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Research Article

A RANDOMIZED CONTROL TRIAL FOR EVALUATION OF IMPLANT STABILITY, SUCCESS RATE AND LOADING TIME WITH PHOTOFUNCTIONALIZED DENTAL IMPLANTS IN FRESH EXTRACTION SOCKET

Mayank Singh[1]., Lakshya Kumar[1]., U.S. Pal[2]., Abhijeet Awasthi[1]., Aditi Verma[1] and Anwar[1]

[1]Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, UP Lucknow
[2]Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, UP Lucknow

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ABSTRACT

Purpose- In present scenario dental implants have become a predictable treatment option for restoring missing teeth. The use of dental implants in oral rehabilitation has currently been increasing since clinical studies with dental implant treatment have revealed successful outcomes. There are definite advantages of doing immediate implant i.e. saving time and money. The aim was to evaluate the role of photo-functionalisation on enhanced implant stability or early rehabilitation.
Material And Method-the subjects were divided into two groups, in one group implant was placed without any intervention, in the second group, implant was placed with photo-functionalisation and use of PRP, the implant stability was checked with RFA, and subsequent bone loss was measured in radiographs in both the groups.
Result- In our study period we have placed implants in 99 subjects, out of which 60 implants placed in maxillary arch and 39 implants were placed in mandibular arch. Average loading time is decided on the basis of implant stability by measuring ISQ value which is 3 months in photo-functionalized treated implants placed in maxilla and 2.5 months in mandible as compared to average loading time in untreated implant which is 6 months.
Conclusion- With this study we have concluded that immediate implant with photo-functionalization had increased the implant stability with due time till the loading and also with the use of regenerative medicine like PRF at the time of placement & after 3 months with minimum invasive surgical techniques, ease of procedure and in shorter time duration.

INTRODUCTION

New surface innovations in dental implantology have been developed which provide high success and predictable survival rates even in such challenging conditions. Through research, dental implant technology has been constantly improving and providing patients with unparalleled levels of effectiveness, affordability and convenience. Osseo integration is the key to successful implant stability also it is fundamental to success and survival of implant.

Ultraviolet photo-functionalization is proven to reverse the ageing process and increases the bone implant contact to almost 100% which is known as "superosseointegration"[1], and therefore increasing the strength and the primary stability of implants while decreasing the healing time.

Ultraviolet (UV) radiation has been used for many years for surface disinfectionin industrial and medical technologies as well as in titanium dental implants.[2,3] The primary surface composition of dental implants after manufacture is passified titanium surface. This passified surface is primarily titanium dioxide(TiO_2) which gives the capability of osseointegration with bone. However, the TiO_2 of manufactured implants may lose some ability to bioactively integrate with the bone after a storage time of as little as 2 weeks, [4] during which time there is a degradation of bioactivity. However, the bioactivity can be regained with exposure to UV.

Patricia Miranda Burgos, Lars Rasmusson, *et al*. (2008)[5] concluded that the integration of titanium implants with a turned or an oxidized surface to bone is by following different paths. By observing under the light- microscopic level it was found that bone formation occurs directly on the moderately rough oxidized surface, while turned titanium surfaces are integrated by the in growth of bone from the adjacent bone marrow and bone tissues.

Takeo Suzuki, *et al*.(2009)[6] suggested that UV light treatment of the 4 week aged titanium surfaces increased the bioactivity

*Corresponding author: **Mayank Singh**
Department of Prosthodontics , Faculty of Dental Sciences, King George's Medical University, UP Lucknow

to the level equal to or even higher than the freshly prepared surfaces, by the regeneration of superhydrophilicity.

Takeshi ueno *et al*.(2009)[7] examined the advantages of UV-treated titanium surfaces in overcoming a challenging condition of bone- implant integration using a gap healingmodel, as well as the behaviour and responses of bone marrow- derived osteoblasts (BMOs) and periosteal cells on UV treated titanium surfaces.

FuminoriIsawa *et al*. (2009)[8] describe the initial interaction between initial cell and UV photo-functionalized titanium surfaces. They found that on molecular level there were biological evidence of enhanced cell adhesion and possible physio- chemical attractants that are present on the photo-functionalized titanium surfaces.

