Cleft palate repair with the use of osmotic expanders: a preliminary report

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Summary A new method of cleft palate repair by expansion of tissue by means of osmotic expanders implanted in the first stage of treatment is described. Self-expanding expanders manufactured by OSMED (Ilmenau, Germany) were implanted under the mucoperiosteal layer of the hard palate, on purpose to generate more tissue and provide facility for palate repair performed 24–48 h later.

Nineteen children aged from 2 to 3 years were operated from January 2004 to 15 April 2005. In clefts < 10 mm, tissue repair was possible without relaxing incisions. In 11 patients with clefts > 10 mm, cleft palate repair was more difficult and the outcomes were less favourable. Despite more generous dissection of the neurovascular bundles and other adjunctive measures such as mucosal V–Y plasty [Bardach J, Salyer K. Surgical techniques in cleft lip and palate. Chicago, London: Year Book Medical Publishers, Inc.; 1987.] and suturing of the mucosal grafts at the border of the hard and soft palate, seven 2–4 mm fistulae were noted, however.

Concluding, in spite of some shortcomings and unacceptable rate of fistula in wide clefts, the above-presented method seems to be an attractive concept. Despite some technical problems related mostly to still tested optimal filling phase, tissue expansion makes palate repair easier, probably without relaxing incisions and bone denudation. Consequently, some adverse effects on facial growth may be reduced. So far, there is no evidence for it, however, and since this is a preliminary report, there is a need for longer observations and larger material.

Following cleft palate repair factors that might lead to hypoplasia and deformity of the maxilla include extensive dissection of the tissues and the healing of wounds by secondary intention. This is
especially so after Von Langenbeck’s, Veau’s, Peet and Wardill’s methods,1–4 in which the bones are denuded as a result of mucoperiosteal flaps transposition and the use of relaxing incisions. As the result, the healing of the wounds occurs through granulation with subsequent, damaging effect of the post-surgical scars.5–9

Similar results, though slightly less harmful, are associated with the use of vomer flaps,10–15 in which denudation of the vomer and nasal septum may increase its deviation, narrow the nasal ducts and exert an inhibitory effect on maxillary development too.16

Among various methods of so-called saving or low-traumatic management,12–15,17–21 operation on the soft palate with subsequent closure of the hard palate cleft was delayed until a later age is considered the most effective.22–25 However, despite a proven protective effect on the maxilla, the quality of speech and the prolonged therapeutic process are drawbacks.26,27 Thus despite numerous and significant improvements, such as a reversed sequence of treatment,18 Dunn’s method,28–31 supraperiosteal dissection according to Leenstra et al. modality,32 Perko V–Y plasty33 or our own surgical method with the use of an extended vomer flap,12–14 the problem remains.

Since the main problem lies in the deficiency of tissue, the bulk of which should be increased, 8 years ago the author undertook the first trials to insert mini-expanders filled with physiological saline for mucoperiosteal tissue expansion. This resembled to some extent the method introduced by De Mey et al.34 who used a custom-made expander in the treatment of palate fistula in an 8-year-old child. The program was abandoned due to technical problems and it was not until osmotic expanders were introduced and idea was resumed.

### Patients and methods

The osmotic expanders are self-filling devices consisting of an osmotic active hydrogel (copolymer from methylmethacrylat and N-vinylpyrrolidone made by OSMED gmbh according to the requirement of German law/ Medizinproduktegesetz).35

It allows tissue expansion without the use of injection. Once implanted they absorb body fluid, which leads to a predetermined volume and size.

The properties of the custom-made cigar like expanders were determined before and after swelling in 0.9% NaCl solution, to be volume: 5.2 (final volume/initial volume) and linear expansion: 1.75 (final dimension/initial dimension).

According to manufacturer’s data, the maximum volume is achieved after 24–48 h. The material is nontoxic without any systemic effects in several studies.

From 8 January 2004 to 15 January 2005, hard palate mucoperiosteal tissue expansion was used as a method of treatment in 19 children aged from 2 to 3 years, with isolated (5×), unilateral (8×) and bilateral (6×) palatal clefts. An average width of the clefts measured on the border of the soft and hard palate was 11.7 mm.

All the patients were operated by using a two-stage procedure under general intratracheal anaesthesia. Osmotic expanders were used as temporary implants which remained in the body from 1 to 2 days. Before the treatment cleft width measurements on the border of the soft and hard palate as well as dental cast analysis were done in all the patients.

The palate repair with the use of osmotic expanders has been approved by Ethical Committee of Medical Academy in Wroclaw.

### Cleft palate surgery

#### Stage 1

After insertion of the mouth gag and injection of 0.25% solution of xylocaine with 1:200 000 epinephrin, the palatal mucosa and periosteum were incised bilaterally at the length of 1 cm. Initially the incision was performed immediately behind the alveolar process, later it proceeded along the edge of the hard palate. The hard palate was dissected subperiosteally with a curved raspator as far as the alveolar process and the posterior margin of the palatal plate.

