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## Expanding soft tissue with Osmed<sup>®</sup> tissue expanders in the goat maxilla

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### Date:

Accepted 13 April 2010

### To cite this article:

Uijlenbroek HJJ, Liu Y, He JF, Visscher C, van Waas MAJ, Wismeyer D. Expanding soft tissue with Osmed<sup>®</sup> tissue expanders in the goat maxilla  
*Clin. Oral Impl. Res* xx, 2010; 000–000.  
 doi: 10.1111/j.1600-0501.2010.01972.x

**Key words:** bone volume, intraoral, osmotic, soft tissue expansion, self-inflating soft tissue expander, tissue expander

### Abstract

**Objectives:** Soft tissue limitations are encountered in implant dentistry, due to the loss of alveolar bone. The aim of this study is to compare the outcome of soft tissue preparation using Osmed<sup>®</sup> self-inflating soft tissue expanders with different *in situ* times in two implantation techniques.

**Material and methods:** Osmed<sup>®</sup> self-inflating soft tissue expanders were implanted in goats using a tunnel approach and a flap approach. The animals were sacrificed after 1 h (controls) and 40 days (treated). A tattoo technique for stereographic measurements was used to look for soft tissue surface gain. Histological and histomorphometric analyses were performed to quantify and compare the changes in soft tissue volume and bone volume after 1 h and 40 days of implantation.

**Results:** After 40 days, the expansion was visible and none of the goats had shown any inflammation. The space between the soft tissue and the bone was filled by the completely expanded expander and surrounding connective tissue. Between the test groups and the control groups, there was no histological difference in the structure of the soft tissue.

**Conclusions:** All the tissue expanders expanded to their maximum size (2.8 times) and were a reliable product for creating a space between soft tissue and bone. The overlying soft tissue remained in excellent shape. There was no difference in the soft tissue volume and the bone volume between the tunnel and the flap approach after 40 days.

Lack of sufficient bone and soft tissue is a common challenge when performing implant dentistry. Different surgical approaches for bone augmentation are known and have been shown with successful results (Buser et al. 1999; Mattout & Mattout 2000; Esposito et al. 2006; von Arx & Buser 2006; Aghaloo & Moy 2007). For successful bone augmentation, sufficient soft tissue is a prerequisite. Primary wound coverage should be accomplished in order to reduce the risk of infection (Wang & Boyapati 2006).

Enlargement of soft tissue volume as well as soft tissue surface is a natural

phenomenon, seen in obesity and pregnancy. Soft tissue enlargement can be achieved using a soft tissue expander. In 1957, a balloon was used for skin tissue expansion in repairing an ear defect (Neumann 1957). In 1982, the interest in tissue expansion in reconstructive surgery was revived by a description of a tissue expander in breast reconstruction (Radovan 1982). In the same period, a self-inflating osmotic expander was used for the first time in guinea-pigs (Austad & Rose 1982). Conventional tissue expanders have several limitations: they need post-operative fillings, and have pressure peaks

and a filling valve at a certain distance from the expander. In order to overcome these problems, a self-inflating tissue expander was developed. However, every model self-inflating soft tissue expander has its own swelling curve. This means that the tissue expansion can only be controlled by choosing the appropriate expander. After implantation of the self-inflating tissue expander, there is no possibility to adjust the expansion speed and/or the end volume of expansion. A novel self-inflating hydrogel tissue expander and its biomaterial was described previously (Wiese et al. 2001), which resulted in the Osmed<sup>®</sup> (Illmenau, Germany) tissue expander.

