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243

Distraction Osteogenesis for Lengthening of the Hard Palate: Part II. Histological Study of the Hard and Soft Palate after Distraction

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To correct velopharyngeal incompetence, a new treatment concept was proposed in *Distraction Osteogenesis for Lengthening of the Hard Palate: Part I* (using lengthening of the hard and soft palate by distraction osteogenesis). Cephalometry and computed tomography showed successful elongation of the posterior hard palate with gradual calcification. Here the sequential use of fluorochrome markers (oxytetracycline, xylenol orange, DCAF [2,4-bis-N-N′-dicarboxymethyl aminomethyl fluorescein], and alizarin complexone) during the distraction and retention period is reported together with the histologic investigations using light and laser scan microscopy without prior demineralization. The experimental gap showed de novo osteogenesis in all dogs. The new bone was always in continuity with the original anterior and posterior palatal bone margins. It either bridged the experimental gap fully or left a small central zone of fibrous tissue, in which eventual ossification occurred. Several distinct zones could be distinguished: A small central zone was found with parallel strains of collagen fibers, oriented longitudinally in the direction of the distraction. Next to this zone a layer of undifferentiated mesenchymal precursor cells was seen in direct contact to newly formed bone. The next zone was coarse woven bone, showing a transition to mature lamellar bone through remodeling. No evidence of endochondral bone formation was found, i.e., all dogs showed exclusively intramembranous bone formation. The soft tissues showed no signs of alteration; in particular, there was no necrosis or scar formation. The soft tissues were not thinned but appeared to have followed the longitudinal displacement. In conclusion, gradual distraction osteogenesis of the hard palate could be a possible method for lengthening the palate to treat velopharyngeal incompetence. (*Plast. Reconstr. Surg.* 100: 1648, 1997.)

In *Distraction Osteogenesis for Lengthening of the Hard Palate: Part I,* a new concept for the treatment of velopharyngeal incompetence was proposed based on posterior distraction of the hard palate. Part II describes the method by which new bone formation in the gap was studied.

Distraction osteogenesis was initially described by Codivilla in 1905[1] and in the 1950s by Ilizarov.[2–4] McCarthy and others have applied this technique experimentally and clinically to the mandible and midface.[5–15] Ilizarov showed that a variety of factors can affect new bone formation during distraction osteogenesis.[16,17] These factors include the type and location of the osteotomy, the stability of fixation, the latency period before distraction, and the rate and rhythm of distraction.

In distraction of the hard palate the Ilizarov rules cannot be followed. The horizontal palatal plate in dogs is only 1.5 mm thick; this is comparable to the human situation. The palatal osteotomy was full thickness, the periosteum on the oral layer was fully elevated with the oral mucosa, and the nasal mucosa was always torn because it is very thin (unlike the situation in man), thus there was concern as to how satisfactory osteogenesis would be.

Most studies have demonstrated that bone formation during distraction osteogenesis is predominantly or totally by intramembranous ossifaction. Collagen formation is seen emanating from a central fibrous interzone into new trabeculae, followed by the deposition of minerals.[18,19] Spindle-shaped cells from the interzone are seen to differentiate gradually into osteoblasts, which produce mineralized os-

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teoids. At the fibrous interzone, no intermediary cartilage is normally seen between the spindle-shaped cells and the osteoblasts. This process, therefore, has been termed intramembranous ossification.

Occasionally, one sees small cartilage islands that have been produced from the interzone.[20] These cartilage islands are then converted to bone by endochondral bone formation. These regions have been felt to represent areas of increased ischemia or instability. Under conditions of greater instability, fibrous tissue formation, and in some cases, degenerative cyst formation, is seen[21]; thus stability is important for satisfactory distraction osteogenesis formation in the extremities. In our clinical experience these rules seem not to apply in facial bone distraction.

During the fixation phase the fibrous interzone normally ossifies. In the extremities remodeling of the medullary trabeculae proceeds until complete recanalization of the medullary canal is seen. At the end of the process, the new bone is a normal tube of bone identical to that of the host bone. This finding is in contrast to the new bone seen in fracture healing, in which there is a disorganized collagen network of woven bone that frequently never returns to its original tubular shape.[22] Mandibular distraction osteogenesis is predominantly intramembranous.[23]

The mechanism of new bone formation under controlled mechanical distraction osteogenesis is relatively well understood[23–25]; but there is less understanding of the histogenesis of soft tissue. Examples of the latter are abundant in nature. There is a 900-fold increase in uterine size under the expansion force of the fetus, and there is no question that new uterine or abdominal wall soft tissue has been regenerated during the gradual distraction from within. Ilizarov investigated the effects of distraction on skin, muscle, tendon, fascia, blood vessels, lymphatic channels, and peripheral nerves.[16,17] Controlled mechanical distraction of soft tissues has also been performed with soft-tissue expanders.[26] There are two predominant mechanisms: reorganization of collagen in response to stretch and neohistogenesis. For example, dosed distraction of the fascia causes initial reorientation of the collagen network[27] followed by increased fibroblastic activity. Muscle initially stretches without cell proliferation followed by a combination of stretch and cellular response.[28]

In peripheral nerves new Schwann cells and active myelinization occur.[20] Structural features typical of fetal tissue but atypical of adult tissue were observed in the nerves, muscles, and most of the soft tissues. Ilizarov has stated that tension stress stimulates tissue to regress into a fetal state with the corresponding generation potential.[16,17]

MATERIALS AND METHODS

Six adult, mix-bred dogs were anesthetized, and the palatal mucosa was elevated. A midpalatal transverse and two lateral osteotomies were preformed. Tantalum bone markers for cephalometric analysis were placed, and an individually fabricated, orthodontic-like distraction device with an expansion screw in a sagittal direction was inserted. The device was stabilized onto the premolars and fixed to the palatal bone with titanium miniscrews. Gradual distraction began after a latency period of 10 to 18 days. The rate of the distraction varied from 0.25 to 0.75 mm/day. The device was left in place for 6 to 8 weeks after the expansion to allow for bony consolidation.

Injections of fluorochrome markers were made at fixed intervals to follow the patterns of bone growth in the developing distraction zone. These fluorescent dyes are incorporated into periosteal and endosteal surfaces as new bone is formed, serving as a temporary reference for the dynamics of bone growth.[29–32] Each dog was given a sequence of four fluorochrome labels (Table I) throughout the distraction and the retention period, at the following intervals: (1) oxytetracycline (Pfizer, Inc., Clifton, N.J.) (30 mg/kg of body weight intravenously) once 12 to 40 days postoperatively; (2) xylenol orange (Sigma Chemical Company, St. Louis, Mo.) (30 mg/kg of body weight intramuscularly) once 2.5 to 6 weeks postoperatively; (3) DCAF (2,4-bis-N-N′-dicarboxymethyl aminomethyl fluorescein) (ICN Nut. Biochemical Company, Cleveland, Ohio) (20 mg/kg of body weight intramuscularly) once 3 to 10 weeks postoperatively; (4) alizarin complexone (Sigma Chemical Co.) (30 mg/kg of body weight intramuscularly) once 4 to 14 weeks postoperatively. Assessment was by direct examination, cephalograms, and computed tomography in axial and coronal planes.

After the dogs were anesthetized, their heads were scanned in the sagittal plane with a high resolution helical scanner (SR 7000, Philips

TABLE I
Sequence of Fluorochrome Labels*

	Dog											
	1		2		3		4		5		6	
Treatment	A	B	A	B	A	B	A	B	A	B	A	B
Tetracycline	0	12	20	40	13	28	10	28	5	15	5	15
Xylenol orange	5	17	40	60	26	41	20	38	15	25	10	20
DCAF	10	22	60	70	45	60	—	—	22	32	15	25
Alizarin complexone	15	27	70	80	85	100	—	—	50	60	35	45

* A, days after beginning distraction; B, days after operation.

Medical Systems, Eindhoven, The Netherlands). For technical reasons it was impossible to scan the dog in this plane during the experiment. Direct sagittal scanning allowed additional measurements of the achieved palatal bone lengthening to be obtained (Fig. 1). Killing of the five successfully distracted animals was carried out between 5.5 and 8.5 months postoperatively.

