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Title: ***Mo² Maneuver, a stress-free novel protocol method for predictably restoring***
immediately loaded All-On-4® patients

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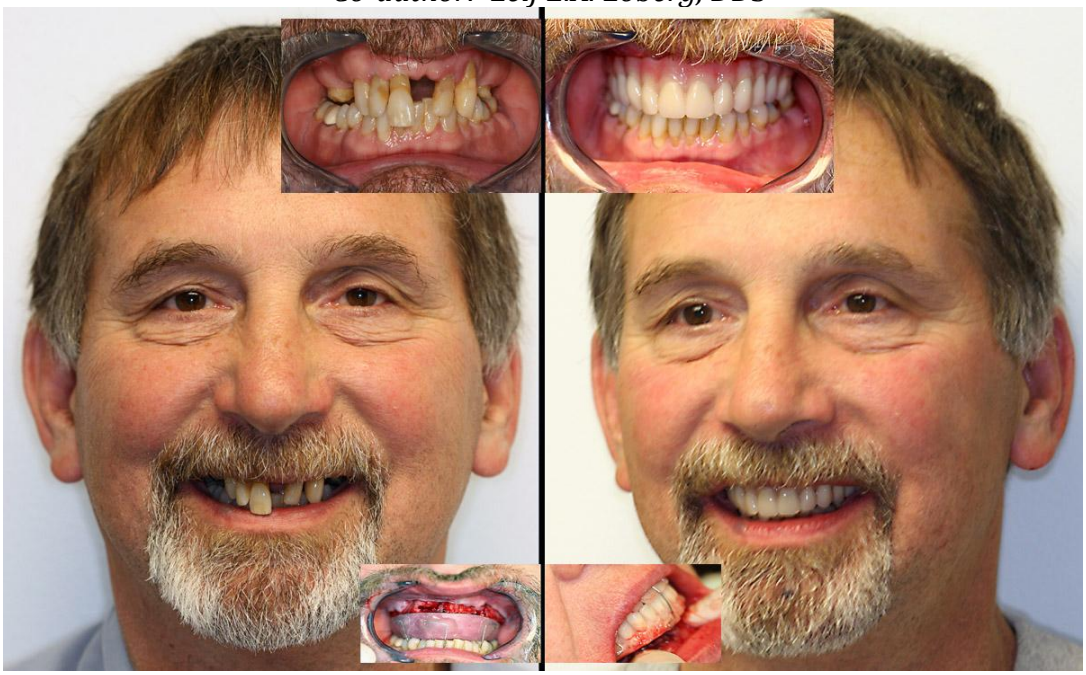

This innovative **patent pending** application is describing a totally novel method to be applied in conjunction with All-On-4® protocol on the patient with terminal dentition and especially where the restorative team members, i.e. surgeon, restorative clinician and implant lab are not within the same location.

Introduction: Receiving both surgical and prosthetic rehabilitation in one single visit, a signature of any immediately loading protocol in general and All-On-4® procedures in particular, has been undoubtedly incredibly rewarding for the patient- thus one of the reasons for the enormous explosion in popularity.
Although relying "only" on four implants, the entire All-On-4® rehabilitation process is highly delicate and complex procedure, requiring unison in-sink ***multidisciplinary*** performance of the entire restorative team in order to successfully restore each patient!

Nevertheless, having to puzzle together multiple extractions of terminal dentition; apply bone remodeling reciprocal to model planning; define adequate trajectory of newly placed

implants; correctly redirect angles of the prosthetic abutments; totally rearranged occlusal plane and reestablish new esthetic smile line based on visualizing calculation attempt to restore originally collapsed vertical dimension;; conclusively convert entirely new tooth set-up makeover into the screw-retained interim prosthesis delivered at the end of the entire surgical and prosthetic procedure -is obviously not always that easy to accomplish, especially not in one visit!

Background:

In a traditional All-On-4® protocol performed on already fully edentulous patient both surgical and prosthetic restorative parts and procedures are well documented both by the clinicians as well as the implant manufacturers and therefore fairly recognizable.

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Already in a very early stage of implant dentistry (1970), Brånmark *et all*[1] have determined that standard protocol needed for proper osseointegration of maxillae (upper jaw) and mandible (lower jaw) was 6 months respective 3 months of proper healing time until the implants are to be exposed in 2nd stage surgery and loaded with prosthesis. In 1989 Albertsson and Zarb[2] as well as many others after them[3,4,5] have concurred with that protocol as a standard for rehabilitation of the fully edentulous patients.

In a traditional All-On-4® protocol performed on already fully edentulous patient both surgical and prosthetic restorative parts and procedures are well documented both by the clinicians as well as the implant manufacturers and therefore fairly recognizable.

