The Brånemark Novum Protocol: Description of the Treatment Procedure and a Clinical Pilot Study of 11 Cases

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The Brånemark Novum system is a new procedure for the one-day reconstruction of periodontally hopeless or edentulous mandibles. It consists of a series of four drill templates and eight drill guides to precisely position three implants that are completely level and parallel to one another. A prefabricated lower bar is attached to the implants. A prefabricated upper bar attaches precisely to the lower bar. The restorative clinician takes a bite registration at a previously established vertical dimension of occlusion. The case is waxed up and tried in the same day and delivered after processing. The procedure is described in detail, and 11 cases are reviewed. (Int J Periodontics Restorative Dent 2003;23:459–465.)

The Brånemark Novum concept (Nobel Biocare) is an evolutionary step in the development of implant dentistry for the treatment of the edentulous mandible. Since the introduction of osseointegration into clinical practice, there have been numerous modifications and enhancements of the classic procedure, including implant placement into immediate extraction sites and the use of autografts, allografts, and membrane therapy. These led to the use of single-stage implants and immediate loading.

The Brånemark Novum system is an approach to “same-day teeth.” It can be used to treat periodontally hopeless or edentulous mandibles. However, the mandible must have an appropriate shape and be approximately 12 to 13 mm in height and 6 to 7 mm in width. Brånemark Novum can be best used in Class I and III jaw relations, since the jaw preparation moves the ridge lingually.
Brånemark Novum system

The system uses a series of four drill templates and eight drill guides to position three implants that are totally level and parallel to one another. Once the three implants are placed, a prefabricated lower bar is attached to the implants. Prior to the surgery, the restorative clinician makes an impression of the maxillary teeth or denture, mounts the model using a facebow, and selects the mandibular teeth. Immediately prior to the surgery, marks are made on the nose and chin, and the vertical dimension of occlusion is recorded (Fig 1). Upon completion of the surgery and placement of the lower bar, an upper bar is attached to the lower bar. The restorative clinician then registers the jaw relation to the previously recorded vertical dimension. The upper bar and bite registration are transported to the laboratory. A setup is done. The wax try-in is completed and adjusted, and the case is processed and delivered later in the day.

The implants come in two lengths and two widths: 4.5 and 5 mm in diameter, and 11.5 and 13.5 mm in length. They are designated 4.5 × 11.5/6, 4.5 × 13.5/7, 5 × 11.5/6, and 5 × 13.5/7. A threaded portion is inserted into the bone, and an unthreaded collar portion above the bone essentially functions as an abutment, although it is all in one piece. The collar height is 6 mm in the 11.5 implant and 7 mm in the 13.5 implant.

Preoperative evaluation

The preoperative evaluation of a potential Novum patient is even more critical than in a conventional case, considering both medical health and local anatomy. Adequate jaw shape, height, width, and bone density and enough space between the mental foramen on each side are mandatory. A height of 50 mm is necessary to obtain access for the drilling components, templates, and implants. A Dentascan (Columbia Scientific) is invaluable for preoperative planning. It enables measurements to be taken in oblique and panoramic views to determine suitability for the Novum system. Life-size axial views are used to check the shape of the mandible in relation to the guide template. The implants are 16 mm apart, center to center (Fig 2). Suitable clearance is evaluated in relation to buccolingual undercuts, angulations, and mental foramina.

Advantages and disadvantages

There are numerous advantages to the Novum system:

1. One-day teeth
2. Reduced cost of surgery and prosthetics compared to other types of fixed cases
3. One surgical procedure
4. One anesthetic procedure
5. Immediate positive psychologic reinforcement for patient; no extended treatment
6. No casting
7. No impressions
8. Minimal laboratory expenses

The disadvantages are as follows:

1. Presence of lower bar when patient pulls down lower lip.
2. Inability to provide individual crown-and-bridge units.
3. Inability to use for Class II division I patients.
4. Lack of additional implants if one implant fails.
5. Restorative clinician must be present for surgical procedure.
6. Difficulty of coordinating with dental laboratory.
7. A laboratory technician needs to be assigned to the case until completion.
8. Labor-intensive surgery.
10. Expensive, dedicated, reusable components.
11. Patient selection limited by mandibular height, width, shape, size, and density and mental foramina position.

Surgical treatment

All of the cases treated were managed with an anesthesiologist providing conscious sedation and monitoring with an electrocardiogram and pulse oximeter. In the present cases, the full Brånemark operating room protocol was used in a dental operatory specially designed for implant treatment. After face preparation with Hibiclens (Zeneca Pharmaceuticals) and mouthrinsing with chlorhexidine, oxygen is
administered and the patient is completely draped. The anesthesiologist sets up the intravenous sedation, and local anesthesia is administered. The cases can be well managed with infiltration local anesthesia.