Custom-made osmotic expanders manufactured by OSMED with a 5-fold swelling factor were inserted into the formed tunnels. The initial size of the expanders was tailored according to the age of the patient, size of the palate as well as the planned scope of its action. Three types of cylindrical expanders and an hourglass expander were used as follows: 15 × 6, 9 × 6 and 12 × 4 mm, which expanded to the size of 25 × 10, 15 × 10 and 20 × 6.7 mm, respectively.

The expanders were most commonly inserted into the posteriomedial part of the hard palate. In five cases, double expanders, 9 × 6 and 12 × 4 mm, on both sides of the cleft were inserted. The wounds were closed with 4/0 Vicryl sutures.

Until the time of the second operation, the patients were fed parenterally. The oral cavity was checked every 3 h in case the expanders discharged spontaneously and to prevent possible asphyxia.
The second stage of treatment was performed after 24–48 h depending on the condition of the expanded tissue. In the initial period, when only 15 × 6 mm expanders were used, the treatment protocol according to which the osmotic expanders were left for 48 h had to be changed. Faster than expected increase of the bulk of the tissue and resultant excessive tension necessitated operation after 24 h in fear of spontaneous discharge of the expanders and/or necrosis of the tissue. Cyanosed or pale tissue as well as significant tension that might eventually result in dehiscence of the wound was regarded as an indication for intervention on the day after the first procedure. In patients with normal-looking tissues, the second stage operations were performed after 48 h.

After the removal of the sutures and swollen expanders, the margins of the soft palate were incised and dissected, the aponeurosis was cut transversely and the palatine muscles were translocated backwards. In narrow clefts, delicate dissection of the tissue around the palatal vessels was enough to close the cleft by means of 5/0 and 4/0 Vicryl sutures (Fig. 1). The wider clefts were managed by dissection of the neurovascular bundle36 from small, stab incision (3×) and one patient had V–Y plasty with mucosal flaps according to Perko’s method.33 Dissection of the neurovascular bundle was associated with hamulus processes infraction in one patient and with detachment of the tendons of the tensor veli palatini muscles in another one (Fig. 2). Despite quite important gain of expanded tissues in three recently repaired wide clefts the simple suturing on the oral side has been considered too risky due to excessive tension. Therefore, the small mucosal grafts were applied.

Results of treatment

Cleft repair according to generally accepted criteria was obtained in all patients. No tissue necrosis occurred, and to our surprise, even badly cyanosed tissues regained their colour almost immediately after the removal of expanders.

Among eight patients with clefts < 10 mm, two patients developed mini-fistulae on the border of the soft and hard palate. In 11 clefts more than 10 mm wide (mean, 14.2) as measured at the level of the posterior nasal spines the results were less satisfactory, however. Despite the adjunctive procedures described above, the mini-fistulae (2–4 mm) were noted in seven of the above-discussed cases (Fig. 3).

Apart from this, both the surgical procedures and the post-operative course were uneventful. No complications were observed in early follow-up examinations carried out after 4–6 months.

Discussion

Tissue expansion is a popular and effectively used modality of treatment. Therefore, the idea of hard palate mucosal augmentation seems to be justified especially as palatal tissue elasticity and the stretch-relaxation phenomenon37,38 allow closure of cleft defects that are even wider than those predicted on a geometric basis alone. According to Bardach and Salyer37 and Furlow,39 many palatal defects can be closed without exposing bare bone because of various angulations of the palatal shelves and downward rotation of the mucoperiosteal layer. For example, when both palatal shelves are 10 mm in actual width and are angled at 60 degrees with respect to the horizontal plane of closure-equation $C = A(1 - \cos(x)) + B(1 - \cos(y))$ shows that a 10-mm palatal cleft can be closed without tension by rotation of the mucoperiosteal tissues from their initial position on the palatal shelves into the horizontal plane (Fig. 4).37

Despite the calculations, the above-described method can be applied to narrow clefts only, because ‘...while the absence of relaxing incisions has theoretical merit, in practice the closure of a wide cleft in this manner is probably beyond the skill of most of us’.40

Therefore, using expanders and generating additional palatal tissue may enhance cleft repair and reduce the extent of the surgery.

In palate clefts, difficulties in maintaining conventional expanders as well as the abundance of microorganisms in the oral cavity do not favour this method and for that reason first trials of tissue augmentation were limited to short-lasting expansion during the same surgical procedure. The so-far used methods included several times repeated injections of 1% solution of lignocaine with epinephrine to the soft palate41 as well as tissue expansion at the hard and soft palate border by means of 5 cc Foley’s catheters.42 In view of lack of further reports published on that subject, it may be assumed that the procedures fell into disuse and were abandoned, as with our own trials of using classical mini-expanders.

The use of self-inflating hydrogel expanders seems to solve these problems, provided that some difficulties associated with precise calculation of a desirable volume and expansion time are secured. After implantation, the expanders cannot be controlled, risking inadequate tissue expansion or damage caused by excessive tension and
compromised blood supply. Although we did not experience such complications, recently we decided to study this problem thoroughly on the model of expanded rabbit’s palatal tissue.