The self-inflating device consists of an osmotic active hydrogel, a copolymer from methylmethacrylate (MMA) and vinylpyrrolidone. The hydrogel can generate physical swelling pressure *in vitro* of approximately 235 mmHg, which corresponds to 31.3 kPa (Wiese 1993). The volume of expansion depends on the concentration and the ion content of the medium in which the tissue expander is located (Wiese et al. 2001). The first-generation tissue expanders were designed without a silicone envelope. The expanders swelled relatively quickly, which, in some cases, resulted in complications (Rees et al. 2008). For this reason, the expander was wrapped up loosely in a silicone envelope. The envelope has a sealed extension, through which a fixation screw can be placed, and some pores through which fluids reach the osmotic active hydrogel. The silicon envelope itself thins after expansion because of stretch. A comparison of expanders with and without a silicone envelope in mini pigs showed that the swelling curve in enveloped tissue expanders was flatter than that in non-enveloped tissue expanders (Anwander et al. 2007). The use of a silicon envelope to reduce the expansion speed has a positive effect on the results. Rapid expansion leads to high-pressure peaks that may cause hypoxia in the tissue and may lead to damage of the expanded tissue (Wiese 1998; Bergé et al. 2001). The volume that the hydrogel can reach at expanding can be limited by wrapping the hydrogel up in a silicone

envelope, the swelling speed, the maximum reachable volume and the minimum reached swelling pressure can be affected.

Simple rules for successful tissue expander insertion have been described (Hudson & Grob 2005). Osmed<sup>®</sup> self-inflating soft tissue expanders are often used in plastic surgery with varying degrees of success. Four years of clinical experience in extraoral use in 58 patients with different indications were described (Ronert et al. 2004). They had a success rate of 81.5% without a silicone envelope and up to 91% with a silicone envelope. Success was achieved when there was soft tissue gain after explantation and a good final aesthetic result. A 3-year clinical follow-up of 20 expanders in nine patients in extraoral use showed a lower success rate (Obdeijn et al. 2009). A cleft palate repair study (Kobus 2007) reported seven fistulae in 19 patients. It must be noted that Kobus used tissue expanders without a silicone envelope. This results in a rapid expansion, so that the overlying tissues have no time to adapt. A rabbit study (Abrahamsson et al. 2009) showed that the osmotic soft tissue expander model for intraoral soft tissue and periosteal expansion suggests a promising method for creating a surplus of soft tissue that can be used to cover bone grafts.

A goat's palate is about the same size as a human palate. The goat's mucosa of the hard palate is firm and thick. Because of natural phenomena such as the fact that a goat does not have incisor teeth, and that it pulls off food by pressing it between the tongue and the palate, resulting in heavy mechanical loading of the palatal tissues, it can be seen as a suitable model for testing intraoral use of Osmed<sup>®</sup> expanders. Tattoos are used in several studies as a reference point or line for stereographic measurements (Wijdeveld et al. 1987; In de Braeck et al. 1992; Wiese 1998; Bleustein et al. 2001). This method was used to determine whether soft tissue surface enlargement (expansion) took place.

The purpose of this study was to gain localized soft tissue volume or area as well as space between bone and soft tissue by expanding intraoral soft tissue with an Osmed<sup>®</sup> self-inflating osmotic tissue expander. The changes in bone and soft tissue volume in a defined reference area, as well as the expander's clinical biocompatibility, were evaluated. Two different expander

insertion procedures were compared: a flap approach and a tunnel approach.

## Material and methods

### Tissue expanders

All the tissue expanders used were type 352-3070-S with a volume of 0.7 ml in a silicon envelope manufactured by Osmed<sup>®</sup> GmbH (Illmenau, Germany). A Straumann Crosshead<sup>®</sup> mini-screw was used to fixate the tissue expanders to the bone through the extension of the silicone envelope. The volume of the tissue expanders was determined by weighing before implantation and after explantation.

### Study design, animal model and surgical procedure

The study comprised 28 goats. On three goats (control group), no treatment was performed at all; undamaged palatal mucosa was obtained from these three goats. In each of the 25 goats, eight tattoos were placed and stereographic measurements were taken before surgical placement of the tissue expander. The 25 goats were divided into four groups: seven goats in the 40-day flap procedure, six goats in the 40-day tunnel procedure, six goats in the 1-h flap procedure (control group) and six goats in the 1-h tunnel procedure (control group) (Fig. 1).