Akio noro, Morio Kaneko *et.al*.(2012)[9] conclude that surface modification of surface topography or physiochemistry, especially of blast/acid etching as well as O2 plasma treatment and UV treatment, resulting in superhydrophilicity by greatly increasing the surface wettability.

AkiyoshiFunato, Masahiro Yamada, *et al*.(2013)[10] found in their study that though more frequentuse of shorter and smaller diameter implants, faster loading protocol without compromising the success rate was achieved by photo-functionalization. In the present study application of Platelet Rich Plasma with the described protocol was associated with improved stability of immediate loaded implants in the period between second and sixth week of their loading. Also the presented protocol found to improve the success rate of immediate loaded implants.PRP help in stimulation of fibroblast chemotaxis and production of collagen and fibronectin by cells while inhibiting collagen degradation by decreasing proteases, all of which favour fibrogenesis

Treatment with platelet rich plasma did not affect pain, bleeding, and /or numbness, but resulted in decreased inflammation.

MATERIAL AND METHOD

Study was conducted in department of Prosthodontics, crown and bridge, faculty of dental sciences, KGMU, Lucknow, UP. Patients were included according to predefined inclusion and exclusion criteria. Diagnosis was made on basis of history, clinical examination and relevant radiological investigation (OPG, Dental CBCT). Adequate bone dimension was measured from radiographs (IOPAR) to accommodate the implant within its axial inclination. Patients written consent was obtained before starting the treatment.

Case group subjects were randomized in two groups i.e. photo-functionalized (group1) implant and use of Platelet Rich Plasma (group III) with graft during dental implant.

Placement by computer generated random number. The control group (group II) include subject in which dental implant was placed using standard root form tapered dental implant. The study and rehabilitation protocol were standardized for all the groups. All subjects were evaluated for success rate, aesthetic outcome, marginal bone loss, and implant stability.

Resonance frequency analysis (RFA) was used to measure implant stability. It offers aclinical, non- invasive measure of stability and presumed osseointegration of implants. Implant stability Quotient (ISQ) is the quantitative unit for representing RFA values, it is on a scale from 1 to 100. An increased ISQ value indicates increased stability[11]. Marginal bone loss was measured by taking standardized intra-oral periapicalradiograph using individualized positioning stent and then evaluated by image J software[12].

The sample size was calculated using the following formula (CharanandBiswas, 2013)[13]

$n=2X(Z\alpha/2+Z\beta)2\ SD2/d2$
where n: Sample size per group
SD: Assumed standard deviation being 0.05.
d: Difference in the means (effect size)
$Z\alpha/2$: Significance level, $Z\beta$: Power of the study

The treatment in two groups will be given as under-

1. **Control Group (N=33)**

Normal untreated implant group

2. **Case Group (N=66)**
   - **Case Group 1(N=33**)Photofunctionalized implant group
   - **Case Group 2 (N=33)**PRP treated implant group

Eligibility Criteria

Gender- Male and Female both

Inclusion criteria for patients are given below:

a. Ability to understand and provide informed consent before starting the study.
b. Adequate oral hygiene to allow for implant therapy.
c. Freshly detected cases as well as pre diagnosed cases of chronic periapical infection.
d. Patients having tooth root stumps
e. Traumatized or fractured tooth

Exclusion Criteria

a. Smoking habit with moderate or tobacco chewing use or history of alcoholism or drug abuse within the past 5 years.
b. Severe bruxism or clenching habits.
c. Patient currently undergoing chemotherapy/ radiotherapy or drugs that interfere with the study.
d. Pathological change in the jaw bone.
e. Chronic inflammatory rheumatoid disease.

All patient received a prophylactic dose of antibiotic (2gm amoxicillin) 1 hour prior to surgery. After administration of 2% lignocaine with adrenaline (1:80,000) for local anaesthesia, tooth was removed preserving socket walls. Theosteotomy site was prepared with sequential increasing diameter of bone drills. Initial implant stability was achieved by engaging apical and palatal wall of extraction socket. Primary stability was achieved more than 35Ncm. For photo-functionalization implants were placed in photo-functionalization machine for20 minutes at the wavelength of 254 nm and then implants were placed in extraction socket. For PRP surface treatment blood was withdrawn from patient and placed in centrifuge machine at 3500 rpm for 10 minutes. Then implant was dipped in the sediment PRP solution and placed in extraction socket. Control group of implants did not have any treatment. implants were eventually evaluated for success rate, marginal bone loss, soft tissue loss and Implant stability. Resonance frequency analysis (RFA) is a method used to determine stability (the level of osseointegration) in dental implants. The stability is represented as an implant stability quotient (ISQ) value. Stability is directly proportionalto ISQ value. Osstellis a portable deviceusing a non-invasive technology based on RFA.

