CLINICAL EVALUATION OF THE DYNA HELIX® TM IMPLANTS. TWO YEARS FOLLOW UP

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Summary
In this present clinical trial, 12 patients received in both arches 48 Dyna Helix TM implants in one-stage surgical procedure. The new implant design provided excellent primary stability in all cases. After 4 months, the patients received the prosthetic rehabilitations according to their needs. Nine of them received lower overdentures retained by ball attachments (4 implants at the interforaninal area); one received a fixed prostheses (Toronto protocol) on 4 implants in the lower jaw; one received an upper overdenture retained by 6 implants and ball attachments and the last one, was rehabilitated with a lower overdenture retained by two implants and a bar construction. The two years clinical follow up presented the patients satisfaction and the phonetics, mastication and aesthetics were highly improved. No radiograph control showed bone loss around the implants. One implant was lost after one month of the surgical procedure. Conclusion: with the limitation of this clinical research, it could be concluded that the Dyna Helix TM implants and their prosthetic possibilities provided a very satisfactory result in a 2 years clinical follow up.

Introduction

Current implant dentistry is considered to be a safe and predictable method for oral rehabilitation. The clinical success achieved by bone-integrated implants allowed for prosthetic restitution, as well as for its function and aesthetics, for both partly or totally edentulous individuals. The lack of retention, stability and comfort have being a constant worry on very resorbed mandibular alveolar ridges. In the last two decades, implantology has minimize these problems by providing retention for the lower dentures with ball, bar or magnet systems. While some studies presented the bar system offering more retention, others showed similar retention values for ball and bar systems. Other
experiments present important results on photoelastic analysis ⁴ and long term clinical follow up ⁴,⁸,⁹ concluding the excellent results on using these retention devices systems on lower overdentures. The concept of immediate implant loading has recently become popular due to less trauma, reduced overall treatment time, decreased patient's anxiety and discomfort, high patient acceptance and better function and esthetics. Nonetheless, research and understanding in this area are confuse and sometimes contradictory. A large and recent review of the current literature indicated that immediate implant loading achieved similar high success rate as that noted in the conventional approach (delayed protocols). However, a careful case selection, proper treatment plan, meticulous surgery and proper design of prosthesis are essential for optimal outcomes when this approach is adopted.¹. Distal implants are at higher risk for failure in the immediate loaded protocol ⁵

**Objectives**

This clinical study aimed to evaluate clinically and by using panoramic radiographies the DYNA HELIX ® TM implants as retention fixtures for overdentures on edentulous patients.

**Clinical cases**

For this clinical trial 12 edentulous patients, both genders, from 41 to 76 years old were selected. All of them presented normal systemic and health conditions for any surgical procedure. Genders, ages and needs are expressed in the TABLE1.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td></td>
<td>Lower overdenture</td>
</tr>
<tr>
<td>3</td>
<td>9</td>
</tr>
</tbody>
</table>

**TABLE 1.** Genders and needs.

The patients were initially submitted to clinical and radiography evaluations, models were mounted on semi-adjustable articulator. The patients received a pre-surgical medication of 1g of amoxaciline an hour prior to surgery, and a maintenance dose of
500mg every 08 hours for 7 days, and 15 mg of meloxicam also an hour before surgery, with maintenance for 5 days, every 12 hours.

In all the cases, carried out under local anesthesia, the gingival incision was done at the alveolar crest, and the mucosal and periosteum flaps reflected and sharp ridges removed by using drills and osteotomes.

The bone site preparations started with the careful use of pilot drills followed by Lindeman drills in the standardized sequence until the desired diameter was achieved. In most of the cases, due to the bone density (cases on anterior mandible areas), the bone preparation was finalized with the tapping instrument in very low speedy until the final depth preparation.

The implant site was carefully cleaned with saline and the Dyna Helix TM implants, which are based on solids and straight screws cylinder with 2.8mm polished collar, were inserted into the bone with the contra-angle handpiece at the maximum speed of 15 rpm and controlled torque. No irrigation with saline was used at this moment. It could be observed the proper implant surface wettability at this moment, with the blood rapidly covering all surface during the implant placement. The maximum implant placement torque achieved in all cases is presented in the TABLE 2. The implant sizes used are described in the TABLE 3.

