A new callus distraction technique using the Endodistraction Implant in severely atrophic mandibles – long-term results of 18 patients

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A new callus distraction technique using the Endodistraction Implant in severely atrophic mandibles – long-term results of 18 patients

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Key words: bone reconstruction, distraction osteogenesis, edentulous mandible, alveolar ridge atrophy, endosseous implants, distraction vector, bone augmentation, internal distraction

Abstract:

Objective: The aim of this study is to evaluate the surgical and prosthetic results of edentulous patients with highly atrophic mandibles using the Endodistraction Implant.
Materials and Methods: A simple practical device for a new technique of vertical callus distraction osteogenesis has been developed. The initial indication for the Endodistraction Implant was the anterior region of highly atrophic mandibles. The new characteristics of the Endodistraction Implant are the intraosseus placement of the device together with the use of the cortical bone of the basal segment for the tap of the distraction rod and placing the distraction rod on the opposite side of the cranial segment with the reserve length within the soft tissues of the chin. The stable anchorage of the distraction rod within the thick cortex of the basal segment guarantees best the planned distraction vector, and tilting tendency is to neglect. The intraoral appearance of the device can be compared with an artificial crown, which remains at the same level, not compromising the patient. The device can easily be removed without second surgery and any type of Implant system can be applied after the retention time.
Results: From 2000 till 2004, 18 patients were treated surgically and prosthodontically, and followed up at least 36 months. The distribution of 17 female to 1 male is remarkable. The mean age at surgery was 55 years and 8 months. The performed distraction amount ranged from 8 to 14 mm (mean = 10.7 mm). After distraction osteogenesis 4 implants were placed in the interforaminal area (total: 24 Brånemark® and 51 Straumann® implants). 4 implants were lost in one patient due to infection and replaced by four standard implants in a second procedure. All other implants were osseointegrated and followup appointments showed no bone loss after loading. Remarkable is the negligibly tilting tendency (mean = - 2,88°, min = + 2°, max = - 8°), in contrary to conventional devices.
Conclusion: The present data demonstrate that edentulous patients with highly atrophic mandibles can be reconstructed with hard and soft tissues in the anterior aspect of the mandible by means of callus distraction using a new technique of surgery with the Endodistraction Implant. The long term clinical results of 18 patients followed more than 4 years after treatment end showed re-established ideal bony conditions together with a perfect aesthetic outcome. The complication rate and the surgical efforts can be minimized compared to conventional distraction devices.

Introduction:

Several surgical procedures have been described for the treatment of severe forms of mandibular alveolar ridge atrophy (Esser 1999). Previously reported longitudinal study (Keller 1995) demonstrated that dental implants could successfully be inserted in highly atrophic mandibles, even down to a bony height of 5 to 8 mm. On the other hand, later studies (Binger at al. 1999, Schug et al. 1999) reported severe complications following this concept.
Last decade, the new technique of callus distraction of the alveolar process was encouraged utilizing the advantages of the theory of distraction osteogenesis. However, early experiences on that scientific field have been reported by orthopaedic research group working on the treatment of shortened tubular bones (Ilizarov 1971, 1989a, 1989b). Early in the 1990s, the concept of distraction osteogenesis was introduced into the speciality of oral and maxillofacial surgery for the treatment of micrognathism in young children (Mc Carthy et al. 1992, Wangerin and Gropp 1994, 1995). In 1994 the preprosthetic alveolar ridge augmentation with Ilizarov´s callus distraction was applied using intraoral appliances (Chin and Toth 1997, Gaggl et al. 1998, 1999, Klein et al. 1999, Hidding et al. 1999, Lazar et al. 2000, Millesi-Schobel et al. 2000).
All distraction devices have several disadvantages for the patients. Some of these have bulky intraoral rods, which compromise the patient's comfort and aesthetics, particularly in the anterior region of the mandible. They also could have a tendency of uncontrolled lingual tilting during the distraction period due to the pull of muscles of the tongue. Furthermore, many of these devices are anchored with two miniplates and a number of screws, which have to be removed in a second surgery. To prevent the previous disadvantages a new technique was developed offering an alternative treatment method when comparing with Gaggl's distraction implant (Gaggl et al. 1998, 1999) or the Groningen Distraction Device (Raghoebar et al. 2000, 2002).

