Pushing Back the Limits of Implant Dentistry by Combining Anatomo-Physiological Root-form Implants and Diskimplants with Stem Cell Activation

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Abstract: Treatment of patients with extremely resorbed jaws is a major public health challenge. Anatomo-physiological Diskimplants (APD) and microthreaded, self-tapping, smooth surface root-form implants (APR) were developed in the early 2000s to overcome these difficulties. Used with an immediate functional loading procedure, patients can be equipped with fixed teeth 48 hr. post-op. Application of bone matrix Osseotensors to activate the patient’s own stem cells improves both the initial bone quality and neangiogenesis, thereby reinforcing the highly atrophic recipient bone sites for placement of these implants. This combined approach allows the surgeon to manage completely resorbed jaws in a much simpler and safer manner than previously thought possible.

Keywords: Basal implantology, Bone matrix Osseotensor, Diskimplants, Severely atrophic jaws, Stem cell activation.

INTRODUCTION

As life expectancy has increased, the number of completely edentulous individuals who are difficult to equip with conventional prostheses has risen drastically. Furthermore, removable dentures are often poorly tolerated and can require considerable amounts of adhesive to stay in place; they also accelerate bone resorption year after year. Such oral invalids are hard to manage without prior complex surgeries that patients are frequently reluctant to undergo. Self-tapping and press-fit microthreaded tubero-pterugoid Fractal implants and Fratex bone-expanding implants for narrow ridges can provide stable anchorage in critical sectors. Stress-absorbing plate-form Diskimplants with eyelets for osteosynthesis screws can be safely installed in and/or on the native living bone of the zygoma, the canine pillars and the ramus sectors, then covered over with innovative bone substitute materials (Ivory, CoreBone, BioOss, etc.) and PRF. Along with the contribution of stem cells, this approach makes it possible to increase the initial bone volume and quality.

Predictable implant management for completely edentulous, severely atrophic jaws using conventional two-stage surgical techniques [1-3] remains a challenge in implant dentistry. Jemt reported a cumulative survival rate of only 69.9% with machined, grade 1 titanium screws (Branemark) placed in almost 100 severely resorbed maxillae. Jaffin reported a 56% rate of implant loss when implants were placed into maxillae with Type IV bone [4]. Over the years, controversy has existed between advocates of immediate implant loading and proponents of delayed protocols. Early research on immediate loading with root-form implants was conducted with vitallium screws in the 1930s by Alvin and Moses Strock [5] and was often criticized for inducing fibrosis and increased implant failure. The two-stage surgical approach of Branemark, using a submerged healing period, became the treatment of choice for root-form implants from 1980 to 1990. Schnitman [6] reintroduced the concept of immediate loading for completely edentulous patients in the mandible with a threaded, machined titanium implant in 1990. Tarnow [7] also published a pilot study and expanded the procedure for fixed restorations in completely edentulous maxillae. These combined trials of 19 patients over a 9-year period gave an implant survival rate of over 93% (21 of 25 implants for Schnitman and 67 of 69 implants for Tarnow).

A recent review of the outcome of 1690 machined artificial titanium dental roots (including 754 laterally-inserted anatomo-physiological Diskimplants) installed in 248 patients with extremely resorbed fully edentulous jaws by the same team from Feb. 2000 to Feb. 2019 revealed the efficacy and the benefits of this alternative to more invasive and complex bone grafts that can often be avoided. This approach has also proven useful for rescue of clinical situations in which
bone grafts have failed or are insufficient for the placement of conventional implants. All of the implants used had a non-modified, machined smooth surface *ad modum Branemark*. As a result, peri-implantitis was practically inexistential (less than 0.1%) in this 19-year follow-up study. Since October 2003, a post-graduate program on the use of these medical devices has been organized in the Maxillo-facial Surgery Department of the University of Nice-Sophia Antipolis Medical School in Nice, France.