Before treatment, all the goats received general anaesthesia with a xylazine hydrochlorite injection (Lanzhou Zhengfeng Pharmaceutical Co. Ltd, Lanzhou, China, 0.1 g/5 ml, 0.2–0.3 ml/goat; IM) 10 min before surgery, and an additional local anaesthesia was performed at the surgery site of 5 ml lidocaine hydrochloride injection (Shandong Yinhu Pharmaceutical Co. Ltd, Shandong, China) 0.1 g/5 ml, and 1:200,000 adrenaline. The animals received no antibiotics. The study was approved by the ethics committee of Inner Mongolia Agriculture University, China.

In the flap procedure, a flap was raised by making an incision about 20 mm long on the buccal site of the palate at the border between soft tissue and palatal tissue. A perpendicular relaxation incision was made in the frontal part from the border to the midline of the palate (Fig. 2). A full-thickness triangular flap was raised. The expander was placed and fixed to the bone by a Straumann Crosshead<sup>®</sup> mini-screw. In the tunnel procedure a tunnel was created by

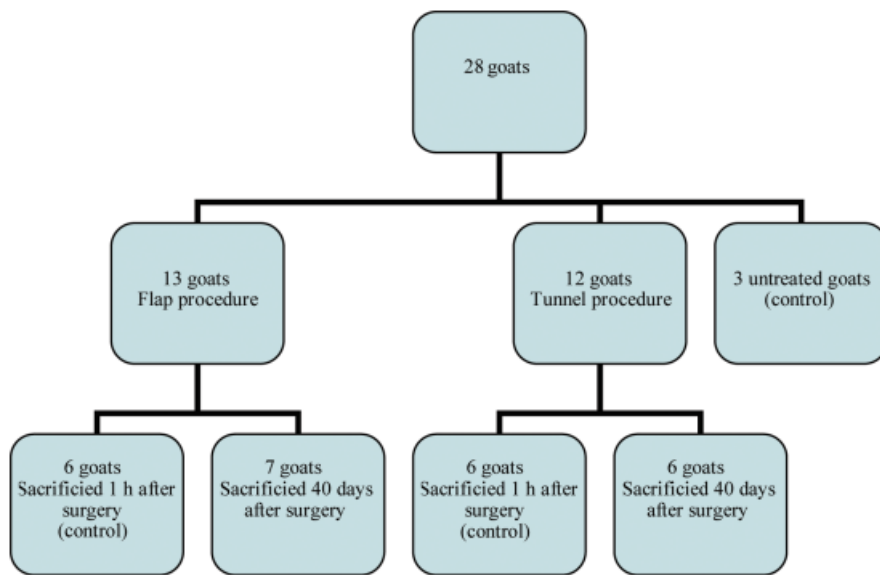


Fig. 1. The distribution of 28 goats over five groups.

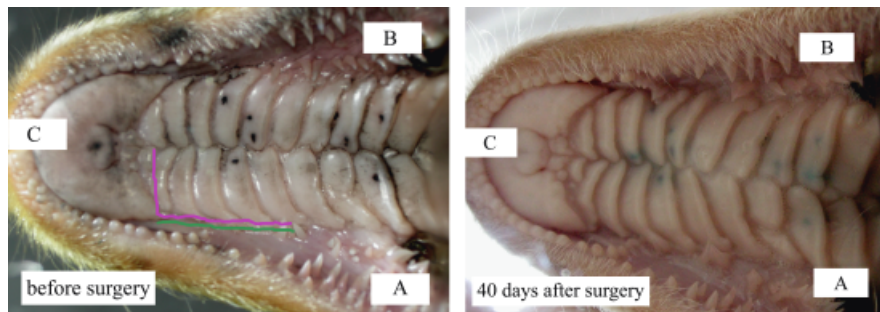


Fig. 2. Three fixed reference points were used to measure the expansion. The mesial cusp of the first right (A) and left molar (B) and the tattoo in the front (C). Before surgery, eight tattoos were placed and the distances to each reference point were measured. Two tattoos were placed after surgery. After 40 days, the tissue was clearly expanded. The tattoos had become slightly unclear. The distances from each tattoo to each reference point were measured again. The pink line shows the incision for the flap procedure and the green line shows the incision for the tunnel procedure.

making an incision about 20 mm long, on the buccal site of the palate, at the border between soft tissue and palatal tissue (Fig. 2). A blunt surgical instrument was used to create a pocket from the incision to the midline of the palate to insert the tissue expander. The expander was placed and fixed to the bone as described above. The wounds were sutured with Ethicon-Coated Vicryl 2.0 X-1.