Material and Methods

18 patients aged between 43 and 66 years have been treated using the newly developed distraction device between January 2000 and September 2003 and prospectively followed up till April 2007. The mean age of 55 years and 8 months and the distribution of 17 female patients to 1 male are remarkable showing such severe atrophies of the mandible. The mandibular atrophy was evaluated according to the classification of Atwood (1963). In contrary to the metric Cawood Classification (Cawood and Howell 1998) the Atwood Classification deals with different typical types of alveolus atrophy. However, the Atwood classes may be difficult to assign, due to the different sizes of the mandibles. Therefore, it was necessary to use templates with different magnifications. Moreover, the six classifications were modified with additional five intermediate stages (Table 1). The evaluation of the patients was performed by preoperative lateral transcranial x-rays.

Table 1. Distribution of the 18 patients due to the Modified Atwood Classification

Modified Atwood Classification (Total = 18):						
Class	3 - 4	4	4 – 5	5	5 – 6	6
Number	1	3	4	5	2	3

Characteristics of the Endodistraction Implant:

The new developed technique of callus distraction uses a special device *(Fig. 1)*, which is anchored within the centre of the bony arch of the jaw and the osteotomized alveolar segment. It has the ability to separate the bony segments gradually up to a particular amount in the desired direction *(Fig. 2-a, 2-b)*.
The new ideas of this simple technique are firstly the anchorage of the threaded rod in a tap hole in the compact bone of the basal segment and secondly the placement of the excessive length with the end of the threaded rod in a sterile pocket of the soft tissues subjacent to the bony chin. The subcutaneous layer with its poor blood supply of the fat pad is in danger for infections. Therefore, oral hygiene, chlorhexidine rinsing and systemic and perioperative local antibiotics for the operation are mandatory.
The right hand threaded rod is guided in a tap hole in the body of the jaw. This rod rests in a hollow implant, which is permanently fixed in the osteotomized alveolar ridge by means of a left hand thread. Turning up the rod counter clockwise it is not possible to unscrew the treaded hollow implant during the distraction process due to its left hand tap. The gap between the hollow implant and the threaded rod is watertight against saliva by means of a silicon seal.

Surgical procedure:

Surgery under general anaesthesia is recommended due to danger of bleeding in the floor of the mouth (Krenkel et al. 1985, Krenkel et Holzner 1986). Furthermore there are better conditions for coagulation in case of bleedings, as well as to fulfil strict sterile conditions during surgery.
Fully vascularized surfaces in the site of the osteotomy are essential preconditions for an optimal distraction osteogenesis. This can be achieved by supraperiostally dissection of the osteotomy segment. Moreover, the osteotomy gap with the blood clot should be protected, if possible, against ingrowths of soft tissues by a preserved periosteal flap. This is performed by a special preparation technique of the mandibular body, which changes from supraperiostally to subperiostally near the mental foamen.
The dissection of the soft tissues is a modified Edlan Mejchar technique (Edlan Mejchar 1963). The difference is in creating a superior pedicled periosteal flap for coverage of the osteotomy gap. The next would be the identification of the mental nerves for the lateral extension of the osteotomy. A minimum height of the bone of approximately 8 mm should be available to obtain at least 4 mm height for both bony segments, to avoid a high risk for a pathological fracture. Then the osteotomy is performed parallel to the lower borders of the mandible (mandibular plane). Usually the direction of the distraction in the lower jaw is approximately 90° to the mandibular plane due to a normal inclination of the teeth. Compensatory inclinations +/- 10° are possible in case of a skeletal relation Angle class II or III. According to the planned direction, one or two parallel right hand threaded tap holes (Ø = 2,0 mm) are prepared in the body of the basal segment for the long threaded rods. In the osteotomy segment one, or two larger parallel left hand threaded tap holes (Ø = 3,2 mm) are prepared for the hollow implants. Next the tapping for the distraction rod (Ø = 2,7 mm) and the hollow implant (Ø = 4,0 mm) are performed. The threaded rod is firstly inserted into the bony arch subjacent to the superficial osteotomy segment. It may project up to 12 mm into the soft tissues of the chin *(Fig. 3-a)* and its oversize in relation to the actual height of the ridge would determine the amount of bone that would be gained by distraction. The threaded rod protrudes with his square shaped end through the hole of the hollow implant 5 mm above the alveolar crest for the use of the screwdriver.

The threaded rod is surrounded by the threaded hollow implant, which is permanently anchored in the marginal bone segment. A ring-shaped shoulder on the threaded rod prevents upward slippage through the hollow implant during the distraction period.
When the long, threaded rod is gradually turned up in the bony threads of the mandibular arch by the patient, it takes along the hollow implant together with the osteotomy segment thus creating a gap for callus formation *(Fig. 3-b)*. The right hand thread of the threaded rod in combination with the left hand thread of the hollow implant guarantee the stable fixation of the hollow implant when gradually unscrewing the threaded rod during distraction.