**Peri-Implantitis**

**Rough Implant Surfaces**

Claiming to increase implant stability and promote faster osseointegration, rough surface [8], root-form implants progressively replaced machined, smooth surface implants *ad modum Branemark* and became the new standard. "All-on-Three", "All-on-Four", and zygomatic root-form implants placed using an immediate loading procedure were proposed as means to avoid prior bone grafting, Lefort surgery, mandibular nerve displacement, and sinus lift procedures in atrophic jaws. Short and ultra-short implants, used mainly with a two-stage approach, were also developed to overcome the lack of bone height in the posterior maxilla and mandible. As use of these implants with moderately to extremely rough surfaces increased, reports of peri-implantitis began to appear in the literature worldwide. Certain studies have concluded that peri-implantitis is multifactorial and that the true causes are still uncertain [9], while another very recent investigation with a 7-year follow-up period found a correlation with rough surfaces [10].

**Smooth, Machined Implant Surfaces**

All of the artificial titanium dental roots reported on in this article had a smooth, non-modified machined surface *ad modum Branemark*. Only 5 of the 1690 implants placed over the 19-year study period developed signs of peri-implantitis. This finding is in agreement with the publication of the University of Nantes (Dec. 2018) that describes the events that occur around the rough surface (and even minimally rough surfaces such as SLA) of implants equipping human jaws during function. Tribological effects, particle wear and metal release from rough implant surfaces under occlusal stress are probably the true origin of peri-implantitis with time, despite the higher torque required for their removal. It should be kept in mind that implants with machined, smooth surfaces *ad modum Branemark* have the longest history of proven osseointegration of any type of artificial titanium roots placed in human jaws.

**Multicortical Anchorage**

Unlike traditional root-form implants, which are primarily designed to be supported by trabecular bone, the approach described in this article used Diskimplants, which are inserted from the basal lateral aspect of the host bone and provide multicortical support, and root-forms with an apex that was purposefully engaged in the remaining skeletal cortical basal bone. This is of paramount importance because cortical bone is less sensitive to the deleterious effect of osteoporosis due to aging and the hormonal changes that occur after menopause [11-15].

**MATERIALS AND METHODS**

From February 2000 to February 2019, 248 patients (158 women, 90 men) equipped with a total of 1690 anatomo-physiological implants (Table 1) were entered into this study. The mean age at implant surgery was 66 years (range 42–91 years). All patients had severely resorbed, completely edentulous jaws (Misch-Judy division D resorption) as determined by analysis of cone beam (Vatech) 3D imaging [16, 17]. None had any general health problem that would contraindicate implant surgery and all were considered psychologically fit to undergo the procedure. Informed consent was obtained after explanation of the benefits and risks of the proposed technique as well as other implant alternatives (i.e. submerged two-stage surgery, one-stage non-submerged, bone grafting from the ilium or cranium, and/or removable conventional full dentures retained by implant-supported bars, O-rings or Locators). Candidates were informed that frequent office visits would be required during the week following surgery, and that 48 hr. were required for fabrication of the prosthesis, during which time no prosthesis was to be worn. The deleterious effects of smoking were also stressed, as was the need for proper oral hygiene and, in particular, peri-implant maintenance.

### 1. Patient Selection

A. All patients presented highly atrophic, totally edentulous jaws that could not be equipped without prior maxillo-facial surgery, extensive bone grafting or lateral mandibular nerve displacement, Lefort maxillary orthognathic surgery, a sinus elevation procedure, or a pedicular graft from the fibula or scapula, etc. They all refused such procedures.

B. The completely atrophic jaws of these patients were not safely manageable with any type of
Table 1: Severely Atrophic, Completely Edentulous Jaws Treated by the same Team with Anatomo-Physiological Artificial Titanium Dental Roots (Standard Diskimplants®, Horizontal plate-form Diskimplants® and Root-form Implants) using an Immediate Functional Loading Protocol (Feb. 2000 to Feb. 2019). All implants had the same smooth machined surface *ad modum Branemark*. Patient Age Range: 42 to 91 yr (mean 66). Total 248 patients (158 women, 90 men)

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<th>Mandible Disks and Plate-form Disks</th>
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conventional root-form implant (including zygomatic or tilted implants). Two ridge types were identified:

- Type EFR: extremely flat ridge (less than 3 mm of available bone height remaining regardless of the bone width) (Figures 1,2)

Figure 1: Lateral osteotomy allows installation of a Diskimplant at a depth of 1.5 mm. EFR (extremely flat ridge).

Figure 2: Clinical results after 10 years of service. No bone loss but rather a bone gain. Since 1984, the titanium Diskimplant with a smooth surface is the world’s shortest successful implant system that can be safely placed in a bone height of less than 4 mm.

