Randomized controlled clinical trial of immediately loaded mandibular 2-implant overdenture retained by magnetic attachments: preliminary report.

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Objective

McGill consensus reported Mandibular 2-Implant Overdentures (2-IOD) as first choice standard of care for edentulous patients.[1)] However, few and inconclusive data are available on immediate loading of two unsplinted implants retaining a mandibular overdenture with a freestanding type of connection.[2-7)]
The null hypothesis of this randomized controlled trial was that there was no difference between immediate loading and conventional loading of implant overdentures with magnetic attachments in terms of the implant survival rate and patient reported outcome applying CAD/CAM template guided flapless surgery.

Authors	Year	Attachment	No.of participants	Observation period (Year)	Survival rate(%)
Marzola et al.[2)]	2007	Ball/Gold cap	17	1	100
Pae et al.[3)]	2010	Magnet	6	1	86
Liao et al.[4)]	2010	Ball/Gold cap	10	1	94
Kronstrom et al.[5)]	2010	Ball/O-ring	19	1	81
Roe et al.[6)]	2011	Locator	8	3	100
Buttel et al.[7)]	2012	Ball/Gold cap	20	2	100

Table1. Reports of immediate loading of 2-implant overdentures using stud attachments

Methods

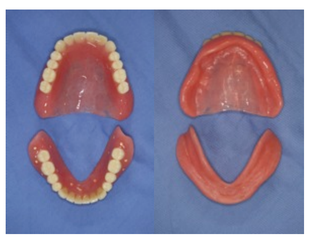
Patient Selection

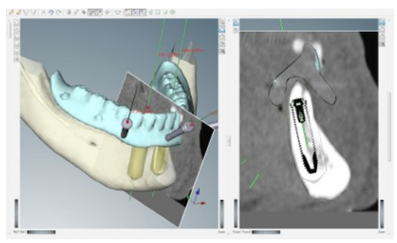
Treatment protocol of this study was approved by the Institutional Review Board of Tokyo Medical and Dental University.
Nineteen patients who had edentulous mandible at Dental Hospital, Tokyo Medical and Dental University enrolled in this study.
The exclusion criteria were as follows; Insufficient bone volume in the interforaminal area of the mandible, severe systemic diseases, radiotherapy and chemotherapy, osteoporosis.

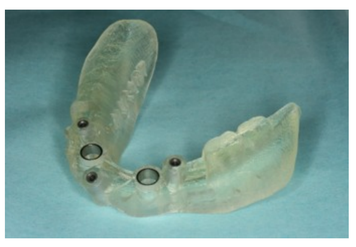
Clinical Procedure

Pre-surgical Treatment

1. A new mandibular complete denture was fabricated for each patient.
2. For radiographic guides preparation, gutta-percha markers were put into the newly fabricated complete denture.
3. The computer planning followed the design procedure (Procera, Nobel Biocare).
4. The surgical guides (Nobel Guide, Nobel Biocare) were fabricated for each patient.


New complete denture.


The computer planning in Procera software.

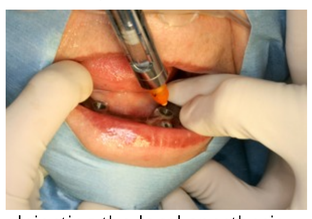

Surgical guide (Nobel Guide).

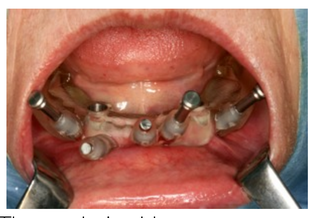
Allocation of the participants

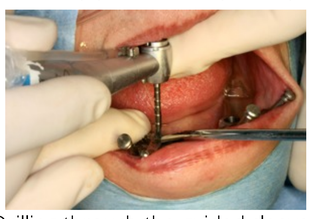
All the participants were allocated to Immediate group or Conventional group based on age, gender, and ACP classification system for complete edentulism.