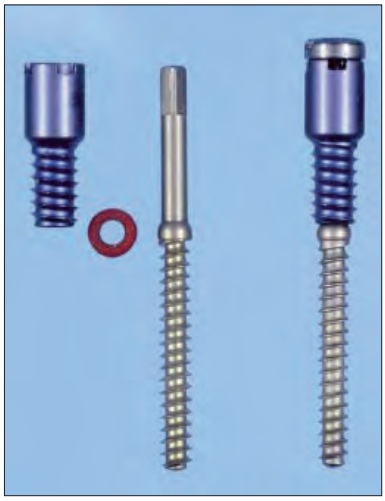

Fig. 1: The Endodistraction Implant System
The cortical screw is placed inside a hollow Implant, which rests on top of the shoulder of the threaded rod. A silicon seal inside the hollow implant prevents contact of saliva to bone

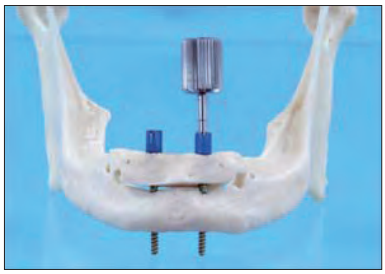

Fig. 2-a: Endodistraction Implant before distraction with the new principle of placing the reserve length of the distraction rod inside the bone and inferiorly in the soft tissues.

Fig. 2-b: Endodistraction Implant at the end of the distraction period with the original reserve length now appearing between the osteotomized bone segments.

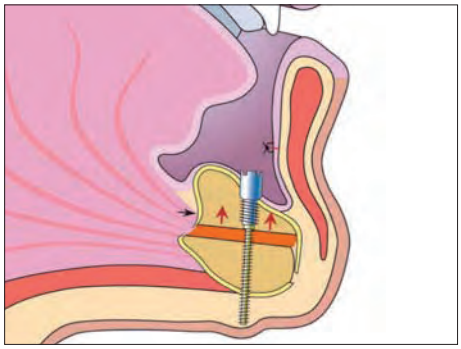

Fig. 3-a: Position of the Endodistraction Implant with an initial gap in the osteotomy line before starting the distraction. The spare length of the distraction rod is hidden in a sterile pocket of the soft tissues.

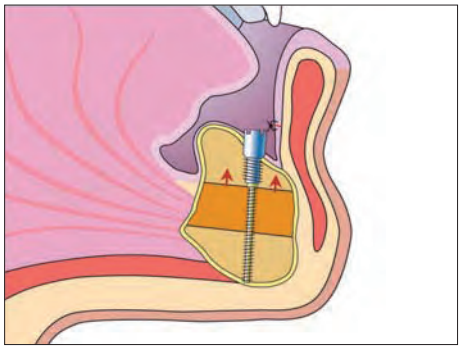

Fig. 3-b: End of the distraction period with the new formed callous between the osteotomized segments during the retention period.

Fig. 4: Enoral distraction performed by the patient with a simple screwdriver.

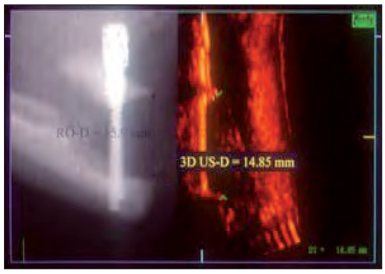

Fig. 5-a: 3-D Ultrasound for monitoring calcification of distraction osteogenesis.

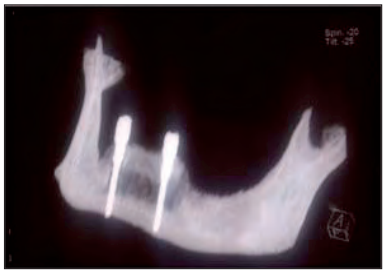

Fig. 5-b: CT scan with 3-D imaging monitors the calcification of the new-formed bone

Fig. 6-a: Simple removal of the hollow implant with its characteristic left hand tap of the Endodistraction Implant

Fig. 6-b: Easy unscrewing of the not osseointegrated tapped distraction rod with its right hand tap of the Endodistraction Implant leaving behind a tiny hole in the mucosa, which can heal like an extraction socket.