The entire animal heads were fixed in formaldehyde. To prepare the palate specimens a bandsaw equipped with a diamond-coated band (Exakt-Cutting-Grinding System, Exakt-Apparatebau, Norderstedt b. Hamburg, Germany) was used. From all palates sagittal and coronal sections of all soft and hard tissue around the distraction zone were prepared for light microscopy without prior demineralization.[33,34] Dehydration was accomplished by increasing ethanol concentration using a dehydration system with agitation and vacuum. The blocks were embedded in a photo-curing one-component methacrylate-based resin (Kulzer 7200 VLC-resin, Kulzer Company, Werheim Ts, Germany) and sliced again on the Exakt cutting-grinding unit. The first three slices were cut in the sagittal direction, and the next two slices were cut coronally. The slices were then reduced by microgrinding and polishing to an even thickness of about 20 μm. These slices were stained with toluidine blue/pyronine G. If present, the width of the remnant fibrous

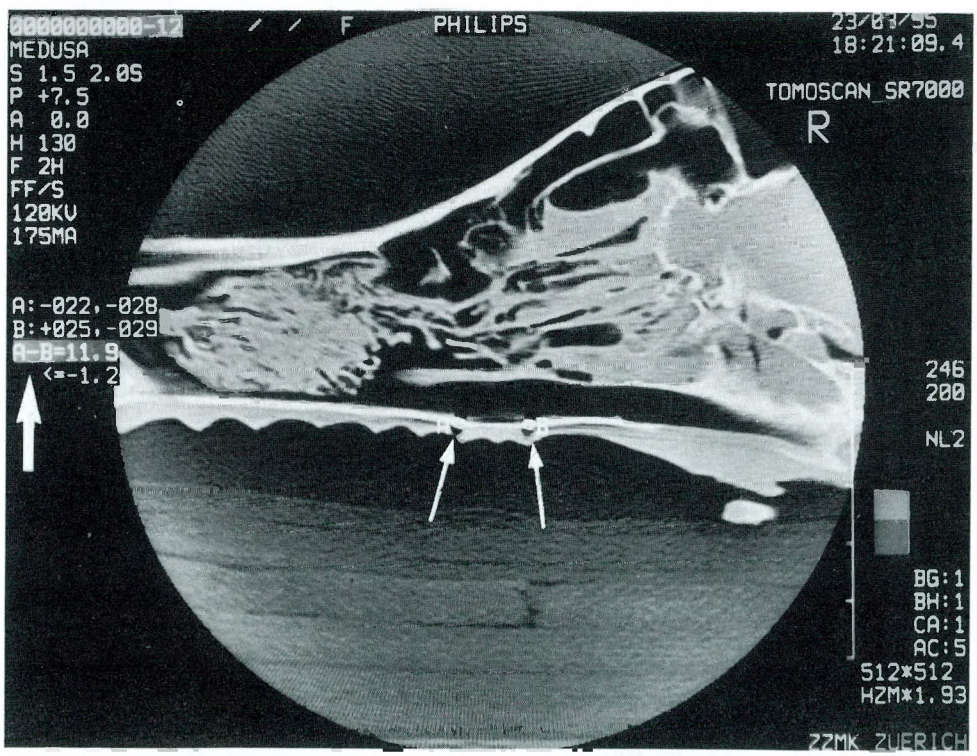


FIG. 1. Direct sagittal scanning (dog 3) after death shows the anterior (*A*) and posterior (*B*) bone markers (*arrows*) and thin newly formed bone in the distraction zone. The distance between the bone markers is 11.9 mm (*large arrow*).

interzone of each dog was measured under the microscope. This measuring was carried out on three randomly chosen slices (Table II and Fig. 2). In addition to light microscopy, the histological specimens were also analyzed with the Bio-Rad MRC-600 confocal system mounted on a Zeiss Axioplan microscope. Pictures were taken by means of an argon-krypton laser using the FITC-filter set (excitation wavelength 488 nm with 522-nm green emission filter). Fluorescent images were merged with transmission images using the COMOS Software (Bio-Rad) and printed out on a Sony Mavigraph color printer.

RESULTS

Cephalometric and analysis showed a distraction of up to 8 mm. At 1 month after completion of distraction, the computed tomographic scan showed the first signs of ossification of the experimental gap from the anterior and posterior bone ends. After 4.5 months this process was almost complete, with a small translucent zone in the middle of the experimental gap. At 7 months ossification was complete.

Consecutive computed tomographic investigations in axial and coronal planes during the experiment and in the sagittal plane after death as well as direct measurements in the histological cuts after death of the animals revealed no relapse of the distraction.

Histological investigations in all dogs showed new bone formation within the distraction zone (Figs. 2 and 3). The new bone was always in continuity with the original anterior and posterior gap margins. It bridged the gap either fully or with a small central zone of fibrous tissue, between 0.1 and 1.2 mm in width (Table 1). In the average this remnant gap was 0.4 mm wide (Fig. 3). The only exception was a gap of 1.1 mm in one dog. In this dog distraction was performed at a higher rate, fixation of the distraction device was somewhat unstable, and the dog was killed after a shorter observation period.

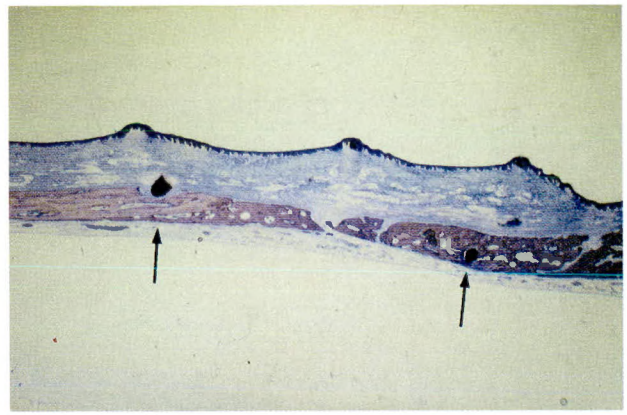


FIG. 2. Histologic section of dog 5, 4.5 months after distraction showing two tantalum bone markers (*arrows*), 11.0 mm apart. The gap is almost fully bridged by osteogenesis, leaving a small fibrous interzone. The region of newly developed bone shows increased vascularity. Toluidine blue/pyronine G staining; original magnification, ×7.5.

The new bone was approximately 1.5 mm thick, this thickness being similar to that of the original palatal bone. No significant difference in bone thickness in animals with higher rates of distraction was noted.

Bony tissue sometimes developed on the external surface of the palatal bone adjacent to the zone of distraction. This region of bone at times showed evidence of remodeling. Excessive osteoid production and deposition was not found.

Three distinct zones of new bone formation could be distinguished: (1) In the center of the experimental gap was a "fibrous interzone," consisting of highly organized, longitudinally oriented, parallel strands of collagen, spindle-shaped fibroblasts, and undifferentiated mesenchymal precursor cells throughout the matrix (Fig. 4); (2) Next to this fibrous gap, osteoblasts, fibroblasts, and undifferentiated mesenchymal precursor cells were seen in direct contact with the surface of the newly

TABLE II

Width (mm) of the Remnant Fibrous Interzone as Measured in Histologic Sections

	Dog					
Section	1	2	3	4*	5	6
Cut 1	0.60	0.00	0.75	—	0.00	1.00
Cut 2	1.10	0.10	0.25	—	0.10	1.20
Cut 3	1.20	0.00	0.00	—	0.75	1.20
Sum	2.90	0.10	1.00	—	0.85	3.40
Mean	0.96	0.03	0.33	—	0.28	1.13

* Dog 4 bridged the experimental gap prematurely.

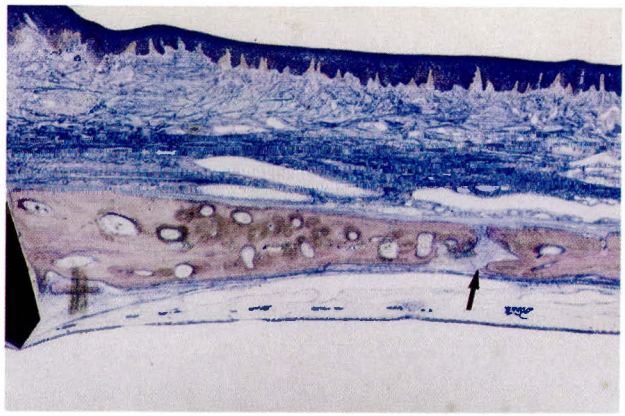


FIG. 3. Histologic section of dog 3, 6 months after distraction showing the gap filled by de novo osteogenesis, remnants of the fibrous interzone (*arrow*), and one tantalum bone marker in the left lower corner. On the left side is the transition zone between the original bone and the newly developed bone. Toluidine blue/pyronine G staining; original magnification, ×26.

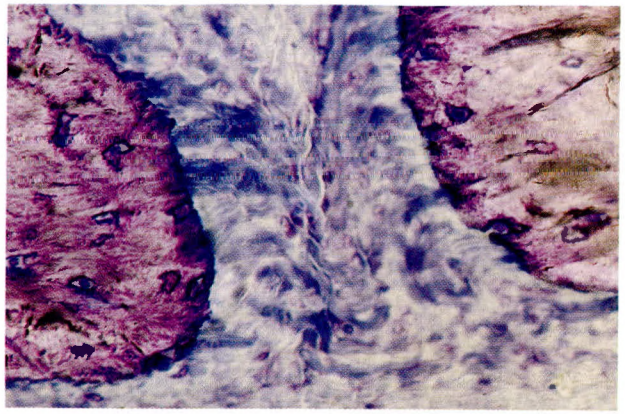


FIG. 4. The center of the experimental gap shows the "fibrous interzone" 0.25 mm wide with strands of collagen, precursor cells, and newly formed bone. The margins of the bone are not yet fully mineralized. Here osteoblasts are transformed to osteocytes. Toluidine blue/pyronine G staining; original magnification, ×400.

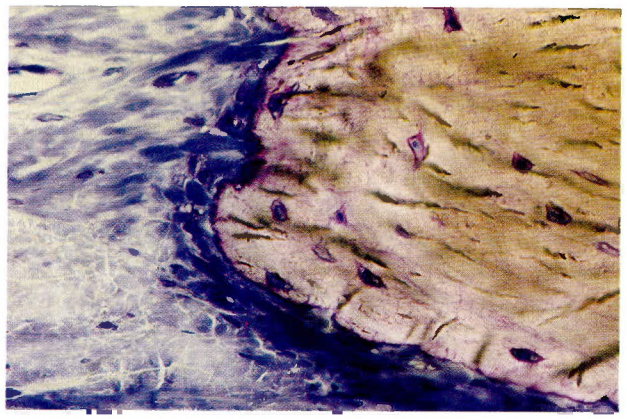


FIG. 5. Strands of collagen, fibroblasts, undifferentiated mesenchymal precursor cells, and osteoblasts in direct contact with the surface of newly formed bone. Toluidine blue/pyronine G staining; original magnification, ×400.

formed bone (Fig. 5). They were oriented in a longitudinal direction parallel to the collagen bundles; (3) there was then a zone of coarse woven bone that was very cellular, showing a transition to mature lamellar bone through remodeling, forming tightly packed osteons (Fig. 6). No evidence of hyaline cartilage formation was found; this was exclusively intramembranous bone formation.