- Type ENR: extremely narrow ridge (less than 3 mm of bone width remaining regardless of the bone height) (Figures 3-5)
Figure 3: ETR: extremely thin ridge with less than 2 mm of bone width at the crest. Bone height 13 mm.

Figure 4: Double Diskimplants are placed in the buccal aspect, secured with orthopedic screws, then completely covered by bone substitute material and autologous PRF.

Figure 5: Maxillo-mandibular reconstruction (ENR and EFR) with an immediate loading protocol.

2. Protocol for All Patients

Creation of the intended prosthetic space (virtual / true (retro planning)) with a conventional full denture taking esthetics, speech and occlusion into consideration.

A. Pre-operative strategy:

- pre-op Botox one week prior to surgery
- activation of the patient’s stem cells using a flapless technique with manual and/or rotary (mandible only) bone matrix Osseotensors (Victory)

B. Surgery: anchor anatomo-physiological basal and root-form implants in the main cortical skeletal pillars of the atrophic jaw

C. Impression taken in the operating room at the end of surgery at completion of suturing for fabrication of an immediate, highly rigid, screw-secured functional prosthesis

D. Fabrication of the prosthesis (with a transpalatal bar for the maxilla) in the dental laboratory within 48 hr.

- long-term transitional screw-secured prosthesis (highly rigid cobalt-chromium framework and resin teeth): transpalatal bar (maxilla only) to be removed after 6 months
- The provisional appliance acts as an external orthopedic fixation device ensuring reliable, long-lasting primary stability.

E. Immediate post-operative care: the patient is examined 24 h after surgery and after placement of the screw-secured prosthesis (all screws are retightened the following day).

F. 6 months post-op: the fixed prostheses are unscrewed; each implant is checked individually and radiographs are taken. The prosthesis is then screwed back in place after any necessary corrections have been made. The patient is then seen once a year (clinical exam and radiographs) or beforehand if necessary. The prosthesis is not retrieved at these follow-up visits if there are no problems.

G. Two years post-op: if desired, replacement of the transitional appliance by a full zirconia (ZirkonZahn) prosthesis; each implant is checked after retrieval of the immediate screw-secured prosthesis. The transitional appliance is used as a transfer by the dental laboratory.

H. Long-term follow-up:

Annual verification includes:

- panoramic, retroalveolar, cone beam imaging
- clinical examination of soft tissues and occlusion
• discussion with the patient concerning esthetics, comfort, cleaning, function, etc.

**Pre-implantation Stem Cell Activation with Bone Matrix Osseotensors [18-24]**

**Rationale for Flapless Bone Activation**

Use of a manual or rotary Osseotensor depends on the intended implant site and bone density. Just as mechanical microtrauma of the periosteum induces subsequent repair, surgical trauma of the cortical bone results in a burst of localized hard tissue remodeling. The microcracks caused by penetration of the Osseotensor (Victory, Nice, France) induce the release of bone matrix growth factors (bone morphogenetic protein and insulin-like growth factor I, II, and beta) that have a range of biologic properties [25-28]. Osteoinductive proteins from the bone matrix recruit stem cells at a distance from the microcracks that participate in the bone remodeling process. Complex interactions have been demonstrated between bone matrix tensions and signaling molecules (extracellular matrix, bone cells, cell nuclei). In addition to the existence of osteoregulation processes based on mechano-transduction, osteotension triggers and regulates bone regeneration. These observations, plus the findings of research in such fields as mechanobiology, tensegrity, corticotomy, distraction osteogenesis, and angiogenesis prompted the development of a specific instrument capable of producing calibrated microcracks without any local metal contamination or heat damage to tissues [29-31]. Transparietal penetration of the Osseotensor through the osteogenic compartments (periosteum, bone matrix, endosteum, vascular walls, bone marrow) instantly modifies the bone matrix tensions implicated in bone homeostasis (Figures 6-9).

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**Figure 6:** Bone matrix Osseotensors (manual and rotary). Their purpose-designed tip is coated with diamond-like carbon (DLC). Lower left: tests of various materials. Lower right: human cell cultures demonstrated the excellent compatibility of DLC.