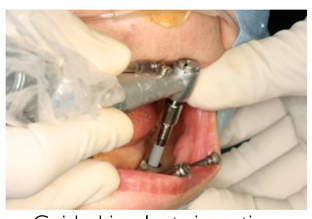
Surgical Treatment

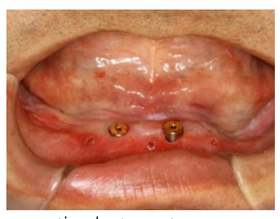
1. All surgical treatment was performed under intravenous sedation (Propofol). The local anesthesia (Lidocaine hydrochloride 2%) was injected through guide hole.
2. Flapless surgery was performed with this surgical guide according to the protocol of Nobel Guide.
3. Two implants, threaded titanium oxide-surface implants (Speedy Groovy, Nobel Biocare)(n = 38 implants), were inserted between lateral incisor and canine positions.


Injecting the local anesthesia.


The surgical guide was positioned with anchor pins.

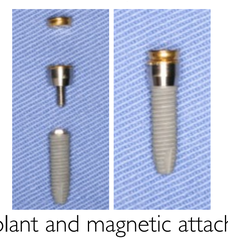

Drilling through the guided sleeves.

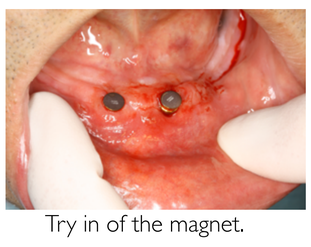

Guided implants insertion.

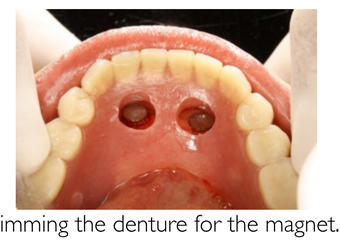

The magnetic abutments were positioned.

Prosthetic Treatment

1. The two magnetic attachments (Magfit, Aichi Steel Corporation, Aichi, Japan) were positioned into the mandibular complete denture at the surgery day in immediate group and 3 months after surgery in conventional group.
2. The patients were instructed not to remove the denture for 0-1 week after operation. At this period the operator cleaned the implants and the denture every other day.
3. For 1-3 week after operation, the patients remove the denture 3 times a day when they brushed the implants. Except the brushing time the dentures were wore.
4. Six months after the operation, the new implant overdenture were fabricated.


The implant and magnetic attachment.


Try in of the magnet.


Trimming the denture for the magnet.


The magnet were picked up into the denture.

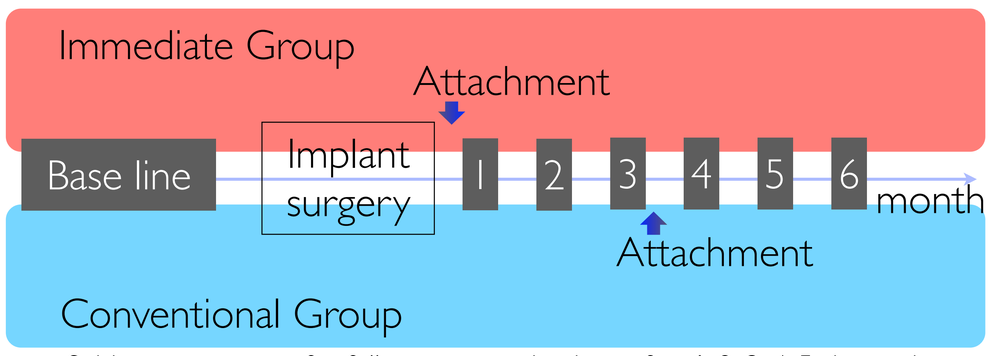
Outcomes

1. Cumulative implant survival rate
The survival of each implant was evaluated clinically and radiographically. Surgical and prosthetic complications were recorded.
2. Patient reported outcome
OHIP-EDENT-J[8)] was used for patient reported outcome.

Statistical Analysis

Kaplan-Meyer analysis was used for evaluation of implant survival rates. The differences from baseline were assessed by t-tests in each month. Significant level was set at 0.05. All statistical analyses were performed on a personal computer with SPSS ver18.

Treatment and Evaluation flow



Subjects were seen for follow-up examinations after 1, 2, 3, 4, 5, 6 months.