The six goats in the 1-h flap procedure (control group) and the six goats in the 1-h tunnel procedure (control group) were sacrificed 1 h after surgery. The seven goats in the 40-day flap procedure and the six goats in the 40-day tunnel procedure were sacrificed 40 days after surgery. After sacrificing, blocks were taken out of the maxilla. The tissue expanders were re-

moved from the blocks, using a dorsal approach, and weighed. The obtained 25 blocks and the collected undamaged palatal mucosa of the three untreated goats were fixated. A reference space was defined. The bone volume and the soft tissue volume in the reference space were determined using systematic random sampling protocols. Histological and histomorphometric analyses were prepared as previously described and published (Liu et al. 2005).

#### Stereographic measurements

Eight tattoos were placed before surgery (Fig. 2) and two after surgery. Fixed reference points were chosen: the mesial cusps of the right first molar (A) and the left first molar (B) and a tattoo at the incisal foramen (C). In all the goats, the distance of

each tattoo to each reference point was measured before surgery. In the 1-h groups (flap and tunnel), the measurements were carried out again directly after placement of the tissue expander. In the 40-day groups (flap and tunnel), the distances between the reference points and each tattoo were again measured after 40 days.

We did not know exactly how the tattoos and the tissue expanders would present themselves after 40 days. As a precaution, we marked after placement of the tissue expander, the position of the screw and the other end of the tissue expander with a tattoo. These two tattoos were excluded from any analysis, because they were not performed in the 1-h groups.

For quantification, a mathematical plane, the triangle ABC, was constructed through the three fixed reference points. Owing to the arched concave shape of the palate, the cusps and the incisal foramen are positioned caudal of the palate. Therefore, the constructed triangle ABC through these points lies caudal from the expander. A Cartesian coordinate system with an  $x$ -,  $y$ -,  $z$ -axis was developed, in which  $A = (0, 0, 0)$ ,  $AB = x$ -axis. ABC is in the plane  $y = 0$  and T is a tattoo (Fig. 3). For each tattoo, the triangles ABT, ACT and BCT were constructed. Because of small measurement round-off variations, the point T does not have exactly the same coordinates for every triangle. Therefore, the triangles were turned around the AB, AC and BC axes. The point of intersection is the top of a pyramid, which is the coordinate of the tattoo. Mathematically, the tattoo can be found cranial or caudal of the reference plane. Clinically, we found all the tattoos cranial of the reference plane. For every tattoo, in every goat, the coordinates  $(x, y, z)$  were determined cranial of the reference plane. The coordinates of the same tattoos before treatment and after treatment were paired within one animal. The resultant is a vector that indicates direction and size. A sum of vectors of the tattoo transfers could lead to zero, and so the data will not show any movement, although considerable movement has taken place. For example, if the movement to the right is equal to the movement to the left, in direction and size, the resultant is 0. For this reason, we calculated absolute values. In every animal, an average of the absolute values before and after treatment