The soft tissues showed no signs of alteration, in particular no hemorrhage, necrosis, or scar formation. There was no thinning in the distraction zone; there was longitudinal displacement without any damage. Both the oral and nasal mucosa including salivary glands looked normal. No inflammatory cells were noted.

Fluorochrome labels showed that the newly formed bone in this experiment underwent mineralization between 4 weeks and 3 months after the operation (Fig. 7). Fluorochrome markers, administered before 3 weeks after the operation, could not be detected microscopically. Some labels administered were not evident or were seen only in small amounts because of remodeling of the labeled bone.

DISCUSSION

This study shows that distraction osteogenesis is possible in the thin palatal bone. Without prior information, the rate and rhythm of distraction were chosen arbitrarily. Distraction was carried out in four animals at a rate of 0.25 mm/day, in one dog the rate was doubled to 0.5 mm/day, and in another it was increased to 0.75 mm/day. The latter was attempted after reports on rapid distraction of the mandible. Computed tomographic investigations during the experiment and histology on all dogs after a period of 5.5 to 8.5 months postoperatively showed no difference in bone thickness or maturity of the bone. A period of 5.5 to 8.5 months postoperatively might be too long to detect differences in histology and further studies are necessary to more precisely evaluate the best rate and rhythm for distraction.

After extremity distraction a retention period of several months is necessary for bony consolidation[35]; in the mandible it is about 3 weeks.[9,15,36] A period of 4 to 8 weeks for the palate seemed to be sufficient.

The fluorochromic markers, which were applied at four intervals, are deposited in mineralizing tissues and fluoresce under ultraviolet

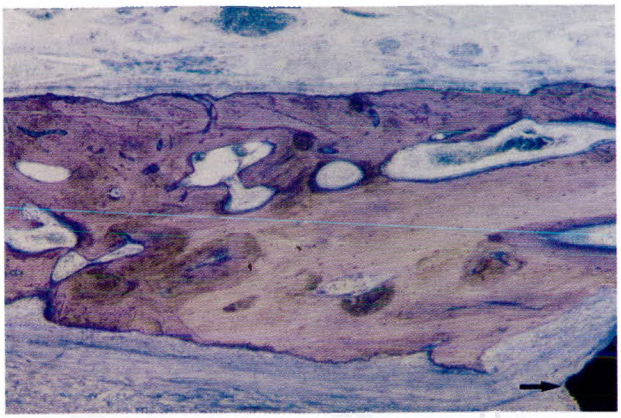


FIG. 6. The transition zone of newly formed bone to the original palatal bone with a tantalum bone marker (right lower corner, *arrow*). Toluidine blue/pyronine G staining; original magnification, ×64.

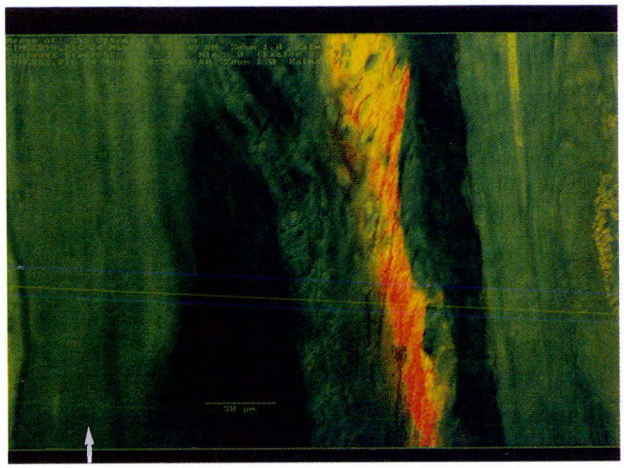


FIG. 7. Fluorochrome label (DCAF) in dog 5, 22 days after distraction, i.e., 32 days after the operation. The left segment of the figure shows original bone (*arrow*), newly generated bone is shown in the central fluorescent layer, and the right segment shows linearly oriented fibrous tissue. Original magnification, ×400.

illumination. This strategy allows the pattern of bone growth to be followed. Because some fluorochrome labels administered were not seen, a longer interval between distraction and the first label is suggested; the intervals between the fluorochromic injection should be shortened.

Histology confirmed that new bone was generated in the distraction zone, that the soft tissues were not damaged or thinned, and that no infection occurred. In all dogs only intramembranous bone formation occurred, as in mandibular lengthening.[23,37]

Because the specimens could not be processed in paraffin, an alternative method was used. A significant innovation was the introduction of a plastic resin for embedding the specimen.[33] The cutting-grinding technique produces thin sections (below 10 μm) for histological examination of specimens that cannot be cut by conventional techniques. These specimens include such tissues as jaw bones with teeth containing fillings, other tissue containing metal implants, fixation material, or brittle bone. In this way the original bone, new bone from distraction osteogenesis, the tantalum bone markers on both sides of the experimental gap, and all soft tissues could be included in one single slice (Fig. 2).

CONCLUSIONS

This investigation showed that distraction osteogenesis of the hard palate in dogs is possible. Histology revealed new bone formation bridging the experimental gap. The soft tissues showed no atrophy nor thinning. Therefore, retropositioning of the palate by distraction osteogenesis in selected patients with velopharyngeal incompetence may be a new treatment concept.

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Distraction Osteogenesis for Lengthening of the Hard Palate: Part I. A Possible New Treatment Concept for Velopharyngeal Incompetence. Experimental Study in Dogs

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Zürich, Switzerland, and Southfield, Mich.

Many procedures have been described to correct velopharyngeal incompetence. Significant complications can occur, and the results may not be satisfactory. If the short soft palate has satisfactory muscle function and if it could be moved toward the posterior pharyngeal wall by distraction osteogenesis of the hard palate, an entirely new concept of treatment for velopharyngeal incompetence would be available. The object of the present study was to explore the possibility of osteogenesis occurring in the hard palate in dogs after gradual distraction (callus distraction). Six adult, mix-bred dogs were anesthetized, and the palatal mucosa was elevated. A midpalatal transverse osteotomy and two lateral osteotomies were performed. Tantalum bone markers for cephalometric analysis were placed, and an individually fabricated, orthodontic-like distraction device with an expansion screw in the sagittal direction was inserted. The device was stabilized on the premolars and fixed to the palatal bone with titanium miniscrews. Gradual distraction began after a latency period of 10 to 18 days. The rate of the distraction varied from 0.25 to 0.75 mm per day. The device was left in place for 6 to 8 weeks after expansion to allow for bony consolidation. Assessment was by direct examination, cephalograms, computed tomography, and histology with bone labeling. Impressions of the jaws were taken preoperatively and after device removal to examine plaster cast changes in the dental occlusion. Cephalometric and computed tomographic scan analysis demonstrated a distraction of up to 8 mm. All gaps were filled with de novo osteogenesis. Comparison of the plaster casts revealed no change in the occlusion. At 1 month after distraction, the computed tomographic scan showed the first signs of ossification of the experimental gap from the anterior and posterior bone ends. After 4.5 months ossification was almost complete with a small translucent zone in the middle of the experimental gap. After 7 months ossification was complete. (*Plast. Reconstr. Surg.* 100: 1635, 1997.)

The incidence of velopharyngeal incompetence after primary palatoplasty in patients with cleft lip and palate is reported to vary between 4.5 and 39 percent, depending on the severity of the cleft.[1–7] Congenital palatal insufficiency, a condition in which the velum is too short to reach the posterior pharyngeal wall, is a further cause of velopharyngeal incompetence. This has been variously termed a short soft palate,[8] congenital short palate,[9,10] or regional growth and development disturbances.[11] Conversely, the pharynx has been considered too spacious for the size of the velum, the so called "box pharynx" or congenitally large pharynx[12] in which all elements of the sphincter are working but are disproportionately small. Intrauterine underdevelopment and palatal bony deficiency may contribute to velar deficiency at birth.[8,13] Less common causes of velopharyngeal incompetence are submucous cleft palate, enlarged tonsils, tonsillectomy, adenoidectomy, and neurogenic causes.[14–21]

Many correction procedures for velopharyngeal incompetence have been described, including palate pushback, pharyngoplasties, and pharyngeal flaps.[22–31] They are designed to alter the special relations of the palate and pharynx to allow the intact musculature to achieve closure; no single operation is a panacea.[32]

Soft-palate lengthening techniques have been described, starting with pushback proce-

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dures with anterior obturator placement as reported by Suersen 1869, Passavant 1878, and Gillies and Fry 1921.[33–35] Even removal of the bony posterior palatine shelf was proposed to allow greater retrodisplacement of the palate.[36] The concept of the present study is exactly the opposite, i.e., lengthening of the hard palate. Palatal lengthening procedures were improved by Veau,[37] and modified by Wardill, Kilner, and Widmaier[38–40] and others.[41–45] Posterior pharyngeal wall augmentation may be used if the closure deficit between the velum and posterior pharyngeal wall is small, i.e., less than 0.5 cm.[46–50] Schönborn[51] described the inferior pharyngeal flap, later popularized by Rosenthal.[52,53] In 1935, Sanvenero-Rosselli introduced the superiorly based flap.[54] If palatal movement is good, sphincter pharyngoplasties are used.[20,23,26,55] In this technique there is no suture line around the sphincter, which minimizes scarring; it can be used in cases of failed pharyngeal flap.

