Early Loading Maxillary Cresco Full Arch Reconstructions. An RCT Trial

JOKSTAD A[1], ELLNER S[2], GUSSGARD AM[1]

[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
Aged ≥ 18 years	Systemic
Edentulous maxilla (at least 3 months before date of surgery) and request for implant-supported screw-retained FDP	Conditions requiring prolonged steroid use
GBR/GTR completed ≥ 6 months before implant surgery	History of leukocyte dysfunction or deficiency, bleeding disorders, neoplastic disease, renal failure, uncontrolled endocrine disorders
Adequate bone quality and quantity for placement of 3.3/4.1 mm implants without bone augmentation	Metabolic bone disorders
Agreement to participate in study up to 3 years follow-up	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
	Inflammation, including untreated periodontitis
	Mucosal diseases
	History of irradiation therapy
	Osseous lesions
	Unhealed extraction sites
	Bone surgery
	Severe bruxism/clenching
	Persistent intraoral infection
	Inadequate oral hygiene

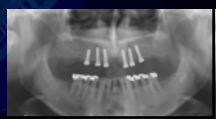
Materials & methods: Surgical protocol

Six solid screw two-part implants ø3.3 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

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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

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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

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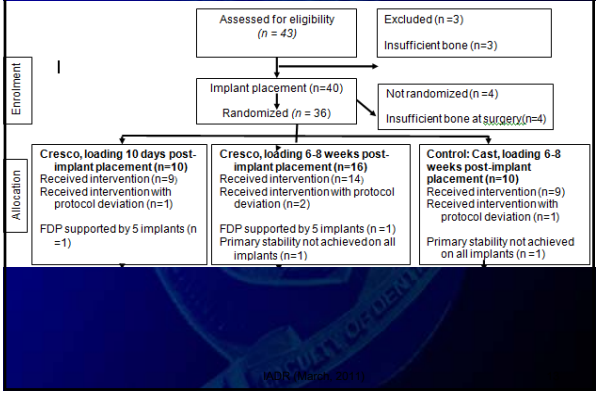
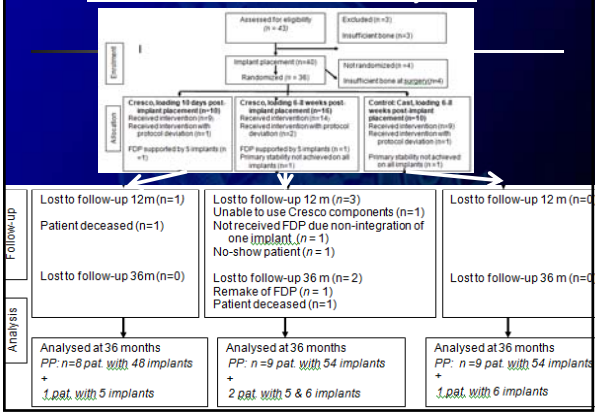
Results: Patient flow



IADR (March 2011)

Results: Patient flow over 3 years



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

Prosthodontic 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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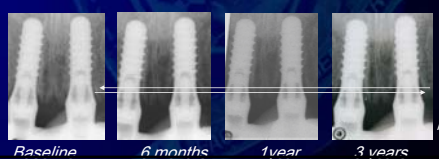
Results: Bone changes at 3 years

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



(#101 for illustration)

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Conclusions 1/2

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

1. Clinically relevant superiority of the Cresco groups vs the control group can be excluded

2. 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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