Distraction and retention periods

After the osteotomy the primary osteotomy gap of approximately 2 - 3 mm would help in the initial thickness of juvenile callus formation (Zöller 2003). The Endodistraction Implant is safeguarded and blocked with a cover screw for the first retention time of approximately one week. The resultant juvenile callus formation would predispose for the anticipated distraction osteogenesis.
The distraction period would start postoperatively after the first retention time and the soft tissue healing. The end of the threaded rod is square headed for the screwdriver to facilitate easy and controlled handling for the patient in front of a mirror. Each thread has a lead of 1 mm for a full turn and a turn of 90° counter-clockwise has an effect of lifting the segment up 0.25 mm.
The patient or one of his relatives should turn the screwdriver for the distraction exactly according to the distraction protocol, as is instructed by the surgeon, on an "at home" basis with weekly controls in the dental office *(Fig. 4)*.
The number and the amount of the daily extension movements would be increased according to the growing thickness and stretch ability of the newly formed distraction callus. The initial start would be 0,25 mm once a day for the first 6 days allowing a "soft start". This is necessary for a safe osteogenesis without creating fresh bleedings within the osteotomy gap, bearing in mind that the daily distraction distance should not exceed more than one tenth of the actual distraction gap. The twist movements would be increased up to 2 x 0,25 mm a day for the next 6 days followed by a period of 3 x 0,25 mm for another 4 to 8 days. Thus, a distraction of 11 to 15 mm would be achieved within 16 to 20 days.
At the end of the distraction period the Endodistraction Implant is again safeguarded and blocked by the cover screw for the second retention period of 3 - 5 months. For scientific reasons ultrasound and occasionally CT scans with 3-D imaging monitor the calcification of the newly formed bone *(Fig. 5-a, 5-b)*. Routine orthopantomograms and lateral cephalograms after operation, at the end of the distraction period and three months later are sufficient for quality control, monitoring the calcification and for finding the ideal period for implantation.
The removal of the Endodistraction Implants at the end of the retention period needs no second surgical treatment and is nearly painless, when twisting out the threaded hollow implant and rod which are not firmly osseointegrated *(Fig. 6-a, 6-b)*.

Implantation and prosthetic treatment

The newly developed technique has no limitations for any type of dental implants. Preference is given to four long cylindrical implants with tap reaching the basal bone. Primary stability of the implants is recommended using a simple individual stainless steel bar without extensions and a soft lining for the temporary prosthesis to enhance both the healing process and the patient rehabilitation. The temporary bar is removed and replaced by the final restoration after 6 months.
Standardized prosthetic treatment is performed either with titanium bar retained over-dentures or nowadays with individual gold bars and dentures retained with a galvano-forming procedure. Additional 10 -15 mm solid distal extensions lead the force distributed to the interforaminal implants, preventing pressure on the mucosa in the molar region. The base of the dentures becomes through repeated grinding in the molar region a free space to the mucosal tissues, vertical bone regeneration due to function is taking place.
Fig. 7 shows a sequence of a 53 years old woman before and after distraction osteogenesis and implantation in the lateral transcranial Cephalometric. The newly formed bone shows ideal bony formation with a cortical layer and spongy bone similar to the original alveolus.

Step by step documentation of a 51 years old woman before and after treatment:

A previous conventional treatment with full dentures was unsatisfactory because of the severe atrophy of the alveolar ridge *(Fig. 8-a)*.
Before starting the distraction period a postoperative radiological control is obligatory (Orthopantomogram and lateral transcranial Cephalometric), *(Fig. 8-b)*.
The patient handles the screwdriver for distraction in front of a mirror *(Fig. 4)*.
The distraction goes on till the clinical controls confirm the desired height of the alveolar crest, leaving enough space for the individual bar and cover dentures. The goal is the harmony between the line of the teeth and the lips.
Fig. 8-c is the documentation after the distraction period during the second retention time with iuvenile callus formation before visible calcification.
The intraoral situation at the end of the retention period is presented in *Fig. 8-d*.
3 till 4 months later four interforaminal implants are inserted and connected by a temporary bridge.
Fig. 8-e shows the final restoration with an individual titanium bar and distal extensions.
Fig. 8-f depicts the radiological examination at the end of the treatment with full functional implants connected by a bar.
The preoperative situation and the satisfying functional and aesthetic result at the end of the treatment are presented in *Fig. 8-g and 8-h*.

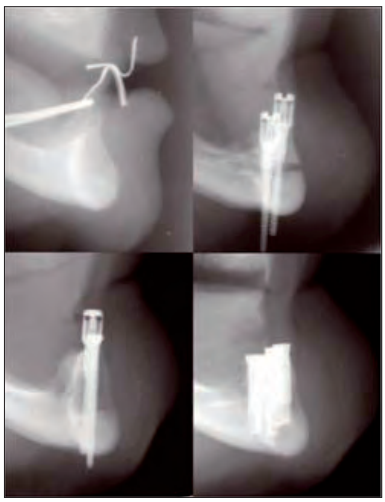

Fig. 7: Example of lateral transcranial radiographs of a 53 years old woman before and after distraction osteogenesis and implantation.