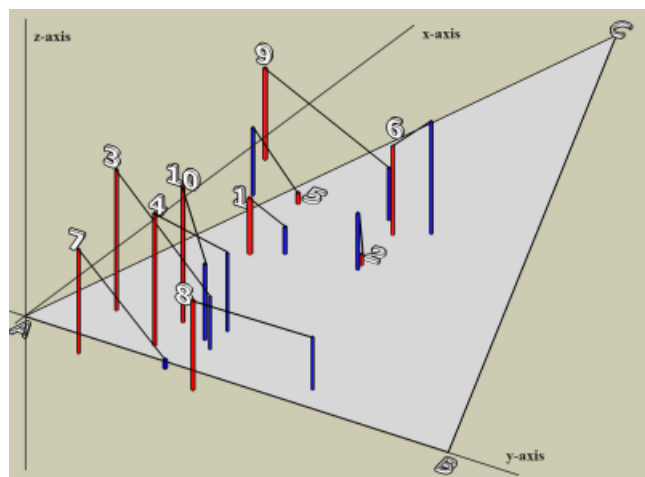


Fig. 3. This figure shows the reference points in the constructed triangle ABC, where A, mesial cusp of the right first molar; B, mesial cusp of the left first molar and C, the incisal foramen. A Cartesian coordinate system with an x-, y-, z-axis is developed and the coordinates of each tattoo (1–8) are determined. Tattoos 9 and 10 were placed after surgery. Every red bar shows one tattoo before expansion. It is connected to a black line to a blue bar, which shows the tattoo after expansion. The constructed triangle ABC lies caudal of the expander because the palate has an arched concave shape. For this reason, the length of the bars will decrease during expansion.

was calculated separately for each of the x, y and z value. For each animal before and after treatment, a resultant was calculated by extracting the root out of the sum of squared means.

$$\text{Resultant} = \sqrt{\left(\frac{\sum |x|}{nx}\right)^2 + \left(\frac{\sum |y|}{ny}\right)^2 + \left(\frac{\sum |z|}{nz}\right)^2}$$

### Histology

A fully expanded expander in a silicon envelope (the extension not included) can reach a maximum length of 20 mm. The size of the obtained blocks was defined in such a way that all the tattoos were included in the sample and that around the expanded expander 3 mm unexpanded tissue was respected as a border. All the samples were constructed from the obtained blocks by cutting off the soft tissue with a scalpel and by sawing the hard tissue with a machine. From the three untreated goats, palatal soft tissue was collected. The samples were fixated in formaldehyde, dehydrated in alcohol, xylol and embedded in MMA and 15% dibutylphthalate. Out of each sample, 10 parallel serial sections were cut, 3 mm apart, perpendicular to the length axis of the sample. The first section was chosen within 3 mm from the fixation screw using a random number table. The sections were numbered and coloured with Mc Neal solution and Fuchsin solution.

### Histomorphometry

The sections were placed under a microscope for photographing. The middle of the left and right sinus was in the centre of focus with the epithelium at the top and the sinus at the bottom. A scale was inserted. Photographs were developed at a five times magnification, saved in a TIFF-file and printed. A reference space was defined, which encapsulated in all the samples all the tissues in the area where the tissue expander had been located.

Bone volume ( $V_b$ ) was defined as the whole mineralized bone and bone marrow volume in the reference area. The soft tissue volume ( $V_{st}$ ) was defined as the whole soft tissue (palatal mucosa) in the defined area, including the connective tissue around the tissue expander. The fixation screw is counted as the medium in which it is located. A cross grid of  $1 \times 1$  cm was placed at random on the sections. The hits for  $V_b$  and  $V_{st}$  were counted according to the Cavalieri principles (Howard & Reed 2005). After counting the hits per section in the reference space, an average of the hits of the 10 parallel serial sections per parameter per sample was calculated.

### Statistics

The Kruskal–Wallis test was first applied for the complete analysis of  $V_b$ ,  $V_{st}$  and the stereographic measurements between the

1-h flap group, the 1-h tunnel group, the 40-day flap group and the 40-day tunnel group. As a post hoc test, the Mann–Whitney test was used.

Differences in the weight of the tissue expanders before implantation between the 1-h (flap and tunnel combined) group and the 40-day (flap and tunnel combined) group were also analysed using the Mann–Whitney test. The Wilcoxon signed-ranks test was used to analyse differences in the weight of the tissue expanders: in the 1-h group (flap and tunnel) before implantation and after 1 h *in situ* as well as in the 40-day group (flap and tunnel) before implantation and after 40 days *in situ*.

