



Early Loading Maxillary Cresco Full Arch Reconstructions. An RCT Trial

JOKSTAD A¹, ELLNER S², GUSSGARD AM¹

¹ University of Toronto, Faculty of Dentistry, Toronto, Canada

² Specialist Dental Care Center, Kalmar County, Sweden

Background - assumptions

Poor fit between a suprastructure and implants is associated with increased risk of technical and biological complications (Brunski 1999)

Conventional casting without distortions is technique-sensitive

New fabrication techniques have been developed to optimize FDP fit, e.g. Cresco laser welding concept (Helldén et al. 1999)

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Study objectives

To appraise feasibility of interchanging conventional FDP with Cresco components in two different early loading protocols.

Hypothesis 1: No difference in bone loss between implants in the two Cresco-component FDPs versus implants supporting the conventionally made FDPs

Hypothesis 2: No difference between the two Cresco groups when using a 10 day- versus a 6-8 weeks post-healing loading protocol.

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Materials and Methods

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Materials & methods: Setting

EC directive 2001/20, Ethics C.s. (N&S), patient privacy ombud (N), C.R.O., ClinicalTrials.gov

One university clinic (Norway) + four public dental health centers (Sweden)

Patients with an edentulous, fully healed maxilla desiring a fixed 10-/12-unit prosthesis

Recruited to partake in a blinded 3-arm RCT

Sample size estimate based on 80% power → n=3x22

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Materials & methods: Study population

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> Aged ≥ 18 years Edentulous maxilla (at least 3 months before date of surgery) and request for implant-supported screw-retained FDP GBRGTR completed ≥ 6 months before implant surgery Adequate bone quality and quantity for placement of 3.3/4.1 mm implants without bone augmentation Agreement to participate in study up to 3 years follow-up 	<ul style="list-style-type: none"> Systemic <ul style="list-style-type: none"> Conditions requiring prolonged steroid use History of leukocyte dysfunction or deficiency, bleeding disorders, neoplastic disease, renal failure, uncontrolled endocrine disorders Metabolic bone disorders Physical handicaps that may affect oral hygiene maintenance. Use of investigational drugs ≤ 30 days before implant surgery Alcoholism or drug abuse HIV infection > 10 cigarettes or cigar or chew tobacco equivalents per day. Any conditions that may prevent study participation or interfere with analysis of results in the investigator's opinion Local <ul style="list-style-type: none"> Inflammation, including untreated periodontitis Mucosal diseases History of irradiation therapy Osteous lesions Unhealed extraction sites Bone surgery Severe bruxism/clenching Persistent intraoral infection Inadequate oral hygiene

Materials & methods: Surgical protocol

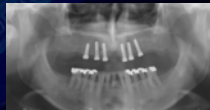
Six solid screw two-part implants \varnothing 3.3 or 4.1 mm (SLA Standard Plus, Straumann, Basel, Switzerland)



Standard implant placement protocol according to the manufacturer

Primary initial stability hand-tested by tightening of healing abutment

Symmetrical spread 15-25 (FDI)



Materials & methods: Randomization

Randomization list generated by external clinical research organization

Sealed, numbered, opaque envelope containing the randomized allocation sent to the clinician prior to each individual scheduled implant surgery

Envelope opened after completion of implant surgery



Materials & methods: Interventions

Test group 1

FDP*, Cresco components (Cresco Ti Systems, Sarl, Lausanne, Switzerland)

Implants loaded within 10 d. post-implant placement

Test group 2

FDP*, Cresco components

Implants loaded 6-8 weeks post-implant placement

Control group

FDP*, conventional components

Implants loaded 6-8 weeks post-implant placement

*10-12 units, screw retained, Centres used Cresco-accredited laboratories & consistent dental technician

Materials & methods: Clinical outcomes

Patient complaints or any complications resulting from a change in health status

Any implant-related complications, e.g., pain, paresthesia or peri-implant infection

Clinical-radiological examinations 3 & 6mths, 1, 2 & 3yrs

Periapical radiographs using customized film holders (Rinn XCP & putty impression)

Peri-implant health and oral hygiene

Patient satisfaction: perceived appearance, ability to chew, comfort, general satisfaction and ability to taste; excellent / good / fair / poor

Materials & methods: Radiography & Statistics

Public domain software ImageJ (NIH, USA)