Fig. 8-a: Enoral situation before treatment showing an high atrophic alveolar ridge of the mandible.

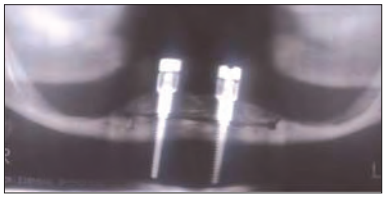

Fig. 8-b: Radiological control after placement of two Endodistraction Implants with an initial gap between the osteotomized segments.

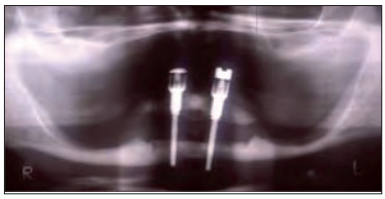

Fig. 8-c: Orthopantomogram during the retention time 8 weeks after surgery.

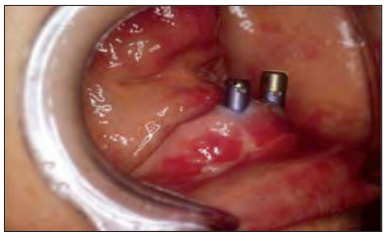

Fig.8-d: Enoral situation during the retention period showing the new formed vestibulum oris

Fig. 8-e: Final restoration with titanium bar and distal extensions.

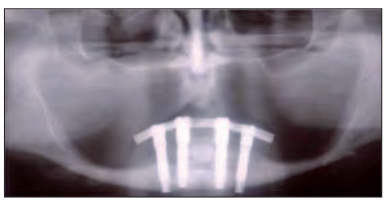

Fig. 8-f: Radiological check at the end of the treatment.

Fig. 8-g: The patients profile at the beginning of treatment.

Fig. 8-h: The patients profile at the end of treatment.

Results

The special interests in this study were focused on the observations during distraction osteogenesis with this new device, the conditions during dental implantation and the complications due to the osteotomy, distraction osteogenesis; implant placement and prosthetic treatment *(Table 2)*.
The mean distance of distraction was 10,7 mm (min = 8 mm, max = 14 mm), which could be achieved in 13 to 27 days (mean: 19,74). The range of the retention time varied from 1 month 7 days to 10 months 9 days (mean = 6 months 3 days). Remarkable was the small angle of tilting of the Endodistraction device in the retention time that was investigated in 17 cases (mean = - 2,88°; min = +2°; max = -8°). In one case we found a poor result with -23° of tilting due to a severe infection. In case No. 3 we observed two weeks after starting the distraction osteogenesis an anchorage loss of the hollow implants, due to a mistake during the operation (weakening of the cortical layer of the osteotomy segment). Four other cases (case No. 7, 8, 13, 14) showed anchorage losses of the hollow implants months after surgery in connection with the temporary prosthesis.
As an average 4 implants were placed in the interforaminal area (total: 24 Brånemark® and 51 Straumann® implants). 4 implants were lost during the healing period in one patient, but could be replaced by 4 standard implants in a second procedure. All other dental implants were osseointegrated and showed no visible signs of bone loss after loading. In the beginning we followed the concept to use long threaded dental implants like positioning screws after a short retention time. Being successful in the first three cases with short retention times, we had to face severe problems in the next two cases due to infections. We suggest mobility of the implants in poor bone quality of the newly formed bone approximately 2 months after the operation. Consecutively we decided to wait with implantation till the calcification could be clearly seen in the Orthopantomogram, leading to retention times over 6 months. In two cases we observed bone fatigue fractures approximately 6 weeks after surgery in severe atrophic mandibles. In the first case a revision operation with miniplate osteosynthesis was performed and the Endodistraction device removed. During the operation a “tumour like” bulky amount of calcified callus was found, already bridging the fracture ends with nearly no mobility. After this experience in a similar, second fracture case the patient was treated conservatively with antibiotics and set only on soft diet. The late result of this case in 2007 shows extra huge bone volume in the area of the fracture, due to a superposition of distraction and fracture callus in the same area.