In the initial calculations of their volume, data from trials with the classical mini-expanders were helpful. As far as swelling time is concerned, the technical conditions associated with the properties of hydrogels had to be accepted. According to parameters of the manufacturer OSMED, a 5-fold increase in the volume of the expanders occurs within 24–48 h, with 98% of the volume reached in the first 24 h.\textsuperscript{35}

Such super-quick expansion of tissues has its advantages and disadvantages.\textsuperscript{43,44} Disadvantages include the risk of necrosis and breaking the sutures. Moreover, an express, thus probably incomplete reorganization of the collagen fibres, may limit the efficacy of tissue expansion and possibly promote its secondary contraction. On the other hand, however, leaving the expanders in place for such a short time reduces both the risk of infection and the costs of treatment.

Despite an unquestionable disadvantage of two-staged operation in a short time, new technical possibilities associated with the use of osmotic expanders may be of interest to clinicians working with cleft patients, if the following conditions are fulfilled.

Apart from the above-described technique, it seems desirable to improve the method of tissue

\begin{figure}[h]
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\caption{(Above, left) Unilateral incomplete cleft palate before treatment. (Above, right) Expanded mucoperiosteal tissue almost closing hard palate gap. (Below, left) Osmotic hydrogel expanders before and after swelling. (Below, right) The palatoplasty performed without any relaxing incisions.}
\end{figure}
expansion on the hard and soft palate border as well as in the area between the palatine foramen and the alveolar process, where a narrow and compact space makes insertion of the expanders difficult. Blunt dissection accomplished from a minute incision is helpful in the area posterior to the maxillary tuberosity, but according to Ross and many others, this sensitive region should not be violated due to the risk of midfacial growth aberrations.

The susceptibility of tissue to expansion may be increased by dissecting the region of the nasal spine as well as medial and posterior palatine margins. This requires solely prolonged or full incision along the cleft fissure. The problem is that the swelling of the expanders acts also beyond the mucoperiosteal cover of the hard palate towards the nasal mucosa and sutured after expander insertion wound margins, which can be unable to withstand the excessive tension. That is the reason why only small expanders (12 × 4 and 9 × 6 mm) with a lower efficacy can be used safely. Limited expansion of the mucosa and periosteum does suffice to close a majority of hard palate clefts, but may be inadequate in clefts >10–12 mm, however. What remains in such cases is the above-mentioned elevation of the hard palate mucoperiosteal flaps to the horizontal plane as proposed by Furlow or as a last resort — the two-flap incision and transposition, followed by partial closure of lateral incisions as proposed by Bardach and Salyer.

As evidenced by first clinical trials, an extensive tension and risk of wound disruption on the oral side cannot be prevented by suturing of minimucosal graft at the border of the hard and soft palate. Though due to delay phenomenon, an expanded and precisely repaired nasal layer makes an excellent vascularised bed, and a relatively loose hard palate tissue adapts well to this area of concavity by quilted suture and tongue pressure, the healing-in of the mucosal grafts is poor.
Moreover, the gain due to horizontal transposition of tissue is strongly reduced in such cases. Since it is a preliminary report, there are still many doubts and dilemmas. So far, the body fluids absorption and swelling pressure were investigated on the model of an expanded rat's skin only. As the skin differs from the palate tissue, and transfer of experimental data to human subjects is rather limited, there is a need for serious clinical investigations such as serial biopsies, blood flow measurements and thorough clinical observations. So far, the few clinical reports are not very useful alas, because they apply to the use of osmotic implants for breast reconstruction, enlargement of anophthalmic sockets and closure of skin defects in other parts of the body. Moreover, according to Ronert's et al. method the filling phase was completed in 40–60 days, while the hard palate tissue expansion takes 1–2 days only.

As it has been mentioned before, apart from supposed tissue necrosis and breaking of the wounds, such super-quick expansion can produce less efficient augmentation of tissues. According to Wee et al. experiments with the use of classic expanders an intraoperative tissue expansion performed in pigs gave a true gain in area of 7.4%, while continuous tissue expansion performed over a 3-day period produced a 22% gain. Therefore, recent introduction of the silicone membrane that encloses the expander and leads to a slower (2–3 days), more gradual and consisting swelling seems to be optimal solution.

Despite an unacceptable so far rate of fistula, expected improvements and refinements make the new philosophy of cleft palate repair very attractive, because replacement of tissue transposition with its augmentation should produce less scars and trauma. And since the principal growth inhibitor seems to be the quantity and distribution of scar tissue that forms after surgery the beneficial effect of this modality may be achieved.

Finally it should be stressed that at the beginning, to be on the safe side, osmotic expanders were used exclusively in the treatment of children scheduled or referred to us at the age of 2–3 years. For about a year, however, the palate and vomer tissue expansions are used also in the treatment of 6-month-old children. So far the results seems to be better, but it would be definitely too early for any conclusions.
References

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