Results and Discussions

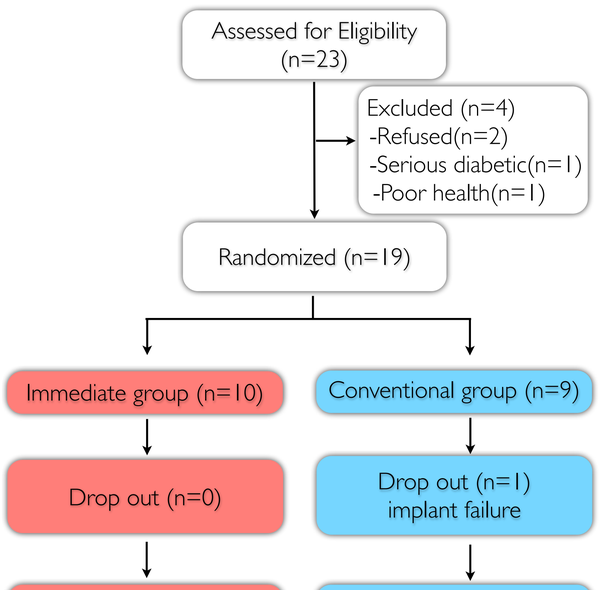


Fig.1 Design of the randomized controlled trial.

		Immediate group	Conventional group
Age (SD) Range		69.2 (10.6) 46 to 81	66.6 (9.1) 59 to 85
Gender	Male	6	3
	Female	4	6
ACP classification	I	2	2
	II	3	2
	III	4	3
	IV	1	2

Table 2. Character of the participants.

		Immediate group	Conventional group
Implant length (mm)	10.0	0	1
	11.5	2	3
	13.0	2	5*
	15.0	14	7
	18.0	2	2
Insertion torque (Ncm)	45>	20	18*
Cumulative survival rate in 6 months		100% (20/20)	88.9% (16/18)

*2 implants were lost.

Table3. Implants variables

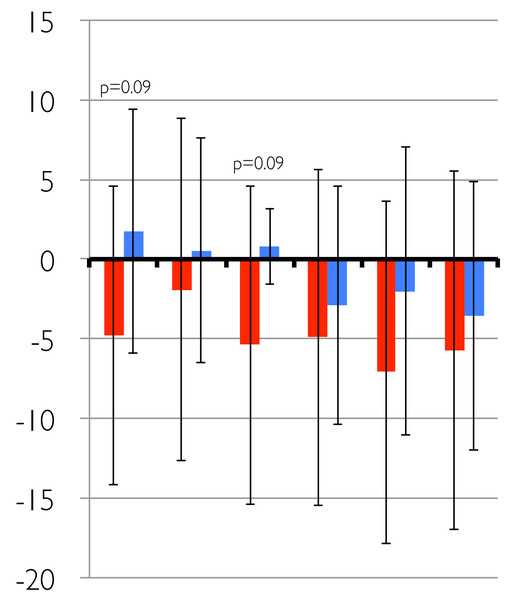


Fig 2. The difference form baseline in summary score of OHIP-EDENT

During the initial healing period (1to 2 month), 2 implants failed in one patient on conventional group. One patients, with two failed implant, dropped out prior to completion of the study. The failed implants were included in the evaluation of cumulative implant survival. The cumulative implant survival rate at 6 months were 100% in immediate group and 88.9% in conventional group.
From the OHIP-EDNET significant decrease trend were found at1month and 3month in immediate group compared to conventional group. This results indicate that immediate loading probably improve oral health related quality of life.

Conclusions

In this 6-month preliminary study, the immediate loading of mandibular 2-implant overdentures with magnetic attachments resulted in favorable implant survival and oral health related quality of life compared to conventional loading.

Refference

1)Feine JS, et al. The McGill consensus statement on overdentures. Mandibular two-implant over dentures as first choice standard of care for edentulous patients. Montreal, Quebec, May 24-25, 2002. Int J Oral Maxillofac Implants. 2002 Jul-Aug;17(4):601-2. Review.
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Acknowledgement

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