If teeth are present and can be removed easily with forceps, this is completed prior to the initial incisions, which makes them easier to carry out and improves access. In an edentulous case, a crestal ridge incision is used. The buccal and lingual flaps are reflected (Fig 3), the mental foramen on each side is identified, and lingual concavities are evaluated. All cases treated were evaluated with a Dentascan, making extensive lingual reflection less necessary. The ridge incision extends to the first molar on each side.

A heavy rongeur is used in conjunction with large Brasseler surgical burs to flatten the ridge. It is critical not to lose orientation of the midline and occlusal plane of the maxilla. It is helpful to inscribe a small bur line on the buccal surface of the mandible at the beginning of flap reflection. If the mandibular incisors are present, this aids the location of the midline. Once the ridge is flattened to 6 to 7 mm in width (Fig 4), somewhat distal to the mental foramen, the first template—the 7-mm-wide guide template—is used (Fig 5). A standard round-bur penetration is made in the midline. It is critical to evaluate the guide template in relation to the mental foramen; adequate
clearance anteriorly is mandatory, being mindful of the anterior loop.

Once the central and posterior sites have been marked, they are evaluated in a buccolingual position. It is helpful at this point to use a standard 2-mm Nobel Biocare 7-15 drill, since it has familiar depth markings that the Novum drills do not have. Once the guide template sites are acceptable, the second template is used (Fig 6). The function of the evaluation template is to check for flatness of the ridge and parallelism to the maxillary occlusal plane. It is also used to continue to drill the three sites in a parallel fashion. It is important to avoid any binding in the drill sites. At this point, changes can be made to correct any discrepancies in the mandibular platform. However, minor discrepancies are not of major concern.

The third template is the positioning template (Fig 7); it properly places the central implant in a vertical direction with the proper buccolingual position. The template is stabilized in the posterior sites with special guide pins. The drill guides are positioned in the template in an anteroposterior direction. Special drills are used, starting at 2.0, 3.0, 3.5, 3.8, 4.0, 4.2, and 4.4 mm. A special drill tap is used at 5.0 mm for a 5.0-mm implant. The 4.5-mm implant is drilled to 3.8 mm and tapped at 4.5 mm. There are drills for the 11.5 and 13.5 implants; the 13.5-depth drills have markings for 11.5.

The implant is placed with a Novum implant mount; each diameter of implant has appropriate implant mounts. The implant is delivered until it bottoms out and is hand tightened with a standard cylinder wrench. At this point, the positioning template is removed and the implant is evaluated (Fig 8). The fourth template—the V template—is attached loosely to the central implant with a temporary screw, and the 2-mm drill guide is placed laterally in the posterior sites. The guide pins are placed in the posterior sites, and the temporary screw is tightened with the cylinder wrench. The 2-mm drill is used to drill two intermediate sites in the V template. Two stabilizing screws are then placed and minimally tightened with the cylinder wrench. At this point, the V template is totally stable and attached to the central implant and the two stabilizing screws. The posterior sites are now drilled following the same sequence. The sites are tapped, and the posterior implants are placed and tightened with the cylinder wrench (Fig 9).

The implant mounts, stabilizing screws, and temporary screws are removed. At this time, three implants are totally level and parallel (Fig 10). The flaps are sutured securely, and a silicone sheet is placed to hold the tissue down, separate the soft tissue, and seal the area in a relative sense. The lower bar is placed, being careful not to trap any soft tissue or the silicone sheet on the implants. Three temporary screws are placed with three compression rings. The

Fig 5  Guide template with guide pins is 7 mm wide. Standard guide pins work better than Novum guide pins.

Fig 6  Evaluation template checks flatness of ridge and relationship to maxillary teeth; correction to platform can be made at this stage.

Fig 7  Positioning template, guide pins, and 2-mm drill guide for central site. It is important to hold down all components to prevent any movement.
implants have a small flange; the cylinder wrench is used to incrementally and sequentially tighten the compression rings until they flatten out and bend the flange, creating intimate contact between the implants and lower bar. The temporary screws are removed, one at a time, and replaced with the lower bar screws by hand; it is critical that they be placed with no resistance. Once the lower bar screws have been tightened by hand, they are tightened to 45 N/cm with an electronic torque controller (Fig 11).

Prosthetic treatment

At this point, the restorative clinician takes over. The upper bar is placed with two upper bar screws (Fig 12). The restorative clinician takes a bite registration using wax or putty and has the patient close to the original vertical dimension recorded at the beginning of the case.