The results of pharyngoplasties are often not entirely satisfying and complications and problems can be severe, e.g., death, nasal airway obstruction with sleep apnea, etc.[56–60] The object of the present investigation was to study a new concept in treatment of velopharyngeal incompetence based on the movement of the intact hard and soft palate toward the posterior pharyngeal wall. After osteotomizing the hard palate an intraoral device would be fixed to the teeth and the osteotomized and nonosteotomized palatal bone. Subsequent distraction of the distal part of the hard palate would then gradually move soft and hard palate posteriorly until it was functionally sufficient (Fig. 1). Gradual distraction of bone is not a new concept, Codivilla[61] satisfactorily elongated a femur by controlled distraction. There was no further development because of complications until Ilizarov reintroduced it in the early 1950s; he used a circular external fixator to align fractured segments of long bones and later to elongate the bones without a bone graft.[62] Distraction osteogenesis has been applied to the mandible and the midface in several animal[63–66] and human studies.[67–72]

Animal Model, Preoperative Preparations, and Distraction Device

Six adult female mix-bred dogs weighing 35 to 40 kg were used. A preoperative high resolution computed tomographic scan (GE 9800, General Electric Medical Systems, New Berlin, Wis.) of the hard and soft palate was obtained. It was noted that the horizontal portion of the hard palate in all dogs was approximately 1.5 mm thick. Impressions of the upper and lower jaws were taken and plaster casts were manufactured. Registration of the dental occlusion was obtained with thinned bitewax, (Bite Wafers, Surgident, Miles Company, Southbend, Ill.) and the plaster casts were analyzed by measuring length and width of the upper and the lower jaws to register any possible changes of the occlusion due to tooth movement during the experiment; 22 measurements were taken

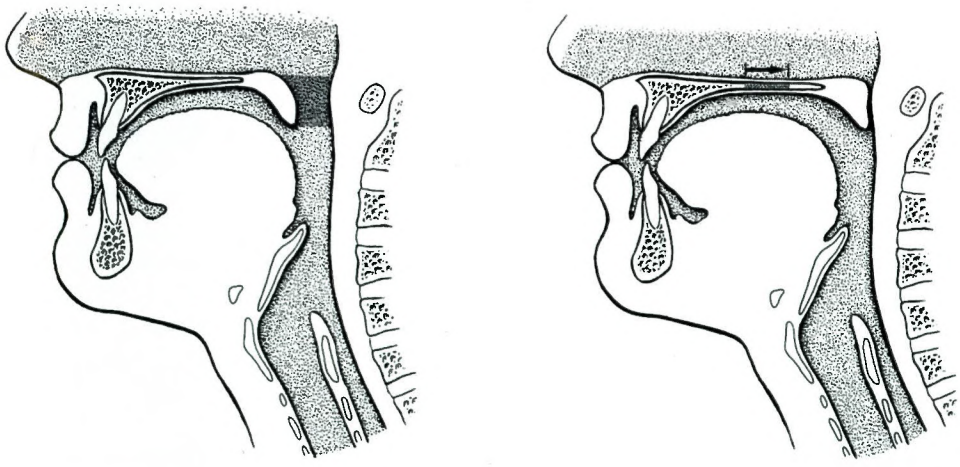


FIG. 1. Diagram of the problem leading to velopharyngeal incompetence and the proposed solution. (*Left*) Hard and soft palate are too short to reach the posterior pharyngeal wall, resulting in velopharyngeal incompetence. (*Right*) If the short soft palate could be moved toward the posterior pharyngeal wall by distraction osteogenesis of the hard palate, velopharyngeal competence could be achieved.

TABLE I
Length and Width of the Upper Jaw before and after Distraction

	Dog 1		Dog 2		Dog 3		Dog 4		Dog 5		Dog 6	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
Length (cm)												
Overall	10.3	10.3	8.7	8.8	10.6	10.6	9.9	9.8	9.3	9.4	9.6	9.6
I1-C	1.8	1.8	1.7	1.7	1.8	1.8	1.8	1.7	1.7	1.7	1.7	1.7
I1-PM3	5.9	5.9	5.0	5.1	4.2	4.2	5.6	5.6	5.2	5.2	5.9	5.9
I1-M1	8.2	8.2	7.1	7.2	8.6	8.6	8.0	8.0	7.4	7.5	7.8	7.8
Width (cm)												
Central groove M2	4.7	4.8	4.2	4.2	5.1	5.2	4.9	4.9	5.3	5.3	5.1	5.1
Right 0.5	2.3	2.4	1.7	1.7	2.5	2.6	2.5	2.5	2.	2.6	2.6	2.6
Left 0.5	2.4	2.4	1.7	1.7	2.6	2.6	2.4	2.4	2.7	2.7	2.5	2.5
C-C	4.2	4.2	3.4	3.5	3.9	3.9	3.9	4.0	4.1	4.2	4.1	4.1
PM3-PM3	4.4	4.5	3.7	3.7	4.5	4.5	4.2	4.2	4.3	4.3	4.7	4.7
M1-M1	5.6	5.7	4.8	4.8	5.8	5.8	5.5	5.5	5.7	5.7	5.8	5.8
M3-M3	5.1	5.1	4.4	4.4	5.5	5.5	5.3	5.3	5.5	5.5	5.2	5.2

between selected teeth and set points (Tables I and II).

Overall jaw lengths were determined by measuring the distance from the interincisal point (I1) to the midpoint of the connecting line between the two distal cusps of the second molar (M2) in the upper jaw or the third molar (M3) in the lower jaw. Four other distances in the sagittal plane for the upper and the lower jaw were recorded: I1-C, i.e., interincisal point to the cusp of the canine tooth (C); I1-PM3, i.e., interincisal point to the cusp of the third premolar (PM3); I1-PM4, i.e., interincisal point to the cusp of the fourth premolar (PM4); and I1-PM1, i.e., interincisal point to the most distal point of the first molar (M1).

The width of the jaws was recorded using calipers at three different levels in the region of the palatal distraction. First, the distances between the cusps of the left and right third premolars (PM3) were measured, followed by the distances between the mesial cusps of the left and right first molars (M1), and third, between the central grooves of the left and right second molars (M2). Further measurements in width were carried out to assess the symmetry of the dental arches. They included the distances from the midline to the left and right second molars in the upper jaw and the first molars in the lower jaws. Lastly, the distances between the tips of the left and right canine teeth (C), the left and right fourth molars (PM4), and the mesial cusps of the left and right second and third molars (M2 and M3) were measured. After completion of the retention period (i.e., 8 weeks after palatal distraction), a second set of impressions were taken, plaster casts were manufactured, and all measurements were repeated and compared with the initial records; this allowed assessment of

TABLE II
Length and Width of the Lower Jaw before and after Distraction

	Dog 1		Dog 2		Dog 3		Dog 4		Dog 5		Dog 6	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
Length (cm)												
Overall	9.6	9.7	8.9	8.9	10.6	10.6	9.9	9.9	9.5	9.6	9.9	9.9
I1-C	1.1	1.1	0.8	0.8	0.9	0.9	0.9	0.9	0.8	0.8	0.9	0.9
I1-PM4	6.0	6.1	5.2	5.2	6.5	6.5	5.8	5.8	5.5	5.6	6.2	6.2
I1-M1	7.7	7.8	6.6	6.6	8.3	8.3	7.6	7.7	6.9	7.0	7.7	7.8
Width (cm)												
Central groove M1	4.9	4.9	3.6	3.6	4.5	4.5	4.0	4.0	4.4	4.0	4.2	4.2
Right 0.5	2.5	2.5	1.8	1.8	2.2	2.2	2.0	2.0	2.2	2.2	2.1	2.1
Left 0.5	2.4	2.4	1.8	1.8	2.3	2.3	2.0	2.0	2.2	2.2	2.3	2.3
C-C	3.6	3.6	3.0	3.0	3.7	3.8	3.5	3.6	3.6	3.6	3.7	3.7
PM4-PM4	4.5	4.6	3.6	3.6	4.6	3.6	4.2	4.2	4.4	4.4	4.6	4.6
M1-M1	5.0	5.0	3.2	3.2	5.1	5.1	4.7	4.7	5.1	5.1	4.8	4.8
M2-M2	4.8	4.9	4.1	4.1	5.0	5.0	4.5	4.5	5.0	5.0	4.7	4.7

any change of the dental occlusion that might have occurred during or after distraction.

A distraction device consisting of two plastic shelves of polymethylmethacrylate (Paladur, Kulzer Company, Wehrheim, TS, Germany) connected by a custom-made orthodontic expansion screw ("Jackscrew") (Summit Orthodontic Company, Cuyahoga Falls, Ohio) was fabricated for each dog by means of the maxillary plaster casts (Fig. 2). The Jackscrews were of stainless steel without a spring and were 14 mm long, 8.5 mm wide, and 4 mm thick. The expansion screw was oriented in a sagittal direction and placed in the midline between the fourth premolar and the first molar; it allowed a maximum expansion of 10 mm. The acrylic part of the distracting device fully covered the first and second premolars and the anterior half of the third premolar to provide caudalcranial stability, thus the palatal mucosa was protected from the compression forces that would occur after fixing the device to the palate with titanium miniscrews. The gingival margins were not covered with acrylic.

