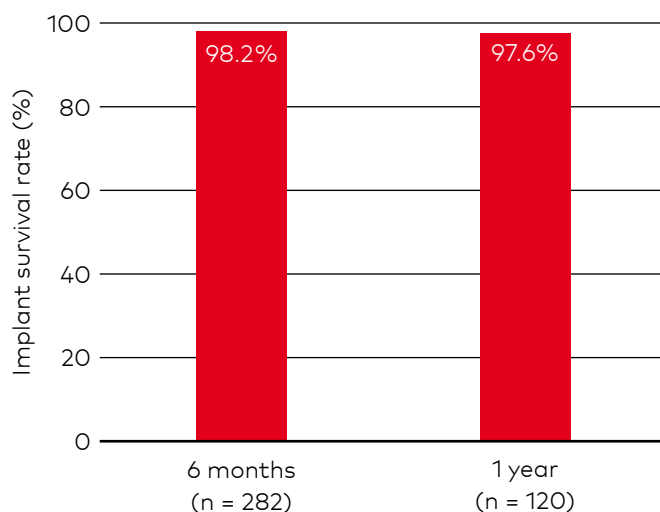
	Mean	±	SD	Median		Range
Surgical time (hours)	1.6	±	0.8	1.5	0.5	– 4.5
Laboratory time (hours)	4.0	±	1.7	3.0	1.2	– 8.0
Prosthesis placement (hours)	0.4	±	0.4	0.3	0.2	– 3.0
Time to prosthesis delivery (days)	2.5	±	2.4	2.0	0*	– 10.0

\*0 indicates same day delivery

## Implant and prosthetic survival rates<sup>1</sup>

- The implant cumulative survival rate was 98.2% (n = 282) at 6 months with 5 implant failures in 4 patients and 97.6% (n = 120) at 1 year with 8 implant failures in 6 patients.
- 2 prostheses were removed due to implant failure; no additional prostheses failed.

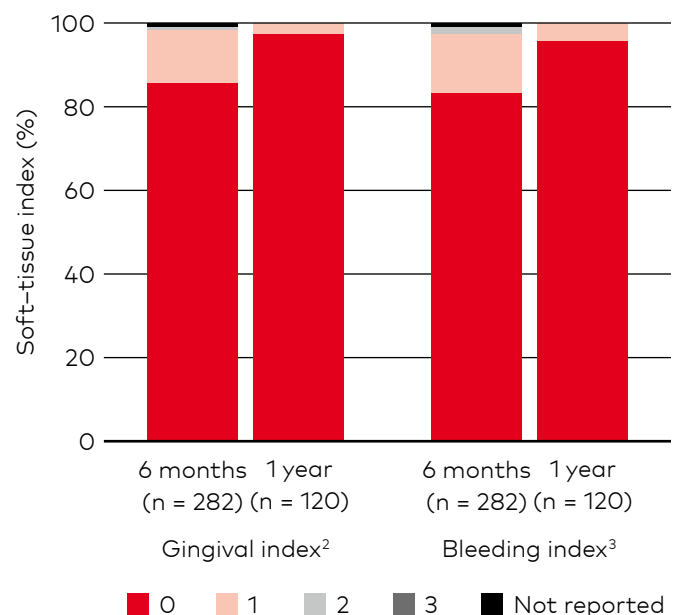
### Implant survival rate



## Soft and hard tissue health<sup>1</sup>

- Marginal bone remodeling from implant placement to 6 months was  $-0.48 \pm 1.14$  mm (n = 177).
- Soft tissue outcomes<sup>2-3</sup> were ideal for most patients (> 75%) across all parameters evaluated.

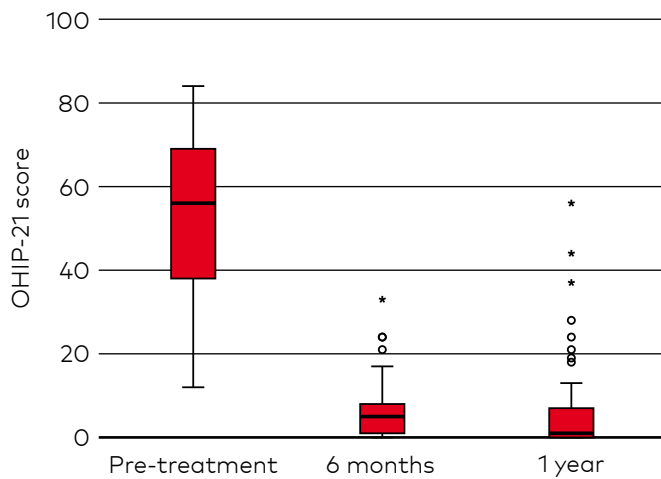
### Soft-tissue parameters (gingival and bleeding indices)



## Oral health-related quality of life<sup>1</sup>

- Oral health-related quality of life improved after prosthetic placement and improvements were sustained throughout the study period (n = 38).
- Functional and esthetic satisfaction was very high (> 9.1) for all follow-up visits according to both patients and clinicians.