It has small measurement meter to display the readings, a measurement probe and smart peg (magnet) which is attached on the implant. To determine dental implant stability measurement probe was attached to the Meterdevice. Each time the measurement probe is moved close to smart peg, it emits electromagnetic pulses to smart peg (small magnet) which is attached to the implant. If probe is close enough to smart peg a beep is produced, sound travel through the probe and translates it to an ISQ value which appears on the screen representing values from 1 to100.The higher the number on screen, higher is the implant stability. Other than ISQ value memory position of the reading and status of battery are also displayed on the screen. ISQ value minimum between the range of 60 to 70 is recommended for loading protocol.

Loss of soft tissue will be assessed by following criteria -

Papillary index- for evaluation of presence and stability of the mesiodistal papilla [14]

Score	Criteria
0	No papilla is present
1	Less than half of the height of the papilla is present
2	At least half of the height of the papilla is present
3	Papilla fills up entire proximal space
4	Papilla is hyperplastic covered to much of restoration

Statistical analysis-Statistical Package for Social Sciences (version 20.0)(SPSS Inc., Chicago, IL, USA) was used for Statistical analysis

RESULT

Implants in 99 patients / subjects *i.e.* Total no. of implant placed using of implant placed using PRP treatment only = 33, Total no. of implant placed using photo-functionalized treatment only = 33, Total no. of normal implant placed = 33.

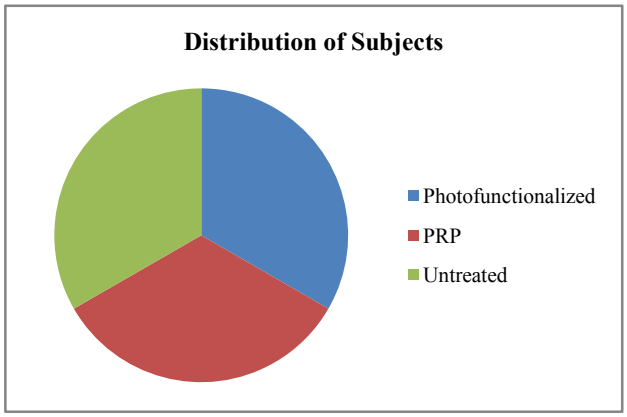

Figure 1

Table 1 and Figure 2 shows the mean difference of bone loss among three groups at different time intervals. It's shows a significant difference were found among groups. Lower mean of bone loss was observed in photo-functionalized group as compared to normal and PRP groups at 3 months and 6 months.

Table 1 shows the mean difference of bone loss among three groups at baseline, 3 month and 6 months of interval

	Groups						
	Photofunctionlized		Normal		PRP		p-value
	Mean(mm)_	SD	Mean	SD	Mean	SD	
Bone loss at baseline	0.00	0.00	0.00	0.00	0.00	0.00	NA
Bone loss at 3 months	0.69	0.13	0.97	0.26	0.82	0.23	<0.001
Bone loss at 6 months	0.67	0.14	1.01	0.29	0.84	0.27	<0.001

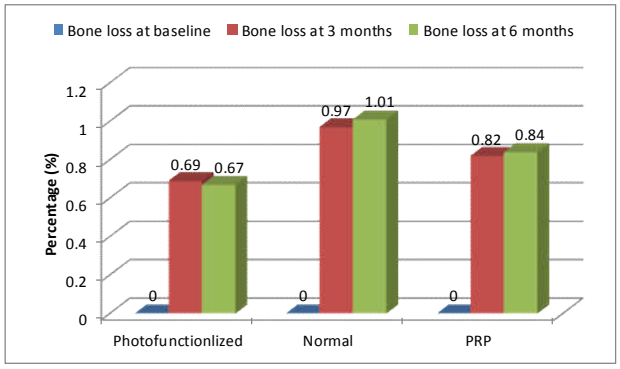

Figure 2

The average bone loss in photofunctionalized treated implants was significantly lower than PRP treated implants and untreated implants as 0.69,0.82,0.97 respectively at 3 months and 0.67,0.84,1.01 respectively at 6 months.