Being an alternative to any grafting, maxillary sinus elevation or other bone-augumentation procedure, the traditional All-On-4® surgical distinction is based on placing *four (4) intraforaminal implants for supporting the entire edentulous jaw.*

Two anterior implants are placed vertically with a perfectly straight trajectory and with the implant access hole distally of the second lateral and the middle of the canine. Consecutively, two posterior implants are placed still before foramina, but tilted in order to maximize AP spread thus minimizing the cantilever length. That surgically astute approach, introduced by Paolo Maló in 1993, is substantially decreasing the overall complexity and morbidity of the entire procedure thus probably being one of the main factors for explosive popularity of the technique when restoring edentulous population. Consequently all four (4) implants are prosthetically extended with standardized and off the shelf taper prosthetic abutments, called Multi-Unit abutments. The Multi-Unit abutments for two frontal anterior implants, are straight or as a 17˚ alternative and in the back on the posterior tilted implants, as a 30˚ alternative.

However a common denominator for most All-On-4® procedures reported lately by other authors[6,7] it doesn't focus on restoring genuine fully edentulous patients anymore but it consist of removing all existing terminal dentition, remodeling the bone by optimizing new horizontal ridge level and repositioning of the new smile line creating a total makeover. With the implants placed immediately into the fresh extraction socket and if primary stability is achieved, the industry recommendations is to proceed consecutively with the immediate loading of the implants delivering the prosthetics at the very same moment of surgery.

Therefore it is of importance to highlight that in the context of All-On-4® immediate loading restoratives there are two (2) groups of what is considered as to be ***fully edentulous*** patients: A.) currently fully edentulous (i.e no dentition present) and B.) fully edentulous to be (terminal dentition to be removed until no teeth present).
It is to be recognized that both groups are distinctively different when comparing its diagnostic and planning options hence diverse surgical and restorative characteristic approach to follow.

As an example, the value of DICOM CT-scan data and advances of current computerized guided dentistry is unfortunately still not that effective on the patient with terminal dentition as it is for traditional fully edentulous All-On-4® patients due to very preexistence of dentition that will be initially removed first in conjunction with the surgical phase of the All-On-4® protocol, hence not justifying for any functional STL file reproduction nor rapid prototype guide stent being pre-made.

Additionally it is to be recognized that operationally there are currently two (2) distinctive All-On-4® restorative subgroups with a different modus operandi and different logistic:

First group, group A, represents a group of clinicians and specialists that are embracing intimate interdisciplinary interaction operating via so called "one-stop-shop" dental clinics that are focusing exclusively on performing All-On-4® procedure. Experience gathered through personal participation and other data reports high level of predictability, repeatability and overall success.

Second group, group B, represents a typical stand-alone dental office environment with the restorative team working only occasionally and assembled temporarily for a particular procedure. Again, experience through personal participation and gathered data reports there are varieties of possible reasons that are impeding against ultimate stress-free success.

It is of importance to underline that this observation on unequal outcome predictability within both groups had nothing to do with expertise level of any particular part of the restorative All-On-4® teams since personal participation in both environments witness to high level of special knowledge on the subject within both groups.

However, it was conclusive that both A and B group of representative All-On-4® restorative teams are experiencing numerous problems along their All-On-Four protocols.
(again, based on the personal experience operating within both groups)

Furthermore it is to recognize that repeatability alone and high frequency performance of the same procedures is always contributing factor to perform a task or a procedure with more conformity to pre-set quality standards.

Despite all, the main observed difference was that group A, belonging to specialized All-On-4® dental implant centers, were (are) more compliant with the protocol, interactive and

almost instantaneously responsive in resolving fast arising problems during the procedure while the group B consisting of "independent" sole practitioners that are assembling parts of their team occasionally for particular procedure (99% of traditional MO) have had harder to "get back on track" after some major set-back, often caused while performing previous task by other " chain link" of the All-On-4® team i.e. other restorative team member, whether being surgeon, periodontist, implant lab technician…

The major observation, that was most devastating for the overall outcome was that the inclusion of the error was always undetected until the very end of the procedure.
The second observation was that there was no distinct and disciplined protocol compliance simply because there was nothing to comply to i.e. lack of interconnecting roadmap guide to follow.
Not only this caused extremely **discontent patient** and disappointed restorative teams but possibly great financial disruption.

Therefore based on all these observations and the experience obtained from both representative experts groups restoring All-On-4® patients, the new methodology consisting of several different tasks has been developed and continuously to be called **Mo^2 Maneuver** representing all steps performed in coherence.

Mo^2 Maneuver, a patent-pending methodology**,** consist of few different tools and tasks that becomes self-censoring blueprint based on checks and balances, a guiding vehicle throughout the entire All-On-4® procedure.

Mo^2 Maneuver is firmly "forcing" each clinician, participant of particular All-On-4® protocol, to get out of their own silos and in full compliance and self reliance (i.e. no need to have error pointed out but detecting incompliance by itself) reassuring predictably successful protocol outcome (i.e. no left, no right guessing, thus name Maneuver) jand NO occlusal adjustment whatsoever!

Moreover **Mo^2 Maneuver** will for the first time allow clinicians to present the patient with the representative mock-up of the new smile just 10-15 min into the lengthy procedure!! That has tremendously positive impact on the patient positive attitude and cooperation throughout the entire procedure to follow reducing burden from performing clinician(s) and increasing overall mutual comfort!