Surgical Procedure

Anesthesia was induced with thiamylal sodium (Surital, Park Davis Company, Morris Plains, N.J.) 200 mg intravenously and atropine 0.4 mg intramuscularly, and was maintained after endotracheal intubation with isoflurane 2% and oxygen 5 liters/min. The palatal mucosa was infiltrated with 9 cc of lidocaine HCl 0.5% mixed with epinephrine 1:200,000.

Paragingival sulcus incisions were made posterior and medial to the second molar and carried anteriorly to the first premolar bilaterally; these were then connected by a transverse incision. A posteriorly based mucoperiosteal palatal flap was elevated to the posterior border of the hard palate, maintaining the palatal vessels. An osteotomy was made across the hard palate at the anterior half of the right and left fourth premolar; it ended about 3 mm medial to these teeth. It was then extended sagittally to the posterior end of the hard palate. It ran about 2 mm medial to the palatine vessels and ended just medial to the medial pterygoid plate (Figs. 3 and 4). Before the osteotomy, two to four tantalum bone markers (University of Washington, Scientific Instrument Division, Seattle, Wash.) were placed on either side of the scored transverse osteotomy line approximately 3 mm from each other. The bone markers were rectangular, 0.5 × 1.5 mm in size, and were placed perpendicular to the palatal bone with a "bone marker gun" (University of Washington). Placement of the markers was sometimes difficult because of the thin and relatively brittle bone. If a bone marker seemed unstable, it was removed immediately. If it perforated the thin bone it was replaced with a titanium microscrew (1.5 × 2.0 mm) (Titanium Micro, Leibinger & Fischer LP, Irving, Texas) (Fig. 5). The osteotomized palatal segment was very mobile, and thus it was left attached to the nasal septum/vomer. The palatal flap was returned in its original position and sutured with Vicryl 4-0 single sutures. The distraction device was inserted and fixed with eight titanium 2.0-mm diameter miniscrews (Walter Lorenz Surgical Instruments, Inc., Jacksonville, Fla.) of 11, 13, and 15 mm length (Fig. 6, *left*). Four screws were placed into the anterior palate and four screws in the mobile palatal segment.

Postoperative Management

Prophylactic antibiotics were given (20,000 IU/kg; Flocillin, Fort Dodge Company, Syracuse, N.Y.) for 4 days. Pain medication was given during recovery from anesthesia (0.2 mg/kg; Buprenorphine, Reckett and Colman Company, Richmond, Va.). Water and a soft

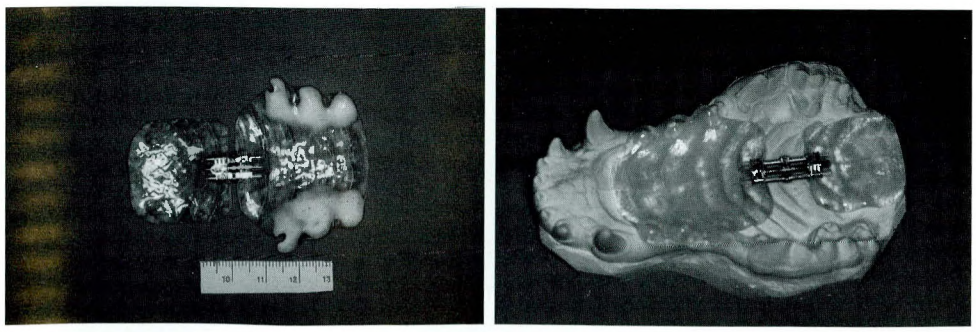


FIG. 2. (*Left*) Distraction device, not expanded. (*Right*) Fully expanded distraction device placed on a preoperative plaster cast to indicate the possible extent of expansion.

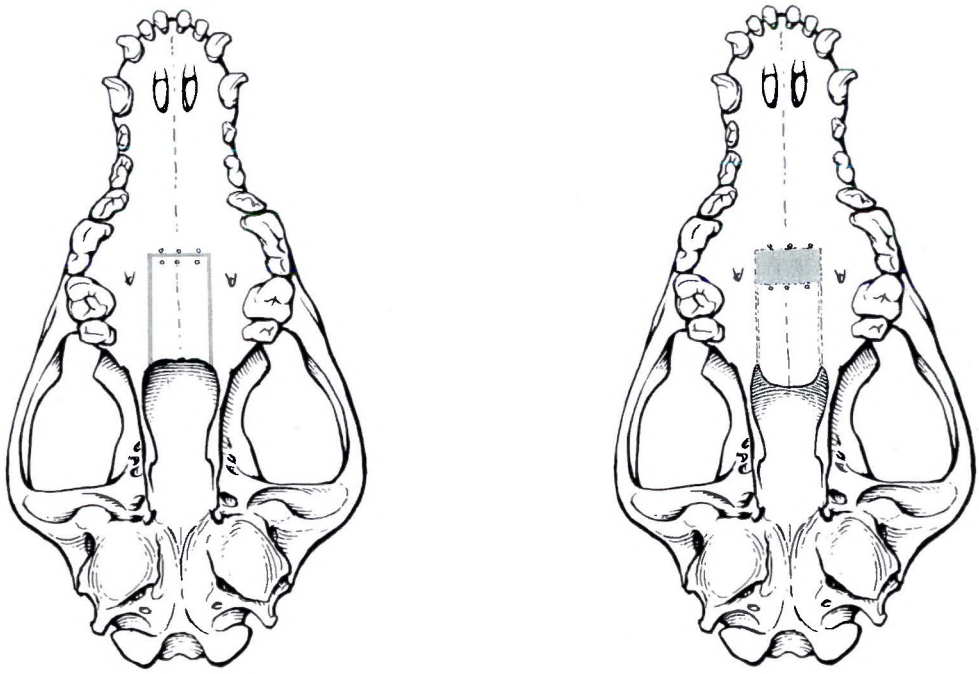


FIG. 3. (*Left*) Diagram showing the transverse and bilateral sagittal osteotomies with insertion of six tantalum bone markers. (*Right*) Diagram of the distracted palatal bone.

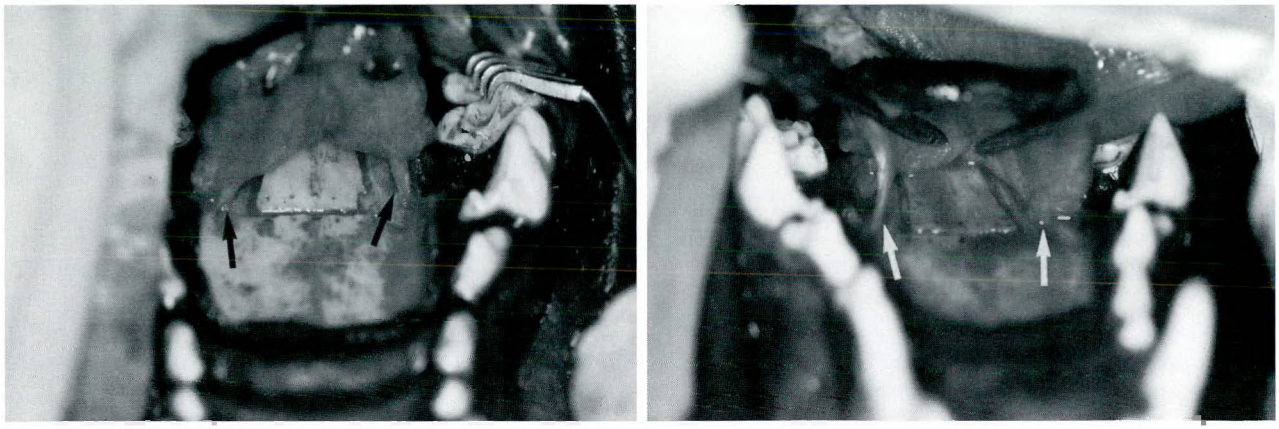


FIG. 4. (*Left*) Close-up view of the transverse osteotomy and anterior portion of the two sagittal osteotomies with preservation of the palatine vessels (*arrows*). (*Right*) Close-up view showing the left and right sagittal osteotomies. It was impossible to show the distal extent of these osteotomies photographically. The intact palatine vessels can be seen (*arrows*).

diet were given the next day. Five days after surgery, under sodium pentobarbital sedation the intraoral mucosa was inspected and stability of was checked (Table III).

Latency Period

Because there was no prior information on palatal distraction, the protocol was somewhat variable. In a pilot project on one dog, distraction was started 4 days after the surgery at a rate of 1.0 mm per day; at 7 days a palatal mucosal tear occurred in the expansion zone. Because of this, distraction was started in dog 1 and dog 2 after a latency period of 12 days. Dog 3 underwent distraction 3 days later, i.e., 15 days after surgery. In dog 4 the latency period was increased to 18 days after surgery, but active distraction was not possible because of reossification of the distraction zone. Thus, in dogs 5 and 6 the latency period was decreased to 10 days.