The data were analysed using SPSS (SPSS Inc., Chicago, IL, USA, version 16.0) The level of statistical significance was set at  $P < 0.05$ .

## Results

### Macroscopic evaluation

No inflammation was seen at any time in any of the animals. All the wounds healed completely without complications. In all the goats in which a tissue expander had been *in situ* during 40 days, a clear expansion of the palatal mucosa was visible (Fig. 2). The expanders were clearly palpable. The expanded tissue did not differ clinically from the unexpanded tissue.

### Stereographic measurements

The tissue expander was located in its intended place with screw fixation. The tattoos were still visible after 40 days, although some of them faded slightly (Fig. 2). The tattoos moved as a consequence of the expansion. The soft tissue did not expand symmetrically, leading to an asymmetric movement of the tattoos. The average distance in mm in the 40-day group is a dimension for the total expansion, as it is a dimension for the expansion due to the implant procedure in the 1-h group. The difference between these two calculated average distances is the effect caused by expansion of the tissue expander. The value after 1 h can be seen as a 0-value for the calculations. The Kruskal–Wallis test for stereographic measurements just reached the level of significance ( $H = 7.8$ ;  $P = 0.050$ ). Therefore, we performed post

hoc Mann–Whitney tests that revealed no differences in the stereographic measurements between the 40-day flap group (range 3.4–7.1, median 5) and the 40-day tunnel group (range 3.1–5.3, median 4.1) ( $U=11$ ;  $P=0.181$ ); the 1-h flap group (range 2.8–6.3, median 3.4) and the 1-h tunnel group (range 3–4.7, median 3.2) ( $B$ ;  $P=0.937$ ); and the 1-h tunnel group and 40-day tunnel group ( $U=9.5$ ;  $P=0.180$ ); the 1-h flap group and the 40-day flap group ( $U=8$ ;  $P=0.073$ ).

### Tissue expanders

All the tissue expanders expanded till the silicone envelope was completely filled and stretched (Fig. 4a). Explantation showed the entire tissue expander firmly surrounded by connective tissue. The weight of the tissue expanders showed an average increase of 278% after 40 days *in situ* (Fig. 4b). Before placement, there was no statistical difference in weight ( $U=68.5$ ;  $P=0.586$ ) between the tunnel group (1-h and 40-day; range 0.25–0.27 g, median 0.26 g) and the flap group (1-h and 40-day; range 0.24–0.27 g, median 0.25 g). The difference in the weight of the expanders in the 1-h groups before placement (tunnel and flap; range 0.24–0.27 g, median 0.25 g) and after 1 h *in situ* (tunnel and flap; range 0.25–0.28 g, median 0.27 g) was significant ( $Z=-2.9$ ;  $P=0.004$ ). There was also a significant difference ( $Z=-3.2$ ;  $P=0.001$ ) in the weight of the expanders in the 40-day groups between the weight of the expanders before placement (tunnel and flap; range 0.24–0.27 g, median 0.26 g) and 40-day *in situ* expanders (tunnel and flap; range 0.67–0.77 g, median 0.70 g).

### Histology

The hard palate is covered by an ectodermic, multilayered, orthokeratotic epithelium with a stratum granulose with keratohyaline granules. The epithelium is firmly connected through the basement membrane with the lamina propria, which is connected with the periosteum through a tight connective tissue. The lamina propria has quite high papillae, which shows regularity in distance and height. The thickness of the epithelial layer and the height of the papillae had not decreased. Visual comparison of the epithelium between 40-day flap, 40-day tunnel, 1-h flap, 1-h tunnel and untreated animals obviously showed no differences (Fig. 5). Comparison of the photos indicates that the interpapillae distance and the papilla heights do not differ much.

### Histomorphometry

Owing to technical problems in sampling, one sample of the 1-h flap group as well as one sample of the 1-h tunnel group were excluded. Out of the counted hits per section in the reference space for  $V_b$  and  $V_{st}$ , averages of the hits per parameter per sample were calculated (Fig. 6).