There are several complex but also few main and defining moments within a typical All-On-4® protocol in restoring patients with terminal dentition to be ultimately resolved in full compliance..
These three (3) specific main reasons that could cause failure of the entire All-On-4® procedures are categorized as following:

- ***Correlation of bone remodeling*** level with the pre-op planning and creation of makeover smile within an interim prosthesis. Possible scenario: The implant position is great but the bone height optimization was not sufficient and not in compliance

with model preplanning resulting often in compromised or mechanically failed interim prosthesis due to the lack of vertical space and compromising with the dimension requirements

- ***Reassurance of adequate implant trajectory*** assuring proper esthetic and mechanical properties and functionality of the interim prosthesis. Possible scenario: The prosthesis esthetics are great but unsatisfactory implant position is impeding against achieving good esthetics when the screw access holes exposed

- ***Reassurance of proper prosthetic abutment*** orientation reassures proper aesthetic as well as proper draw of insertion. Possible scenario: bone optimization as well as the implants position is highly satisfactory but due to the inadequate abutment positioning neither fundamental functionality nor basic esthetics obtained.

To proactively address all abovementioned obstacles it is simply to prescribe "All-On-4® per **Mo^2 Maneuver**" instead of explaining lengthy procedural intent .
The box containing newly calculated interim prosthesis together with the articles in a **Mo^2 Maneuver box t**hat will tie all roles of restorative team members into one sequential, surgical and prosthetic roadmap to follow, reassuring pre-determined success of each particular procedural step alone, as well as the entire All-On-4® procedure as a whole.

It prevents for possible error induced into the chain of events by a sole independent team member and creates highly disciplined and effective interdisciplinary mutual blueprint to be followed by the entire restorative team.

Mo^2 Maneuver box contains following:

- **Mo^2 Maneuver *Interim Prosthesis***, a signature and a 'source code" of Mo^2 Maneuver methodology including its exclusive calculation and way of generating the new makeover smile based on face and stone model reading formula! Partially flange-less PMMA acrylic prosthesis that is again following the Mo^2 Maneuver method, thus it is instantaneously attached (snapped) to the opposing dentition through the clasping mechanism!
  This **groundbreaking novel** thinking is pre-setting the occlusion of Mo^2 Maneuver interim prosthesis as a default key, which is setting the foundation for the entire assembling procedure against the implants.
  The hands of the clinician remain free and most important -the prefect orbital occlusion is pre-set and reassured
  The intaglio surface of the *Interim Prosthesis is* flat bedded and uptakes the original vertical space as well as correlates to bone reduction guide used in the first phase of All-On-4® surgical procedure.

  Therefore this revolutionary way of thinking doesn't require <u>any further occlusal adjustment at the end of any All-On-4® procedure!</u>

- ***Bone Reduction Guide***, a vertical rim equivalent to dento-osseous vertical topography that was removed from the patient's mouth by surgical and restorative

dentistry in the starting phase of the All-On-4® procedure. As a diagnostic vertical key mold, the rim is to determine new bone remodeling plane which will continuously become the platform for future implants.

- ***Surgical Bone Level Guide & Prosthetic Trajectory Guide,*** a transparent replica of the Interim Prosthesis used by the performing surgeon to simply define optimal implant trajectory despite raised flap and later by the restorative clinician to define optimal Multi-Unit abutment trajectory. In this step the surgeon will place four protocol implants correctly and within the contours of to interim prosthesis contours..

Results: The overall satisfaction was subjectively evaluated by several involved clinicians as well as tvelve**(12) featured All-On-4® patients** (# 5.maxillae only; # 4.mandible only; # 3. Maxillae & mandible) and experience was extraordinary, positive and significantly superior compared to experience with present All-On-4® protocols with no correlated roadmaps to follow.
Mo^2 Maneuver reduces burden for the first time for the performing clinician(s) providing for them explicit tools to follow a predetermined restorative roadmap and allowing them to show to the patient the mock-up of the final result a just few minutes into the procedure!

Conclusion: If performing All-On-4® treatment following **Mo^2 Maneuver**, the grand finale of the entire procedure is spent on rewarding cherishing moments of a remarkable stress-free makeover and the beginning of a new quality life for the patient instead of seemingly never-ending adjustment of the occlusion and other misalignments!

Restorative value of what become to be called **Mo^2 Maneuver** (pronounced ”mo square”) is showing superior result when compared to all other existing All-On-4® protocols both in the terms of user-friendliness and the overall patient satisfactory rate, thus making it something that is worthwhile to be shared within dental community!

The esthetic makeover is so powerful that it will always result in enormous enthusiasm and positive cooperation by the patient throughout the entire procedure!

Additionally, due to the development and procedural efficiency of this methodology, further advantage has been detected in regards to preparation work needed between the interim and final delivery phase!

Both the number of needed appointments and the time requirements for the clinical appointments was decreased substantially, so much so that in the best scenario only one additional visit was necessary!

Acknowledgment of tremendous efficiency improvement and its multiple effect on clinicians’ overall performance will be measured from the future empirical data collected on the subject and reported accordingly.