Distraction Period

Under isoflurane 4% and oxygen 5 ml/min mask anesthesia for 2 to 3 minutes, the expansion screw was turned. The rate and rhythm of the distraction varied slightly. In dogs 1, 2, and 3 the distraction was 0.25 mm per day. In dogs

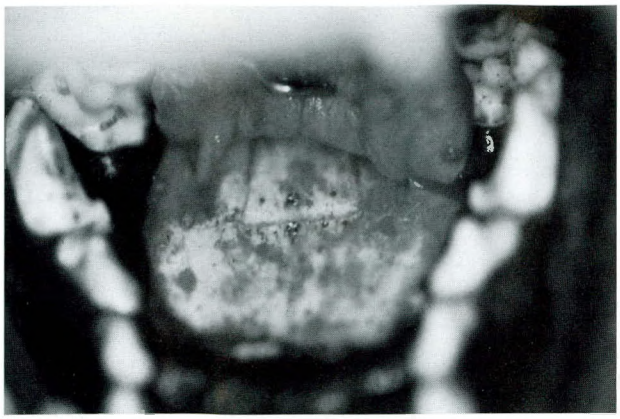


FIG. 5. The relationship of the bone markers to the transverse osteotomy. Two microscrews are also shown.

4, 5, and 6 it was 0.5 mm per day. In dog 6 it was increased after 5 days from 0.5 mm per day to 0.75 mm per day, and the rhythm changed from once to twice a day. Some expansion screws became slightly unstable after about 8 to 9 mm, thus expansion was stopped after 8 mm if necessary. The device was cleaned daily with water.

Retention Period

On completion of distraction, the device was left in place for between 5 and 8 weeks to allow for bony consolidation of the distracted area (Table III). Device removal was performed under sodium pentobarbital sedation. Fluorochrome markers were injected at fixed intervals throughout the distraction and the retention periods to follow bone growth patterns in the distraction zone (see *Distraction Osteogenesis for Lengthening of the Hard Palate, Part II*).

Postoperative Investigations

During distraction, on the last day of distraction, and during retention, the gap in the distraction device was measured with calipers and intraoral photographs were taken (Fig. 6, *right*). Cephalograms and CT scans in two planes were taken, the former in the lateral and the submental-vertex projection using a cephalostat (Porta-Stat Company, Sterling Heights, Mich.) designed for transcranial x-rays. The latter uses a mainframe to which the image receptor, the head, and the x-ray source are referenced for standardization of image and magnification distortion in cranial x-rays.[72] Cephalograms were carried out before distraction, immediately after the last distraction, and after removal of the distraction device (Fig. 7). Axial and coronal computed tomographic scans using the same protocol allowed observation of the degree of ossification in the distraction zone on several occasions (Table IV, Figs. 8 through 10). These were on average of five contiguous slices (slice thickness 1.5 mm, table increment 1.5 mm, 120 kV, 170 mA, scan cycle 2.0 s) in the axial plane with orientation parallel to the hard palate and an average of 30 continuous slices in the coronal plane with orientation perpendicular to the hard palate. When the postoperative axial scans did not show the entire horizontal palatal bone in one single slice the radiological information of two slices had to be combined (Fig. 9, *left*). Conformation was obtained from axial scanning. Using these radiological investigations, palatal lengthening was measured by the increase of the distance between the tantalum bone markers, the process of ossification was followed, and any possible resorption of the thin palatal plate could also be detected.

As mentioned earlier, a second set of upper and lower jaw impressions was taken after removal of the distraction device, casts were fabricated, and the occlusion was studied. The preoperative measurements were repeated for comparison at between 6.5 and 8.5 months.

RESULTS

Clinical Observations

All dogs recovered satisfactorily; the distraction device was well tolerated, and healing was uneventful apart from dog 6 (in this dog a fistula occurred; see the Complications section). The appliance was cleaned daily during expansion and two to three times a week during retention, because after about 3 mm of distraction, food went through the gap in the plate. The dogs had no breathing problems and their bark was not altered. After the device was removed, the miniscrew mucosal defects healed uneventfully.

The preoperative computed tomographic scan showed that the hard palate in the region of the distraction zone was only about 1.0 to 1.5 mm thick, thus a minimum of seven titanium miniscrews were used for fixation of the distraction device; this number gave stability in five dogs but not in dog 6.

The custom-made expansion screw was elongated to the predetermined length, depending on the stability of the screw. On completion of distraction, the gap in the distraction device

TABLE III

Experimental Data/Postoperative Management and Timing*

Event	Dog						
	Pilot	1	2	3	4	5	6
Operation date	4/6	4/29	6/6	7/6	7/8	8/19	9/1
Distraction start date	4/10	5/10	6/18	7/21	7/26	8/29	9/11
Retention start date	4/17	6/7	7/24	8/30	8/15	9/18	9/24
Removal of device date	4/17	7/26	9/19	10/5	—	11/18	11/10
Latency period (days)	4	12	12	15	18	10	10
Distraction period (weeks)	1	4	5	6	3	3	2
Retention period (weeks)	0	7	8	5	5	8	6
Killed date	6/2	11/18	2/1/95	3/22/95	8/28	2/4/95	3/22/95
Killed months after distraction started	2	6	7.5	8	1	5	6.5
Elongation of the expansion screw (mm)	4	7	8	10	10	10	7.5
Distraction of the experimental gap (mm)	4	6	7	7	0	8	6

* All dates refer to 1994 unless indicated with "/95" (killed dates for dogs 2, 3, 5, and 6).

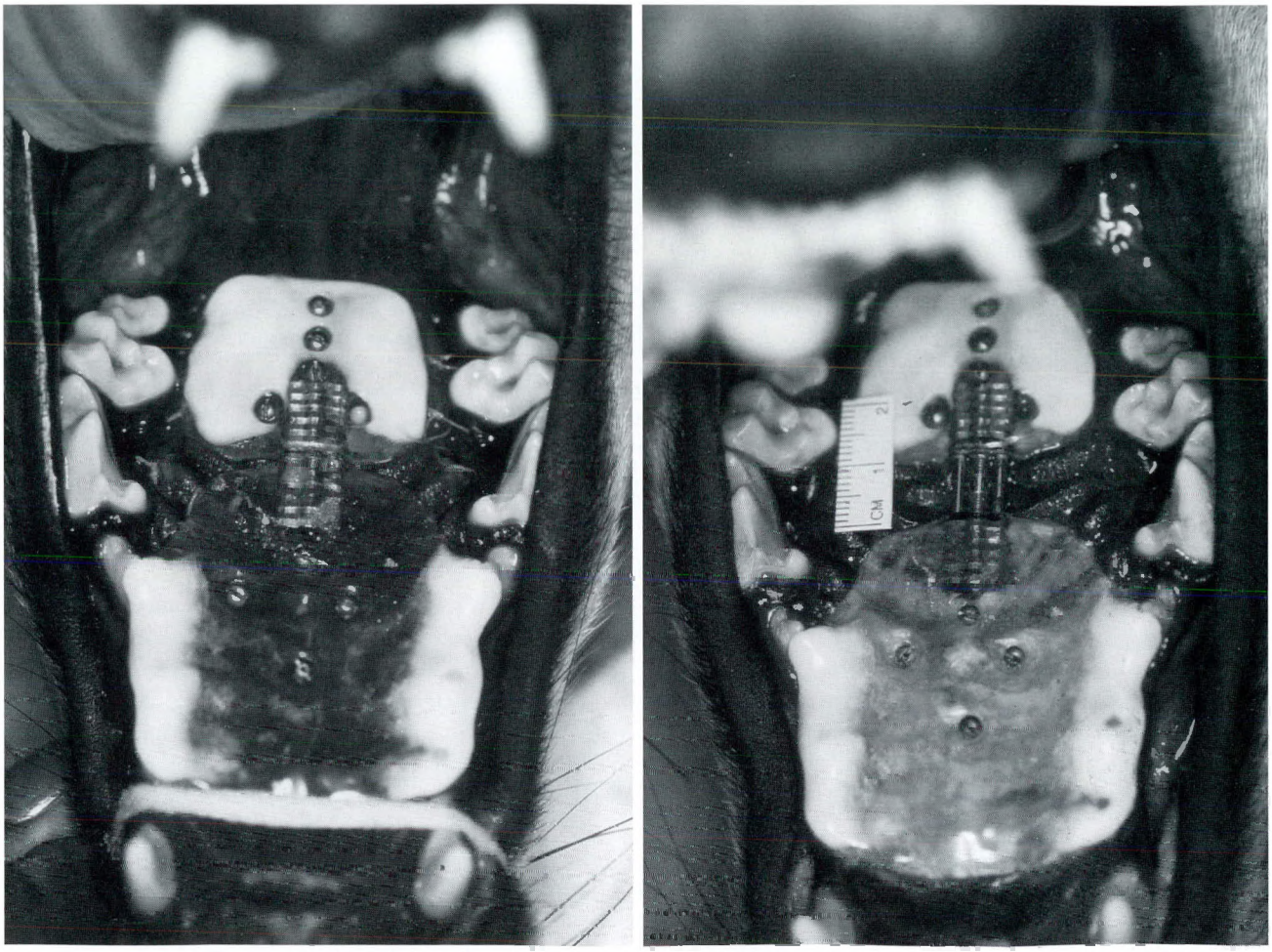


FIG. 6. (*Left*) Unexpanded distraction device in-situ in dog 3 covering the first two premolars and the anterior half of the third premolar. Four screws fix the distal part of the device and four additional screws secure the anterior part. (*Right*) The same distraction device in dog 3 after 10 mm of expansion. Some food debris can be seen underneath the transparent anterior part of the device.