**Figure 7:** Flapless penetration of the bone matrix Osseotensor through soft and hard tissues in order to promote new bone regeneration several weeks before implant installation.

**Figure 8:** Timetable of biological events following penetration of the bone matrix Osseotensor.

**Figure 9:** Clinical use of bone matrix Osseotensors in the sinus region. The Fractal Lift technique is performed 45 days after application of manual Osseotensors that creates a bone gain thanks to stimulation of local stem cells. No bone substitute material is required.

**Anatomo-Physiological Implants (Figure 10) [32-34]**

A total of 1690 anatomo-physiological machined titanium implants with a smooth, superclean surface were installed over a 19-year period (Diskimplants and root-forms) (Figures 11, 12). Designed to engage lateral regions of cortical bone, Diskimplants are impacted laterally into an osteotomy site prepared by a dedicated titanium osteotome mounted on a high-
speed air turbine under copious irrigation operating at 60 psi. Single-, double-, or triple-disk models (depending on available bone dimensions) were inserted to achieve multicortical support. In many cases, they were combined with axially inserted root-form Fractal or Fratex crest expanding implants of various lengths, primarily in the region of the tuberosity and anterior thin ridges. These macrothreaded root-form implants, which are also microthreaded, are self-tapping and offer an increased surface area.

The artificial dental roots used in this study were designed to be anatomo-physiological fixtures: they respond to both the static anatomical challenge of the maxillo-mandibular skull and various dynamic physiological components (bone density, shearing forces, and tribological effect under the permanent stress of mastication) with little if any release of titanium particles in the peri-implant tissues. This is particularly important because an immediate functional loading procedure was used (Figure 13).

Figure 10: Front view of anatomo-physiological root-forms and Diskimplants (eggshell-thin maxilla and highly atrophic posterior mandible) (EFR).

Figure 11: Titanium cutter, Fratex implant, Diskimplant, Fractal implant, Structure implant: all of these implants present a machined, smooth surface ad modum Branemark.

Figure 12: Horizontal plate-form Diskimplants with eyelets for orthopedic screws. These implants are placed partially into the jaw bone and then completely covered by bone substitute material and PRF.

Figure 13: Maxilla: Diskimplants in service for 35 years (1984-2019).


Immediate Loading Protocol

Patients were premedicated with Atarax (100 mg), a Lamaline suppository, amoxicillin (1.5 g), and diazepam (20 mg) 45 minutes before surgery. Regional and local anesthesia (Alphacaine) was administered 25 minutes before surgery. Bone volume, density, and the perimeter of the arch determined the number of anatomo-physiological implants of various shapes to be placed. Bone height around each implant was recorded at insertion. Transgingival, cylindrical abutments for screw retention, selected as a function of gingival thickness, were connected to the implants at the end of the implantation procedure and were tightened to 20 N-cm. The flaps were sutured around these abutments for primary closure. Machined titanium impression copings were screwed onto the implant abutments and then bound together with dental floss and Duralay resin (Dentsply) or Luxabite (PRED). A pick-up impression with soft and hard silicone was taken without an impression tray. Bite registration was performed with a class A, irreversible hydrocolloid or silicone which transferred the locations of the impression copings into a stone cast, thereby permitting prosthesis fabrication to be completed using the indirect technique.
Bone quality is determined preoperatively by tactile sense with a manual Osseotensor and cone beam CT and at the moment of surgery. An accurate tool for achieving tricortical anchorage, the specially designed titanium osteotome (cutter) is compatible with use in extremely small bone volumes as well as in low-density bone.

**Figure 14:** ETR: lateral osteotomy with a titanium cutter. The cortical bone ridge is less than 2 mm thick (the cutter shaft measures 1.8 mm). Following osteotomy, a triple Diskimplant is impacted laterally into the bone site.

**Figure 15:** Lateral bone bed in ETR. It is of paramount importance to maintain bone cell communication by avoiding passing completely though the thin bone wall with the vertical cutter shaft. Only the cutter base can pass slightly through if required.

**Figure 16:** Series of multi-disks are then covered by bone substitute material and PRF.

**BASAL LATERAL OSTEOTOMY (Figures 14-17) [35-38]**

A full-thickness flap is first carefully elevated so as not to damage the periosteum. The recipient bone site for the future Diskimplant is then prepared using a 300,000-rpm high-speed turbine (>60 psi) under copious spray and lateral saline irrigation. Use of a small 5-mm-diameter cutter to start the lateral T-shaped incision allows verification of bone quality.