The upper bar is removed and sent with the bite registration to the laboratory. A silicone protection rim is placed over the lower bar to protect the tongue during the day. The teeth, which have been previously selected, are set; the case is tried in later that day. Any corrections in the setup and occlusion are made, and the case is processed. Later in the day or the next morning, the case is delivered and any occlusal corrections are done (Fig 13). Postoperative radiographs are taken to verify the fit and evaluate the bone (Fig 14).

The patient is followed postoperatively, and 1 or 2 weeks later, the silicone sheet and sutures are removed and the patient is instructed in proper oral hygiene and care of the restoration. The four upper bar screws that hold the restoration are tightened to 45 N/cm.
Case reports

To date, 11 cases have been treated with the Novum protocol (Table 1). The longest follow-ups have been more than 1 year. Among the medical conditions that the patients presented with were lupus erythematosus, diabetes, rheumatoid arthritis, osteoporosis, hypertension, and smoking.

One case was unsuccessful. The lower bar screws were not passive, and ultimately the implants were lost. There must have been some movement of one of the templates and the parallelism was lost, causing a nonpassive fit that caused torque to the lower bar screws, which was transferred to the implants. The drill guides sometimes have a tendency to lift up and must be firmly held down by both the surgeon and the surgical assistant. The case was subsequently treated successfully in the classic method with four implants.

Based on only 11 cases treated in a clinical practice, there was a nearly 91% success rate, which will improve as more experience is gained with the procedure.

The Novum protocol has numerous advantages and specific disadvantages. It is necessary to treatment plan these cases quite carefully. The procedure is very demanding, offering a unique ability to provide patients with one-day treatment from start to finish. It is another treatment modality that has tremendous potential to treat a specific category of patients in a safe and predictable way with immediate loading of the mandibular fixed reconstruction. The Novum system has the potential to bring implant reconstruction into mainstream dentistry.

Acknowledgments

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References

Table 1  Summary of treated cases

<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age (y)</th>
<th>Health status</th>
<th>Dental status</th>
<th>Implant size</th>
<th>Postoperative follow-up (mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>50</td>
<td>Lupus erythematosus</td>
<td>Maxillary teeth present; advanced mandibular periodontitis</td>
<td>(3) 5 × 11.5/6</td>
<td>15</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>75</td>
<td>Hypertension; glaucoma; former smoker</td>
<td>Hopeless maxilla (immediate denture); advanced mandibular periodontitis</td>
<td>(3) 5 × 11.5/6</td>
<td>14</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>70</td>
<td>Heavy smoker, 50y</td>
<td>Hopeless maxilla (immediate denture); advanced mandibular periodontitis; caries</td>
<td>(3) 5 × 13.5/7</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>55</td>
<td>Negative</td>
<td>Maxillary teeth present; advanced mandibular periodontitis</td>
<td>(3) 4.5 × 11.5/6</td>
<td>12</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>77</td>
<td>Former smoker</td>
<td>Completely edentulous</td>
<td>(3) 4.5 × 11.5/6</td>
<td>*</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>66</td>
<td>Hypertension (enalapril maleate); osteoporosis (raloxifene)</td>
<td>Maxillary teeth and prior implants; prior mandibular posterior implants¹</td>
<td>(3) 4.5 × 11.5/6</td>
<td>12</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>79</td>
<td>Diabetes (insulin)</td>
<td>Completely edentulous</td>
<td>(3) 4.5 × 11.5/6</td>
<td>12</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>51</td>
<td>Hypertension (fosinopril, felodipine); heavy smoker</td>
<td>Hopeless maxilla (immediate denture); advanced mandibular periodontitis; caries</td>
<td>(3) 5 × 11.5/6</td>
<td>6</td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>64</td>
<td>Rheumatoid arthritis (methotrexate, prednisone); osteoporosis (alendronate sodium)</td>
<td>Complete maxillary denture; advanced mandibular periodontitis</td>
<td>(3) 4.5 × 11.5/6</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>F</td>
<td>65</td>
<td>Negative</td>
<td>Complete maxillary denture; advanced mandibular periodontitis; caries</td>
<td>(3) 4.5 × 11.5/6</td>
<td>4</td>
</tr>
<tr>
<td>11</td>
<td>M</td>
<td>54</td>
<td>Smoker</td>
<td>Maxillary teeth present; advanced mandibular periodontitis; caries</td>
<td>(3) 5 × 11.5/6</td>
<td>3</td>
</tr>
</tbody>
</table>

*Lower bar screws not passive, implants lost; case retreated with conventional implants.
¹Novum implants placed anterior to prior implants.