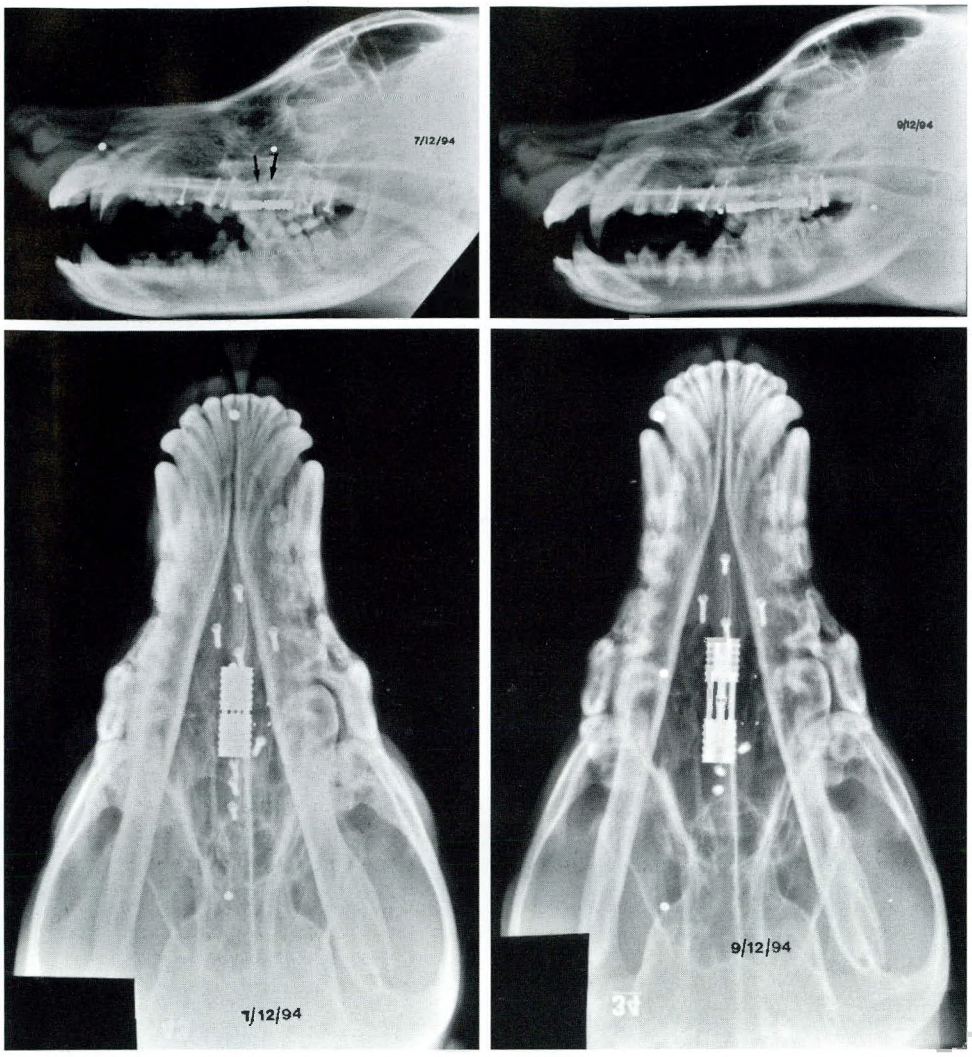


FIG. 7. Cephalograms of dog 3 before and after distraction. (*Above, left*) Lateral cephalogram showing the nonexpanded distraction screw, the fixating miniscrews, and the bone markers (*arrows*). (*Above, right*) Lateral cephalogram showing the fully expanded distraction device 2 months later. The distraction device was expanded by 10 mm and the bone markers by 7 mm due to bending of the fixating miniscrews, which can be seen. (*Below, left*) Submental vertex cephalogram before distraction. (*Below, right*) Submental vertex cephalogram after distraction during the retention period 2 months later.

was measured; it ranged from 7 to 10 mm (mean, 8.75 mm; Table III, Fig. 6, *right*). No clinical difference was noted with daily distraction rates of 0.25, 0.5, or 0.75 mm. Analysis of the jaw plaster casts showed no significant changes in the dental occlusion, and no positional changes of individual teeth.

Radiologic Investigations

Axial and coronal computed tomographic scans in five dogs showed 6 to 8 mm (mean, 6.8 mm) of distraction; the bone distraction was less than the gap in the appliance. This finding was due to the oral part of the fixation screws being bent away from the distraction zone; this also happens in mandibular distraction (Fig. 7, *left* and *right*).

A latency period of 15 days (dog 3) with an elongation of the distraction screw of 10 mm led to a bony distraction of 7 mm (Table III). With shorter latency periods of 10 to 12 days (dogs 1, 2, 5, 6), the difference was only 1 or 2 mm. A latency period of 18 days (dog 4) led to premature ossification, and distraction was not possible.

Computed tomographic scans revealed when the experimental gap ossification, which began at the anterior and posterior ends of the gap 1 month after completion of distraction. After 2 months approximately 50 percent was

TABLE IV
Dates of Impressions, Cephalograms, and Computed Tomographic Scans*

Procedure	Dog						
	Pilot	1	2	3	4	5	6
Impressions (first)	3/30	4/10	5/20	6/28	6/28	8/17	8/30
Impressions (second)	—	10/5	10/3	10/10	8/25	11/20	2/1/95
Operation	4/6	4/29	6/6	7/6	7/8	8/19	9/1
Cephalograms	4/10	5/10	6/18	7/12	7/26	8/29	9/11
	4/17	6/6	7/24	9/12	8/15	9/19	9/24
		7/26	9/22	10/10	8/25	11/20	3/22/95
CT	3/30	5/10	5/20	6/28	6/28	8/17	8/30
	4/8	6/24	6/18	7/21	7/26	8/29	9/11
		7/24	7/24	9/12		9/19	9/24
		10/5	9/14	10/10		10/4	
			9/22			11/20	
CT before death	—	11/18	2 /1 /95	3 /22 /95	8 /25	2 /2 /95	3/22 /95
Killed	6/2	11/18	2 /1 /95	3 /22 /95	8 /28	2 /2 /95	3/22 /95
CT postmortem	—	11/25	3 /14 /95	3 /23 /95	8 /29	3 /15 /95	3/23 /95

* All dates refer to 1994 unless indicated with "/95." CT, computed tomography.

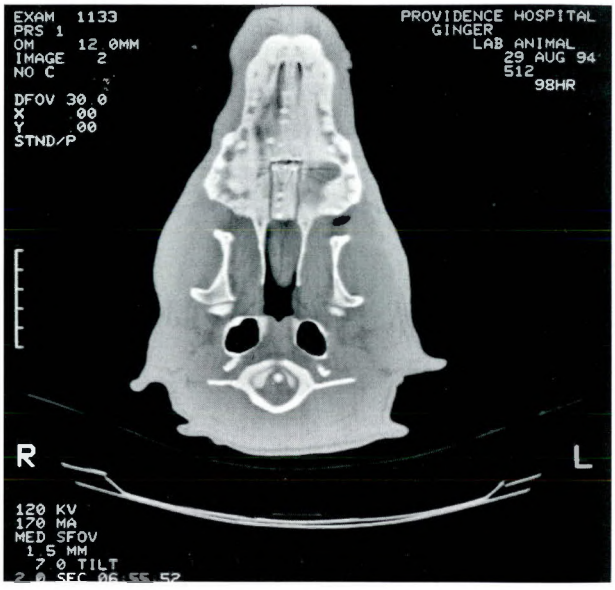


FIG. 8. Dog 5. Axial scan 10 days postoperatively showing the hard palate, the transverse and bilateral sagittal osteotomies, the anterior and posterior bone markers, and the fixating miniscrews.

opacified (Fig. 9, *left*), and after 5 months, there was almost complete ossification save for a small translucent zone in the middle of the distraction zone (Fig. 10, *left*), called the fibrous interzone. After 7 months, this was not detectable.

Complications

Three minor complications occurred in three dogs: resorption—in dog 2 on computed tomographic scan there was resorption of approximately 10 percent of the bony segment around a fixation hole; premature ossification—in dog 4 with the longest latency period (18 days) premature ossification of the distraction zone prevented further distraction; fistula related to food impaction—unstable fixation of the device in dog 6 led to a gap of 1 mm between the device and the mucosa, allowing food impaction. On removal of the device there was a fistula on the right side 2 cm posterior to the expansion zone. It was 5 × 8 mm in size but in 2 months decreased to 4 × 3 mm. The computed tomographic scan at 6 months showed a bone gap of 7 × 10 mm, 12 mm posterior to the posterior tantalum bone maker. Nevertheless, there was good ossification in the distraction zone.

DISCUSSION

Many palate lengthening procedures have been described, but the problem of velopharyngeal incompetence has not been completely solved. Removal of the posterior part of the hard palate was proposed[36] to allow greater retrodisplacement of the soft palate. In the present study the opposite was performed.