Table 2: Descriptive data (n = 18)

Patient No Gender	Age Years	Mod. Atwood Classes	Surgery	Distr. Time (d)	Distr. (Mm)	Ret. time	Tilting angle (- = lingual)	Impl placed	Prosthetic Treatment	Remarks to osteotomy, distraction, implantation, prosthodontic treatment
1. (f)	43	4,5	26.01.00	16	10	2mo 26d	-8°	4 x Br	Yes	
2. (f)	51	5,0	12.07.00	21	10	2mo 09d	-4,5°	4 x Br	Yes	
3. (f)	49	5,0	02.08.00	21 + 24	11	2mo 16d	-2°	4 x Br	Yes	Anchorage loss of 2 Endodistraction Implants – replaced by 3 Endodistraction Implants
4. (f)	60	5,5	24.08.00	25	13	1mo 27d	-23°	4 x Str	Yes	Infection, osteomyelitis, guided bone regeneration (GBR)
5. (f)	46	4,0	29.09.00	20	10	1mo07d	-1,5°	4 x Br 4 x Str	Yes	Infection, loss of 4 Br implants, bone transplantation, second 4 Str implantation
6. (f)	64	5,5	29.01.01	14	11	9mo16d	-1°	4 x Br	Yes	Mandibular fracture, operative treatment,
7. (f)	57	3,5	29.01.01	16	11	10mo 9d	0°	4 x Str	Yes	Anchorage loss
8. (f)	53	4,0	17.04.01	22	11	6mo24d	-4°	4 x Br	Yes	Anchorage loss
9. (f)	65	4,5	21.05.01	27	14	7mo21d	-6,5°	4 x Str	Yes	
10. (f)	60	6,0	06.09.01	16	8	5mo21d	-6°	4 x Str	Yes	
11. (f)	56	6,0	12.12.01	28	13	8mo 20d	-2°	3 x Str	Yes	
12. (f)	46	4,5	01.02.02	16	11	8mo	+2°	4 x Str	Yes	
13. (f)	54	4,5	11.04.02	19	13,5	7mo 8d	-3°	4 x Str	Yes	Anchorage loss
14. (f)	66	4,0	31.10.02	20	11	5mo 28d	-2°	4 x Str	Yes	Anchorage loss
15. (f)	63	6,0	07.02.03	15	11	7mo 19d	-4°	4 x Str	Yes	
16. (f)	57	5,0	03.04.03	23	10	8mo 8d	-7°	4 x Str	Yes	Mandibular fracture, Conservative treatment
17. (f)	59	5,0	11.06.03	19	13	8mo 23d	-1°	4 x Str	Yes	
18. (m)	60	5,0	05.09.03	13	12	6m 22d	+1,5°	4 x Str	Yes	

Br = Brånemark; Str = Straumann

Discussion

The goal of rehabilitation of edentulous individuals is to achieve sufficient reconstruction of the alveolar ridge in the interforaminal region with subsequent implant placement and fully implant supported over-dentures. The aim of the distraction is to reach a sufficient height and width of the alveolar ridge corresponding to "Atwood's class 2" and an appropriate direction to normalize the sagittal interalveolar relation. This leads to physiological circumstances with a "normal" shaped vestibulum oris and plica circumlingualis *(Fig. 8-d)*, also allowing optimal hygienic conditions for the proposed implants in the interforaminal region. In contrary to the conventional technique that provides short implants and long abutments the reconstructed height of the alveolar ridge after callus distraction would give the chance to apply long implants with short abutments to avoid fractures of the abutment or the implants. The reconstructed alveolar crest creates a physiological support to the lower lip leading to a natural look and feeling and would provide the prerequisite for a proper function of the tongue, normal mastication and face esthetics.

A frequently used argument against bony augmentation in edentulous atrophic mandibles is the statement that in nearly all those cases dental implants can be used for fixing dentures. But the necessity of operative treatments of two emergency cases with mandibular fractures, after treatment with implants by two different oral surgeons at an outdoor basis, define the limits of this "conservative" method. The two fracture cases in high atrophic mandibles, treated with short implants and long abutments, were cured in general anaesthesia by bridging plates. Other authors have also reported on fracture complications together with short dental implants in highly atrophic mandibles (Binger et al. 1999, Schug et. al. 1999).

On the other hand Chiapasco´s studies (2001, 2004a, 2004b) have proven that distraction osteogenesis is a reliable technique and the best method of vertical bone augmentation, compared to sandwich osteotomy and direct augmentation (GBR). The vertical bone gain by osteodistraction may reach up to 15 mm and is obtained in a more "physiologic" way, compared to vertical GBR with no need of bone transplantation, thus reducing morbidity. Another advantage may include a progressive elongation of the surrounding soft tissues with very limited risk of wound dehiscence and bone exposure.