Table 2 shows Mean difference of bone loss at 3 months and 6 months in Normal vs Photo-functionlized groups were found statistically highly significant. While mean differences in Normal vs PRP and PRP vsPhoto-functionlized groups were found just significant. Its shows that higher mean difference was found in Normal vs Photo-functionlized groups.

Table 2 Mean difference of bone loss at baseline, 3 months and 6 months among three groups

	NormalvsPhotofunctionlized		Photofunctionlized vs PRP		Normal vs PRP	
	Mean difference	p-value	Mean difference	p-value	Mean difference	p-value
Bone loss at baseline	0	NA	0	NA	0	NA
Bone loss at 3 months	0.28	<0.001	-0.13	0.040	0.15	0.020
Bone loss at 6 months	0.34	<0.001	-0.17	0.013	0.17	0.012

Table 3 & Figure 3 months. It's shows a significant difference were found among groups. Highest stability score was found in photo-functionalized group as compared to normal and PRP groups at 3 months and 6 months. Table 3 shows the difference of mean stability scores among groups at 3 and significant. While mean differences in Normal vs PRP groups were found not significant.

Table 3 difference of mean stability scores among three groups at 3 months and 6 months

	Groups						p-value
	Photofunctionlized		Normal		PRP		
	Mean	SD	Mean	SD	Mean	SD	
Mean stability at 3 months	63.58	2.06	59.73	1.53	60.89	2.42	<0.001
Mean stability at 6 months	67.05	2.26	62.87	2.33	63.66	2.64	<0.001

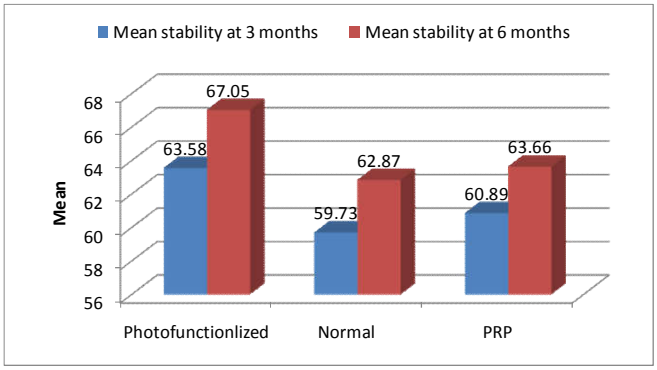

Figure 3

Therefore, it clearly signifies that photofunctionalized treated implants are much more stable in patients than PRP treated and normal implants. Table 4 shows Mean difference of stability scoresat 3 months and 6 months in Normal vsPhoto-functionalized groups and PRP vsPhoto-functionalized were found Statistically highly Above Table 5 & Figure 4 shows the mean difference of WES and PES scores among three groups after prosthesis placement.

Table 4 Mean difference of stability at 3 months and 6 months among three groups

	Photofunctionlizedvs Normal		Photofunctionlizedvs PRP		Normalvs PRP	
	Mean difference	p-value	Mean difference	p-value	Mean difference	p-value
Mean stability at 3 months	3.85	<0.001	2.69	<0.001	-1.16	0.066
Mean stability at 6 months	4.18	<0.001	3.39	<0.001	-0.79	0.405

Table 5 Mean difference of WES and PES scores among three groups after prosthesis placement

	Groups						p-value
	Photofunctionlized		Normal		PRP		
	Mean	SD	Mean	SD	Mean	SD	
WES	7.18	.73	5.18	.68	6.0	1.27	<0.001
PES	7.03	.88	5.33	.65	6.57	.79	<0.001

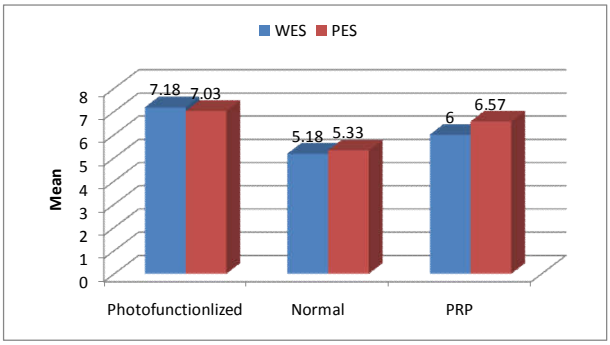

Figure 4

It shows a significant difference were found among groups. Higher mean of WES and PES were observed in photo-functionalized group as compared to normal and PRP groups at 3 months and 6 months.