**Figure 17:** The full thickness flap is then sutured around the implant emergence so the impression can be taken immediately in the operating room; this allows immediate fabrication of a highly rigid, functional screw-secured prosthesis in 48 hr.

**CRESTAL (AXIAL) VERTICAL AND/OR OBLIQUE OSTEOTOMY (MAXILLARY CANINE AND TUBEROSITY REGIONS, MENTAL AREA OF THE MANDIBLE) (Figures 18, 19)**

Bone quality is evaluated by tactile sense with a manual Osseotensor and during crestal (axial) osteotomy with a stepped pilot drill.

Maxilla: Crestal osteotomy is performed at 1,000 rpm solely with a stepped pilot drill, followed by placement of a self-tapping Fractal implant.

Mandible: a Fractal drill is recommended for Fractal implants. For Fratex implant placement in extremely narrow ridges (ENR), use only a bone matrix rotary drill (large diameter) then place the implant.

**POSTOPERATIVE CARE**

During the immediate postoperative period, patients were instructed to refrain from brushing the surgical site. Mouthwashes were also prohibited for 48 hours after surgery. Oral cleaning was performed regularly by the dental team with 3% hydrogen peroxide and disposable cotton swabs. Patients were instructed to consume only soft foods during the initial period required for soft tissue healing. Smokers were
encouraged not to resume tobacco use for at least 3 months.

PROSTHETIC TECHNIQUE

The impressions were poured in stone using implant abutment analogs connected to the pick-up impression transfers. The models were then mounted on an articulator with the appropriate bite registration. Commercial denture teeth (Ivoclar, France; Kulzer, Germany) were luted with acrylic to the titanium impression copings that had been used to take the impression. This device, which was secured to the abutment replicas with titanium laboratory screws, served as a try-in for the denture.

The next day, this try-in acrylic denture was evaluated for esthetics, speech, vertical dimension, and occlusion. A panoramic radiograph was taken and a clinical evaluation performed to check the mechanical fit of all components. When required for cosmetic reasons, detachable or fixed artificial gingivae were incorporated in the prosthesis to support the lips and cheeks. Selection of the type of gingival facade was based primarily on hygiene considerations.

48 hr. after surgery, the highly rigid, cobalt-chromium (CoCr) framework with resin teeth was screw-secured to the implants. Occlusion was rechecked and verified for equal force contacts in centric occlusion. Monobloc transgingival abutment screws were retightened to 20 N-cm. The gold alloy prosthetic retaining screws were tightened to 10 N-cm; these screws were retightened the following day to compensate for the Young’s modulus of the metallic components and the flexibility of the supporting bone (Figures 20-22). 45 days after prosthesis delivery, the screws were evaluated for retention by applying 10 N-cm with a torque wrench, and occlusion again was verified. Hygiene and maintenance techniques were reviewed and evaluated.

FOLLOW-UP

Patients were seen every month for the first 6 months, with special care paid to occlusion and hygiene (the pontics were relieved from gingival contact and there were open embrasures for cleaning). After 6 months, the screw-secured prosthesis was removed for the first time and each implant was
RESULTS

All implants in this study were followed up for at least 9 months after prosthesis delivery. Only 6 of the first 11 patients have been followed up for more than 19 years (Table 1); the other 5 were lost to follow-up for various reasons. Fifty-two patients (22%) (including the 6 first year patients) came for a check-up in 2019 (up to Sept. 2019). All of their implant-supported fixed prostheses were functional, without any signs of pathology or peri-implantitis at clinical and radiological (cone beam, peri-apical x-rays) assessment.

DISCUSSION

Histologic proof of osseointegration of immediately loaded, laterally inserted, single-tooth disk-type implants was first obtained in 1985 when a Juillet T3D titanium implant (precursor of the Diskimplants used in this study) placed in 1976 was removed from a patient prior to therapeutic irradiation. Gross examination of this first human block section revealed a healthy sulcus and absence of crater formation around the threaded shaft of this maxillary implant, which had been in function for 9 years. Light microscopy, tetracycline labeling, and micro-radiography demonstrated new bone formation in intimate contact with this laterally inserted titanium implant with a machined smooth surface. No signs of peri-implantitis were observed.