<table>
<thead>
<tr>
<th>Implants</th>
<th>35 N</th>
<th>40 N</th>
<th>50 N</th>
<th>55 N</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,6 X 13</td>
<td>3</td>
<td>11</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>4,2 X 13</td>
<td>4</td>
<td>8</td>
<td>6</td>
<td>2</td>
</tr>
</tbody>
</table>

**TABLE 2. Implant sizes and implant placement torque**

<table>
<thead>
<tr>
<th>Implant dimensions</th>
<th>Maxilla</th>
<th>mandible</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,6 X 13,0 mm</td>
<td>6</td>
<td>22</td>
</tr>
<tr>
<td>4,2 X 13,0 mm</td>
<td>-</td>
<td>20</td>
</tr>
</tbody>
</table>
TABLE 3. Implant dimensions X implant placement areas

All the 48 implants used in the clinical trial received a 2,0 mm cover screw, and the sutures done around them for an one-stage surgical procedure.

Post operative care was followed by the medication, already mentioned, and the treatment with diode laser 980 nm; 1 watt; 8 minutes /per session/ daily for one week for reducing the post operative discomfort.

The patients did not use the dentures for one week and after that the sutures removed and the dentures relined with tissue conditioners.

The clinical evaluation of all cases were done after one week, two weeks, monthly, and after 4 months when the prosthetic rehabilitations have started.

Anatomic and functional impressions were taken until the proper functional models could be provided for establishing the end limits. Maxillo-mandibular relations were also taken and the models mounted into the articulators.

Teeth were proved and all functional and aesthetic aspects considered. The patients used the finished dentures for 15 days for removing all pressure areas.

According to the patients needs and expectation, they received different prosthetic retention systems available for the Dyna Helix ® TM Implants.

Nine patients received 4 implants in the anterior endentulous mandible (interforaminal area) and 4 smart matrixes ball attachments. One patient received two implants in the anterior area of its edentulous mandible and a castable bar and its retention clamp. One patient was treated with 6 implants in the edentulous maxilla and 6 smart matrixes ball attachments and one patient was rehabilitated with a TORONTO protocol fixed overdenture on 4 implants in the mandible.

Final panoramic radiographies were taken one year after the surgical procedures when the final clinical evaluations were done, presenting a successful clinical result.

The following case illustrates one of the procedures described.
1) Figure 1. Dyna Helix® TM Implant
2) Figure 2. Initial panoramic radiography

3) Dyna Helix® TM Implant and the Octa driver
4) The Dyna Helix® TM Implant being screwed into the bone

5) 4X Dyna Helix® TM implant placed in the mandible
6) The occlusal view of the Dyna Helix® TM + coverscrew 3 months after the surgery

![Occlusal View]

7) Panoramic Radiography : 3 months control

![Panoramic Radiography]
8) Dyna Smart matrixes on the top of the implants

9) Internal view of the denture with the Dyna Smart Matrixes
10) Dentures after finishing and polishing

11) Prostheses in place. 12 months control
12) Rx: control after 12 months

13) Rx: control after 24 months
Results

The two years clinical follow up showed that all the patients were very satisfied with the results. Phonetic, mastication and aesthetics were highly improved. The clinical aspects were very good with healthy gingival conditions around the ball abutments and intense retention provided by the ball attachments and the bar construction. No panoramic radiography presented considerable bone loss around the implants after two years.

One implant in the mandible was lost after one month of the surgical procedure.

Discussion

The rise in the number of patients seeking oral implants as a possiblity of treatment is considerable.

This clinical study has presented very favorable results on the Dyna Helix® TM implants rehabilitations. These results were confirmed by Esposito at al 2007⁶ which concluded in their study, that a 1-stage procedure might be preferable since it avoids one minor surgical intervention and shortens the waiting time to provide the final restoration. The retention increment and dentures comfort were also pointed out by the patients, in all different cases. Even in case when only 2 implants were placed in the interforamina area with 2 Dyna Smart matrixes ball attachments, the retention was highly increased , as confirmed by Marzola at al¹⁰. For those who received more implants or fixed prosthetic reconstruction the retention achieved was even higher. In this moment , is very important to make clear that all the concepts for the denture construction were highly keep, assuring that the mucosa and functional aspects could be preserved despite the presence of the implant retention devices.

The results presented an implant failure in a mandibular case were 4 implants were placed. The reason for early failure was probably caused by a little distance remained between 2 of the 4 implants placed in a very cortical mandible.
Conclusion:

With the limit of this clinical trial, it can be concluded that the two years clinical and radiography follow up of the cases treated with Dyna Helix TM was very positive, indicating the implant system and its prosthetic possibilities on one phase surgery technique.
Bibliography