Table 6 Mean difference of WES and PES score among three groups

	Normal vs Photo functionlized		Photo functionlized vs PRP		Normal vs PRP	
	Mean difference	p-value	Mean difference	p-value	Mean difference	p-value
WES	-2.0	<0.001	1.18	<0.001	-0.82	0.002
PES	-1.70	<0.001	0.46	0.042	-1.24	<0.001

WES score mean difference was found higher in PRP vs Photo-functionalized groups. While mean difference of PES score was higher in Normal vs Photo-functionalized groups.

Average loading time was found to be 3 months in photo functionalized treated implant place in maxilla and 2.5 months in mandible on the basis of implant stability recorded by RFA value which was found to be higher in photo functionalized treated implants, whereas in untreated implant it was about 6 months.

DISCUSSION

In total, 121 patients were assessed for inclusion in the study but 22 patients could not be included in the trial for the following reasons: nine patients decline to participate, seven patients had history of chronic smoking and tobacco chewing since 7-8 years daily, four patients had severe bruxism habit and two patients were in general poor oral health. Ninety -nine patients fulfilling the eligibility criteria were then randomized for the trial (33 in each group) and were treated according to the allocated interventions (normal vsphotofunctionalized).

Patients were divided into three groups randomly. Immediate implant placement in fresh extraction sockets not only provide the advantage of shorter treatment time but also minimize the number of surgical interventions. This is also helpful in reducing patients's morbidity an increasing their level of comfort in terms of surgical procedure. It was found that with this treatment the risk of alveolar bone resorption after tooth extraction was reduced, it was biologically and esthetically advantageous and also the gingival and crestal bone architecture was maintained.

Thirty-three untreated implants, thirty-three PRP treated implants and thirty-three photofunctionalized treated implants were placed in fresh extraction sockets. Photo-functionalization was provided after treating implants with UV light for 15mins at the wavelength of 254 nm using photofunctionalized device immediately before implant placement.

Within one week after implant placement assessment of alveolar marginal bone loss was assessed with the help of intraoral periapical radiograph.

The second stage surgery was placed in each patient after 3months in mandible and after 4 months in maxilla followed by placement of a gingival former over the implant.

For measuring stability of implants, implant stability measuring device (Ostell) was used in each group of trial: firstly, immediately after implant placement secondly, after three months (at the time of second surgery) and last after six months follow up after prosthesis placement.

Assessment of alveolar marginal bone loss was placed with the help of intraoral periapical radiograph in each group: firstly within 1 week which was considered to be the baseline, secondly after three months follow up and final evaluation of marginal bone loss was placed after 6 months of implant placement.

Soft tissue evaluation was placed in each group using pink and white esthetic score after implant prosthesis placement. Data obtained from all the study groups were then subjected to statistical analysis. The success rate of photo-functionalized treated implants in immediate fresh extraction sockets is relatively higher in relation to

1. Bone loss which is found to be comparatively less than other groups at 6 months and
2. Stability which is found to be higher in photofunctionalized treated groups as compare to other groups.

UV treatment reverses the aging process, therefore increases the strength and primary stability of the implants.

UV treatment leads to Hydrophilicity of implants which provides access for proteins &cells, promotes adhesion.

UV treatment makes titanium surfaces super hydrophilic, electropositive, and carbon free whereas untreated titanium

surfaces are hydrophobic, electronegative, and largely contaminated with hydrocarbons. [14]

UV treatment helps in cleaning carbon - contaminated titanium surfaces which reduces the carbon percentage that leads to electrostatic optimization which works as an attractant for protein and cells thus carbon contamination in human body will be almost nil.