Distraction for advancement of the midface has been performed experimentally in sheep[73,74] and more recently has been reported clinically.[75] Expansion of the zygomatic arch and lengthening of the anterior maxilla has been performed in dogs.[76] This study showed that distraction osteogenesis is possible in thin bone such as the palatal shelf. Canine anatomy does not allow the pterygoid plate separation from the cranial base, thus the sagittal osteotomies had to be carried out with extreme accuracy between the pterygoid plates, and they had to be absolutely parallel to each other. The pig and some related animals have pterygoid

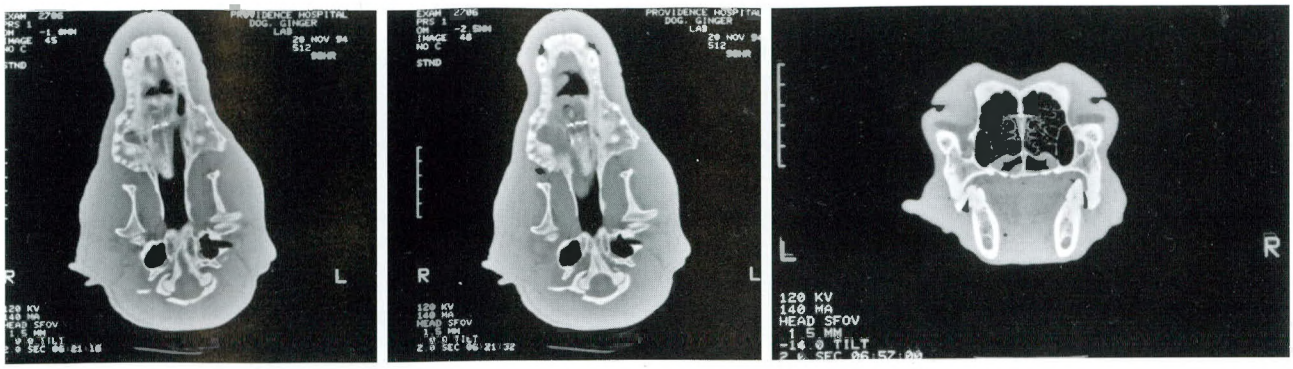


FIG. 9. Dog 5. (*Left* and *center*) Two months after distraction and 2 days after removing the device, two contiguous axial scans show approximately 50 percent ossification in the distraction zone. The holes left by the fixating miniscrews are seen in the posterior portion. (*Right*) Coronal computed tomographic scan of the distraction zone (3 mm anterior to the posterior bone markers) on the same day showing good ossification, the lateral osteotomies are still visible.

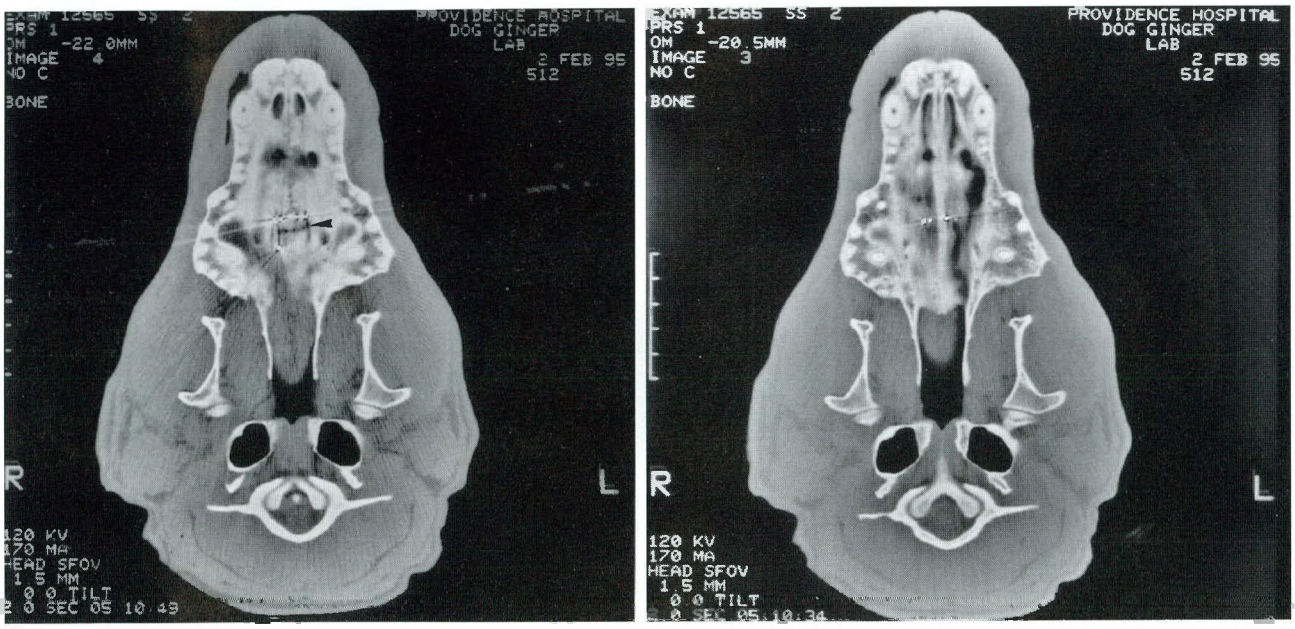


FIG. 10. Dog. 5 (*Left*) Five months after distraction axial scan shows the distraction zone of the hard palate. The fibrous interzone is still visible (arrow). Only one posterior bone marker is visible. The most posterior part of the hard palate is not seen in this scan (slice thickness 1.5 mm). There is no bone resorption as can be noted in the next contiguous slice (Fig. 10, B). (*Right*) Slice confirming that no bone resorption had occurred.

plates that resemble those of man, but the pig has a narrow palate and poor mouth opening. Primates would have been ideal but are not available to us.

In humans the palate lengthening osteotomy would separate the pterygoid process from the maxillary tuberosity as in the Le Fort I osteotomy (Fig. 11), thus the caudal part of the pterygoid process with the hamulus and the lateral portion of the soft palate and musculature could be displaced posteriorly. Should the caudal part of the pterygoid process not be sufficiently mobile, another short straight osteotomy could be made medial to the hamulus (dotted line in Fig. 11). If distraction was contemplated in patients with velopharyngeal incompetence after cleft repair, a preoperative computed tomographic scan would be necessary to determine the extent of the central bony palate defect. The design of the osteotomies would then be modified accordingly. Another possible problem would be reopening of the cleft, which prevent osteogenesis in the distraction zone; however, in dog 6 there was a fistula but osteogenesis proceeded normally and the fistula closed. To prevent rupture of the palatal mucosa the palatine vessels should be preserved, the mucosa should not be compressed by the device, and distraction should be slow.

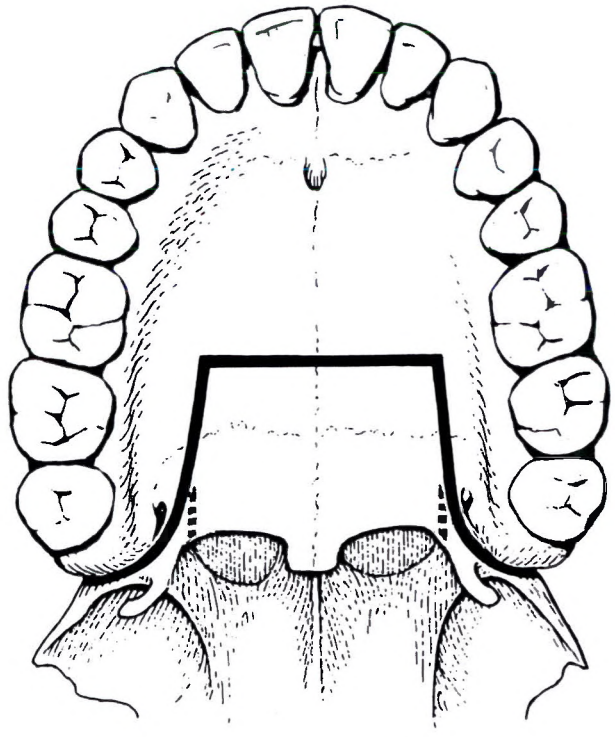


FIG. 11. Proposed osteotomy for distraction of the palate in humans.

It was not known when to begin distraction and what its rate and rhythm should be. In the mandible the latency period is short[67,72]; distracton is commenced on the first postoperative day. Because of the thin palatal bone, a 4-day latency period was used initially, but this resulted in dehiscence, and 18 days produced premature fusion. The ideal period was found to be between 10 and 12 days. A rate of 0.25 to 0.5 mm lengthening per day, and a retention period of 4 to 7 weeks, was ideal.

If used in the human the device may be fixed to the teeth by orthodontic bands depending on the patient's age and dental condition; in addition, miniscrews could be used. Orthodontic banding would allow correction of any occlusal changes that may occur. Dental occlusion was recorded in the present study; however, no changes occurred. This finding is because canine premolars are in infraocclusion. Consequently, the premolar crowns could be totally covered with the acrylic part of the device, thus the dynamic forces were distributed and well withstood. Because the forces applied to the teeth in humans may be more significant, later orthodontic correction might be necessary. A longer expansion screw will be necessary; the 8- to 9-mm expansion achieved in the study would not be sufficient for some velopharyngeal incompetence patients.

The quality of barking was unchanged and snoring was not present during sleep. The latter may indicate a degree of sleep apnea, as can occur in humans after corrective surgery for velopharyngeal incompetence.

If this procedure were performed on the human it could be monitored by surgeon, speech therapist, and relatives, and when optimal correction was achieved the distraction could be discontinued. This would need to be done carefully because, in the dog, without distraction the bone gap is bridged by mature bone, making further distraction impossible. The possible benefits of this procedure in the human would be simple surgery, the absence of complications and scarring, and the possibility of accurate monitoring of palatal position to obtain an optimal speech result.

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