The main indication for this technique is the mandible with severe atrophy classes 4 to 6 according to Atwood´s classification (Atwood 1963). An astonishing observation was the need for this technique in rather young edentulous women aged between 43 and 66 years. Similar gender distribution was found in a recently published paper at the University in Amsterdam (Amir et al. 2006). The early loss of the teeth seems to be caused by periodontal problems and additional bruxism and trism and intensified by immunologic disorders and endocrinal factors. Accordingly, the two main reasons for the development of highly atrophic edentulous mandibles are the early loss of teeth due to periodontal reasons, together with insufficient dentures, resulting in poor function leading to destruction of the alveolar process.

The last decade many authors presented different devices for osteodistraction in the interforaminal region. Conventional devices used for osteodistraction usually need two miniplates in connection with a threaded rod outside the bone, which, due to rotation, separates the osteotomized bony segments. The total length of this rod limits the maximum width of the distraction. At the beginning of the distraction period with this conventional technique the threaded rod projects for a long distance into the oral cavity. This can cause discomfort for the patients and may limit its application. Furthermore because of the open space from the oral cavity to the osteotomy gap other complications using the traditional techniques may occur. There is an additional risk for infections, osteomyelitis or even spontaneous fracture of the jaw (Uckan et al. 2002). Distraction devices fixed with plates need a second surgery for removal and that means a repeated dissection of the Mm. mentalia. This increases for the patient the danger of developing aesthetic problems, worst causing a "witches chin". The main complication of all these conventional devices, is the frequently observed tendency of tilting of the proximal bone fragment to the lingual side due to the muscle pull of the genioglossus or orbicularis oris, even with bidirectional devices with the need for secondary bone augmentation before implant placement (Schleier et al. 2007).

An ideal distraction device for the edentulous mandible should include the following characteristics:

1. Minimal trauma for tissues and blood vessels during application
2. Maximal comfort for the patient during speaking and eating
3. Not compromising aesthetics
4. Guarantee for reaching the planned height and direction of augmentation of the alveolar ridge
5. Minimal risk of infection
6. Chance for continuing distraction in case of problems or pitfalls during the primary distraction period
7. Minimal invasive removal
8. Perfect stabilization of the new formed bone when placing implants
9. No limitations for using any type of dental implants

Realizing that no modification of the conventional distraction devices with plates was able to eliminate the already mentioned problems, it was necessary to look for new solutions following new principles.
This new solution was realized with the Endodistraction Implant, which guarantees many benefits for the patient and the surgeon. A great advantage of the Endodistraction is the low tendency of tilting of the distraction device during the retention time. Expecting a tilting less than 5 degrees we can calculate this to our treatment plan where we add routinely 5° plus, to gain the best distraction vector.

Future bone regeneration at the lateral aspect of the mandible would also become possible due to normal function. The mandible becomes more radiopaque due to recalcification (Bosker 1986, Wowern and Gotfredsen 2001) where, in case of over-dentures fully supported by implants, additional new bone formation at the alveolar crest could be observed. Thus an open mandibular channel, causing neural problems, can again be protected by this new bone formation.

Benefits of this new method:

The new characteristics of the Endodistraction Implant are the intraosseus placement of the device together with the use of the cortical bone of the basal segment for the tap of the distraction rod and placing the distraction rod on the opposite side of the cranial segment with the reserve length within the soft tissues of the chin. The anchorage of the distraction rod within the thick cortex of the basal segment guarantees best the planned distraction vector and tilting tendency is to neglect.
This is also the explanation why secondary bony augmentation was only necessary in cases associated with severe infection – one case from 18 – (case no. 4).
The Endodistraction Implant itself has the same shape and size for all types of mandibles, all directions and all distances of distraction widths. This would secure maximum flexibility in the planning for both the vector of the distraction and the callus distraction width.
Another advantage of the present technique is no need for a second surgery for removal of the distraction device as the threaded rod and the threaded hollow implant are visible in the oral cavity and the removing instruments can be directly applied. On the other hand, conventional distraction devices fixed with plates on the inferior border of the mandible need a second surgical intervention, compromising once again the mental muscles.
Moreover the removal of the Endodistraction device is nearly painless and easy by only unscrewing the hollow implant and threaded rod before setting the dental implants.
One demand of the presented Endodistraction technique using two Endodistraction Implants is the need for an absolute parallel orientation. It is possible to overcome this problem by the aid of the fully developed operating set (special surgical divider and instruments) together with a step-by-step surgical technique.