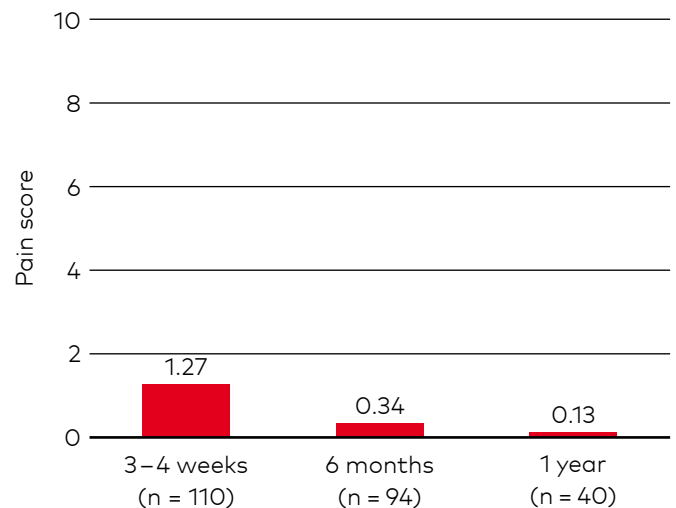
### Oral health impact profile (OHIP)



## Patient-reported pain assessment<sup>1</sup>

Patient-reported pain, assessed on a scale of 0–10 (low to high), decreased from  $1.27 \pm 2.36$  at 3–4 weeks after surgery (n = 110), to  $0.34 \pm 1.22$  at 6 months (n = 94) and  $0.13 \pm 0.64$  at 1 year (n = 40).

### Patient-reported pain



## Conclusions<sup>1</sup>

- The Trefoil system demonstrates successful early clinical outcomes in terms of high implant and prosthetic survival rates, low marginal bone-level change, and short time-to-teeth.
- Patients reported notable improvements in quality of life and, along with clinicians, reported excellent functional and esthetic satisfaction at all follow-ups after treatment.
- The ability to immediately deliver a final fixed solution reduces chair and laboratory time compared with treatments requiring a provisional prosthesis.

## References

- 1 Higuchi K, Davó R, Liddelow G, et al. An adaptive prefabricated full-arch framework on three implants in the mandible: preliminary results. *Clin Oral Implants Res* 2017;28(Suppl)
- 2 Löe H, Silness J. Periodontal disease in pregnancy. *Acta Odontol Scand* 1963;21:533–551.
- 3 Mombelli A, van Oosten MA, Schurch E, Jr, et al. The microbiota associated with successful or failing osseointegrated titanium implants. *Oral Microbiol Immunol* 1987;2(4):145–151.

# A new treatment protocol for patients with an edentulous mandible or failing dentition of the mandible

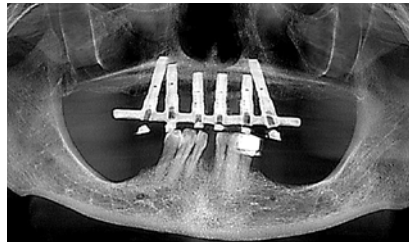
## Clinical case

A 66-year-old female with failing mandibular dentition and a fixed implant-supported maxillary prosthesis was treated with the Trefoil system. After bone leveling, three Trefoil implants (5.0 × 11.5 mm) were placed using surgical guides and tightened to 45 N·cm. The patient received the final prosthesis on the day of surgery.

### Before treatment

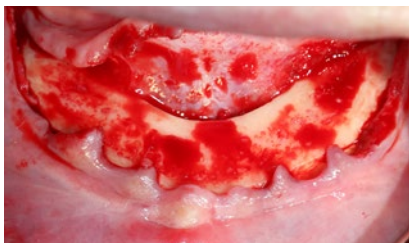


Pre-operative clinical view



Panoramic radiograph

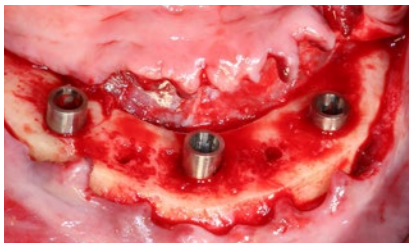
### Treatment steps



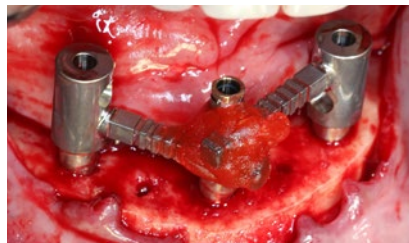
Bone leveling



Guided implant insertion



Three implants placed

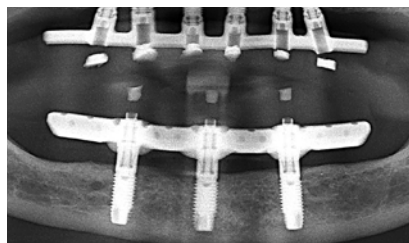


Verification index to create a master cast

### After treatment with the Trefoil system



Clinical view of the definitive prosthesis on the day of surgery



Panoramic radiograph at 16-month follow-up

[nobelbiocare.com/trefoil](http://nobelbiocare.com/trefoil)



Download the poster:  
<http://www.dentalcongressposters.com/eao2017/higuchi.pdf>