Photo-functionalization treatmentincreases direct cell attractiveness by removing any contaminating hydrocarbons and this also imparts bio-functionality to TiO, a conceptuallybioinert material. [15],[16],[17]

The positive outcome of the study was helpful in faster and optimum rehabilitation of the missing teeth.

In the present study, crestal bone loss was significantly lower ($p<0.001$) in group I(photo-functionalized) than group II(control) and group III(PRP) at baseline, 3 months and 6 months.The average bone loss in photofunctionalized treated implants was significantly lower than PRP treated implants and untreated implants as 0.69,0.82,0.97 respectively at 3 months and 0.67,0.84,1.01 respectively at 6 months.

Mean difference of bone loss at 3 months and 6 months in Normal vsPhoto-functionalized groups was found Statistically highly significant. While mean differences in Normal vs PRP and PRP vsPhotofunctionalized groups were found just significant. It's shows that higher mean difference was found in Normal vsPhoto-functionalized groups.(table2)

After one-year bone level was found to be situated 0.5mm below the reference point which was above the first thread of implant. As this implant had 1.5 mm high smooth collar, it was not surprising that this part did not become bone integrated, this was because of the experience from previous branemark implant design with a 3.5mm tapered collar. It has been observed that some surface roughness is needed to better maintain the marginal bone. It was found that Marginal bone loss which was an average of -0.35+-0.71mm at the time of crown placement, had significantly increased to 0.16+-0.53mm after 1 year. This was indicating an overall coronal gain in marginal bone contact which in some cases even exceeded the level of the implant platform($p<0.05$). In particular all marginal bone loss that were apical to platform at crown placementincreased. On the other hand, those Marginal Bone Loss that were coronal to the platform maintained at the same level.

On Radiographic measurements variations in the extent of bone loss between mesial and distal aspect around the implants was revealed. Some implants were placed on ascending alveolar ridge as flat alveolar ridge was not always available at the implantation site. This resulted in different implant-abutment junction positions mesiodistally in relation to the bone level.

Other parameter which was examined is implant stability at the interval of 3 months and 6 months. At initial phase 3 months ISQ value was 65.83, 59.73and 60.89 for group I ,II,III respectively and at 6 months 67.05, 62.87,63.66 for group I,II,III respectively. Mean difference of stability scores at 3 months and 6 months in Normal vsPhoto-functionalized groups and PRP vsPhoto-functionalized were found Statistically highly significant. While mean differences in Normal vs PRP groups were found not significant.

Therefore, it clearly signifies that photo-functionalized treated implants are much more stable in patients than PRP treated and normal implants.

The great success rate in photofunctionalized group is generally attributed to the generation of its superhydrophilic (defined as a contact angle less than 5 degrees) surface after Photo-functionalized treatment, which results in greater Bone Implant Contact (2-3 times) as compared to normal untreated implants. Also, this hydrophilic surface results in greater attachment with osteogenic cell as compared with normal implants (without surface treatment).

The limitations of this study include small sample size, shorter duration of follow up and inability to assess buccal and lingual bone loss due to inherent disadvantage of the radiographic technique employed to access the bone loss.

Proposed null hypothesis regarding group difference for bone loss, stability, and esthetics and success rate was rejected. This research has found that bone loss and implant stability of photofunctionalized group shows significantly less bone loss and greater implant stability when compared with control and PRF treated groups. Whereas the combined esthetic value is found to be significant in photo-functuionalized treated group as compared to other groups and thus success rate was found to be higher in photofunctionalized treated group.

Future studies involving large cohort with longer duration of follow up and employment of advanced radiographic imaging modalities may overcome the limitations of the present study.

CONCLUSION

On the basis of result obtained by statistical analysisand within the limitations of the present study following conclusions have been drawn-

1. There was a significantly less crestal bone loss in photofunctionalized treated implants when photofunctionalized group was compared with control and PRP groups during the study period.
2. Thecrestal bone loss was non-significant when control and PRP groups are compared.
3. Although average loading time in implants got predicted according to stability check of the implants by RFA value however with longer follow up time period and larger sample size we could also compare exact average loading time among all the groups.
4. Further research must be aimed into microbial level, oral environmental, immunologic and nutritional interactions in addition to the success of implants in immediate extraction sockets.

Disclaimer

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