Starting this new technique we faced also problems and complications, due to our learning curve:

Infections: For the two severe infection cases there are several possible explanations: first one has to take in account, that the operation always takes place in an area where totally sterile conditions are extreme necessary. The special high risk of this new technique is the open connection during the operation from the oral cavity to the sub mental fat pad, which is very sensible for saliva infections. To prevent this complication perfect preoperative oral hygiene together with oral mouth rinsing with Chlorhexidine and rinsing of the tap holes with "Baneocin®" and systemic antibiotics for three days are now a routine procedure.

Premature anchorage loss: Clenching and trism associated with early temporary dentures on top of the distraction devices might have overloaded the system and may have been the reason for anchorage loss of the device, which was observed in 5 cases. In 4 of these cases this was associated with extreme long retention times longer than 6 months. This anchorage loss had no severe consequences to the patients, beside of shrinkage of the distraction callus of approximately 25 %. In consequence temporary dentures during the retention time are no proposed any more, and we recommend placing dental implants in the 3. – 4. postoperative month. To prevent damage from occlusal overloading we ask the patient not to wear the upper dentures during the night. During the day the absence of the lower dentures in the retention time causes no aesthetic problems for the patient, because of the already reconstructed alveolus, which prevents the lower lip from slipping backward.

We found a big variety of the patients after the distraction period, till calcification of the callus became visible in the orthopantomographic recordings. Different individual intrinsic factors might play a role in determining the retention time for gaining an optimal calcification for a stable implantation with immediate loading and temporary dentures. Postmenopausal hormonal status, malnutrition, malabsorption, avitaminosis and the interference of calcium metabolism all might result in a poor bone development and may increase the healing period. Therefore neither setting dental implants too early (1-2 months) or too late (9 months) are recommended, because this may end up in infections or early anchorage loss of the device. With the new concept of 4 long implants as positioning screws, reaching into the basal segment, approximately 4 months after the operation and with a temporary bar, we could avoid these problems.

Blood supply: Great attention must be given to a good blood supply especially of the proximal segment to prevent necrosis and infection. This includes a dissection technique, which not damages the end branches of the sublingual arteries. Focusing on these problems, after the treatment case No. 5, we modified the dissection technique from a subperiostal to a supraperiostal preparation.

Fatigue fracture: Analyzing the two cases with fractures of the mandible, due to the already developed callus formation, there was in reality no need for an operative intervention with stabilization, which was performed in one patient. A conservative treatment in such cases can be recommended.

The complications analysis and observations experienced during this first study would set up the following recommendations to be taken into account to avoid problems and failures:

1) Infection free oral cavity during the operation is the most important precondition. An existing parodontitis or periimplantitis are absolute contraindications for an operation with Endodistraction exactly as with implantology.
2) No dissection of the periosteum up to he mandibular crest to avoid damage of the end branches of the sublingual arteries .
3) During osteotomy precise supraperiostal dissection is recommended to guarantee the best blood supply to the bone.
4) No temporary prosthesis after the distraction period until insertion of the implants, to avoid an uncontrolled overloading of the system (bruxism, trism together with inadequate diet).
5) No retention time over four months, if possible, to avoid overloading of the distraction device
6) Fractures of the mandible, if occurred after one month from the osteotomy, do not need an osteosynthesis and can be treated with conservative therapy.
7) Dental implants four months after the osteotomy can be placed in immature bone, acting like positioning screws and are splinted by an immediate temporary bar connection.
8) The splinted dental implants reaching the basal bone are strong enough for fixing a temporary full denture, which has to be removed during the night and should not be loaded by chewing hard food – soft diet for 3 months is mandatory.

Future operative strategy of the Endodistraction Implant:

The Endodistraction technique becomes much easier by using a single device resulting in a much reduced operating set and less risk for complications. Therefore the Single Endodistraction Implant is nowadays the method of first choice for vertical augmentation. Its use has so far been confined to the mandible but further indications are also possible such as the chin, the lateral aspect of the mandible and segmental defects in the upper and lower jaw. For small single tooth defects a smaller device will be developed. The technique is also useful in the maxilla in combination with horseshoe osteotomy to provide a distraction in the desired direction inferiorly and anteriorly. The Endodistraction Implant is principally planned and performed like a conventional dental implant with the benefit of successful application of for example 3 D-Navigation Systems and drill guiding templates based on CT scans.

Conclusion

The present data demonstrate that edentulous patients with highly atrophic mandibles can be reconstructed with hard and soft tissues in the anterior aspect of the mandible by means of callus distraction using a new technique of surgery with the Endodistraction Implant. The long term clinical results of 18 patients followed more than 4 years after treatment end showed re-established ideal bony conditions together with a perfect aesthetic outcome. The complication rate and the surgical efforts can be minimized, compared to conventional distraction devices.

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