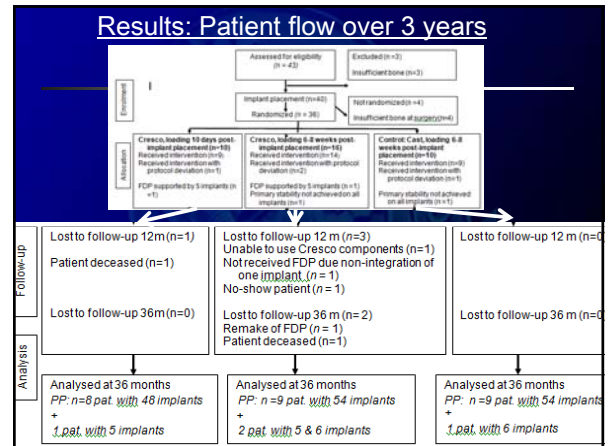
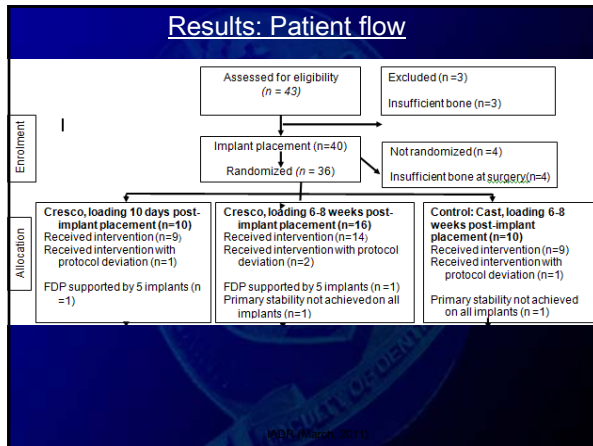
Bone level measurements independently by an investigator unrelated to the study

Dependent response mm change of bone level over time; specifically the difference in bone level between the 3 groups

ANOVA type multivariate statistical model

SPSS statistical software (SPSS Inc.)

Results



Results: Baseline (per protocol groups)

	Cresco 10d (n = 8 patients, 48 implants)	Cresco 6-8w (n = 9 patients, 54 implants)	Control 6-8w (n = 9 patients, 54 implants)
Gender males (%)	5 (63)	6 (55)	1 (11) *
Mean patient age (SD)	64 (12)	64 (11)	67 (7)
Clinical team (1 - 5): patients (n)	1:3 2:1 4:3 5:1	1:3 2:1 3:2 4:3	1:3 2:3 4:2 5:1
Bone quality (I - IV) (%)	II:37 III:50 IV:13	II:20 III:62 IV:18	II:0 III:56 IV:44 *
Bone form: knife (K) - parallel (P) - taper (T) - undercut (U) (%)	K:0 P:65 T:29 U:6	K:2 P:71 T:20 U:8	K:28 P:50 T:11 U:11
Crest width: <5- 6-7-8 >8mm(%)	0 4 17 69 10 0	3 5 8 56 5 6	11 13 11 50 13 2
Bone height: <10- 10/11-12/13 >13 mm (%)	15 15 54 17	2 12 73 23	13 17 69 2
Implant depth (mm) (SD) (min - max) (distance between cortical bone level and first implant thread)	2.9 (0.7) (1.3 - 4.2)	2.1 (0.6) (-0.3 - 3.3)	1.7 (0.9) (-0.6 - 1.9) *

*Significant differences between the groups

Results: Clinical outcomes over 3 years

No implant-related complications

Prosthetic complications and failures were rare (p > .05 amongst groups)

Patient satisfaction scores were high in all 3 study groups regarding general satisfaction, comfort, satisfaction with appearance and ability to chew and taste (p > .05).

Periodontal indices did not differ significantly amongst the three study groups (p > .05).

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Results: Bone changes at 3 years

Crestal bone level changes (adj. means (range):

- Cresco 10 days: -0.7 mm (-1.1 to -0.2)
- Cresco 8 weeks: -0.5 mm (-0.7 to -0.3)
- Control 8 weeks: -0.4 mm (-0.6 to -0.2) (p > .05)

The change from baseline was statistically significant in all 3 groups

Baseline 6 months 1 year 3 years (#101 for illustration)

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Conclusions 1/2

By assuming a non-inferiority margin of 0.3 mm bone loss:

- Clinically relevant superiority of the Cresco groups vs the control group can be excluded
- Inferiority of the Cresco groups compared to the control group cannot be excluded

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Conclusions 2/2

3. An additional change in bone level of -0.3 mm is expected by each 1 mm an implant is placed deeper
4. The vertical placement of the dental implant has more effect on bone loss than the fabrication technique used for the suprastructure and whether the implants were loaded after 10 days versus 6 to 8 weeks.

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