Use of a high-speed turbine (300,000 rpm) to prepare the recipient site for lateral disk insertion does not cause heating harmful to bone. Previous research demonstrated that the maximum temperature during drilling with cutters is 32°C, which is far from the critical temperature of 44°C cited by Ericksson et al. as the upper limit before irreversible bone tissue injury occurs.

The designs of the anatomo-physiological implants used in this study share a number of features that contributed to their clinical success. Increased contact between bone cells and their machined, smooth titanium surfaces and increased adhesion of gingival cells to their smooth cervical segments have been demonstrated in vitro by human cell cultures. The 0.25 mm deep microthread increases bone-to-implant contact and the mechanical strength of the implant body; the design of the abutment and retaining screws reduces the risk of loosening. No implant or screw fractures were noted during this longitudinal study.

These anatomo-physiological implant systems (Disks and microthreaded, machined smooth root-forms) utilize the same prosthetic components, including the same flat emergence profile, which facilitates laboratory procedures, especially when dealing with highly tilted (> 45°) pterygoid Fractal implants. The strong stable initial cortical support provided by these implants allows immediate connection to a screw-secured fixed prosthesis. Potential micromovements are reduced and internal tensions are rapidly dissipated within the bone. This favors bone reconstruction and remodeling around the implants, as confirmed by cone beam analysis. All of the fixed prostheses in this study were screw-retained. Assembly of components by screwing their two flat surfaces together increased stability and maintained accurate passive fit. Cosmetic problems can be avoided by using transgingival abutments that are 1 mm shorter than the gingival depth as measured at implant installation to anticipate tissue retraction.

Five fixed prostheses were completely refabricated (including replacement or retrieval of the transgingival Monobloc abutments) in order to resolve esthetic and
speech problems. Only 20% of the patients in this study requested full zirconia to replace the immediate transitional functional prosthesis (CoCr titanium framework with resin teeth).

This immediate functional loading protocol requires more implants to ensure optimal stress distribution. The primary multicortical anchorage achieved with the large base of laterally inserted implants improves load distribution and initial stability, as demonstrated by finite element stress analysis. These implants also offer an attractive alternative, even in small bone volumes, to conventional root-form placement, which often requires bone grafting. The protruding base of the disk can help to maintain small autologous bone chips (or bone substitute material) placed under the periosteum, which, with the resulting coagulum, enhances osseointegration.

The major difficulty with this technique concerns training of the surgical and prosthetic teams. The impression for the prosthesis is taken immediately after surgery, which increases chair time. In addition, the dental laboratory must be able to handle their responsibilities within the allotted time. The 48 hr period required for fabrication of the screw-retained prosthesis permits delivery to the patient before the bone-repair process has ended. The prosthesis must be fabricated rapidly because macrophagic and osteoclastic activities begin immediately after the surgical procedure and render the bone matrix weaker. Locking the implants in place with the prosthesis as soon as possible after surgery thus has both mechanical and biological justifications; it guarantees the stability of the implant-supported prostheses and eliminates the effects of any prosthetic technical inaccuracies before mineralization and osseointegration occur. As anatomo-physiological disk implants with their relatively malleable titanium bases adapt to the rigid prosthesis, bone formation continues. As a consequence, the fixed prostheses do not have to be sectioned to improve the accuracy of fit.

Immediate loading of cortically anchored implants avoids soft tissue injury that might be caused by a removable appliance; it also promotes blood supply and healing of the bone and periosteum, thereby stimulating osseointegration. Patients appreciate the rapid rehabilitation and are willing to comply with the need for multiple office visits. A single annual radiologic check-up is sufficient after the second year of function.

CONCLUSION

Immediate loading of laterally and crestally inserted anatomo-physiological implants with a fixed, highly rigid, screw-secured functional prosthesis is a safe and reliable method for management of fully edentulous, extremely resorbed jaws without any prior bone grafting procedure. Bone substitute materials and PRF are used immediately after implant installation in native living bone. Coupling high tech with the use of bone matrix Osseotensors helps oral invalids to completely recover masticatory function and esthetics.

REFERENCES