The Kruskal–Wallis test showed no difference for  $V_{st}$  ( $H=4.9$ ;  $P=0.176$ ) but showed a difference for  $V_b$  ( $H=9.2$ ;  $P=0.027$ ). The post hoc Mann–Whitney test for  $V_b$  showed in the 1-h tunnel group (range: 21.9–41, median: 32.3) significantly less bone ( $U=2$ ;  $P=0.032$ ) compared with the 1-h flap group (range: 34–53.8, median: 46) as well as compared with ( $U=2$ ;  $P=0.017$ ) the 40-day tunnel group (range: 34.2–54.1, median: 52.5). No differences were found for the  $V_b$  between the 40-day flap (range: 35.2–56.3, mean:

45.3) and the 40-day tunnel ( $U=19$ ;  $P=0.836$ ) as well as between the 1-h flap and the 40-day flap ( $U=15$ ;  $P=0.755$ ).

## Discussion

### Tissue expander and surgical procedure

Osmed<sup>®</sup> soft tissue expanders are widely used to expand extraoral tissues (Bergé et al. 2001; Ronert et al. 2003; Ronert et al. 2004). Compared with all the extra oral tissues, the palatal mucosa is quite firm. As we started our research, it was unknown how an Osmed<sup>®</sup> soft tissue expander, with a silicone envelope, would behave intra orally. The goat is a ruminant that impairs high masticator tongue forces to the palatal mucosa. We chose the palate of a goat because the palatal tissue of a goat is very tough tissue, hard to expand and expelled to great external chewing forces. We assumed that if an expander can expand there, it can expand anywhere in the mouth. We realized that the shape of a goats palate varies from almost flat to slightly concave, which is an easy shape for expansion. Therefore, all the other conditions were quite unfavourable for expansion. This study shows that Osmed<sup>®</sup> soft tissue expanders can be used intraorally. Because of the low solids content of methyl methacrylate–vinyl pyrrolidone expanders, and a density in the swollen state that hardly differs from the density of aqueous media (1 g/cm<sup>3</sup>), the volume can be determined with sufficient accuracy by weighing (Anwander et al. 2007). The weight, and therefore the volume, of the tissue expanders increased 2.8 times after 40 days *in situ*. The unexpanded as well as the expanded tissue expander do not harm

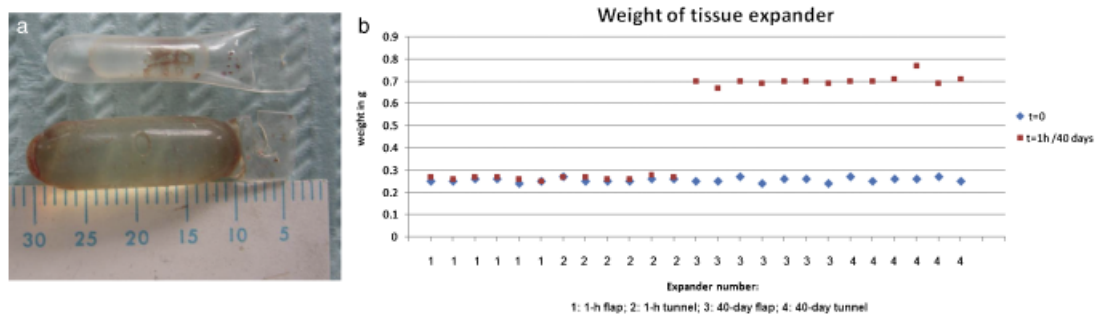


Fig. 4. (a) Figure showing tissue expanders in a silicone envelope. Note the extension of the silicone envelope on the right side for screw fixation. The upper expander had been explanted after 1 h, and the lower expander after 40 days. (b) Shows the weight of the tissue expanders. The blue dots show the weight before placement of the expanders ( $t=0$ ), and the red dots after explantation of the expanders.

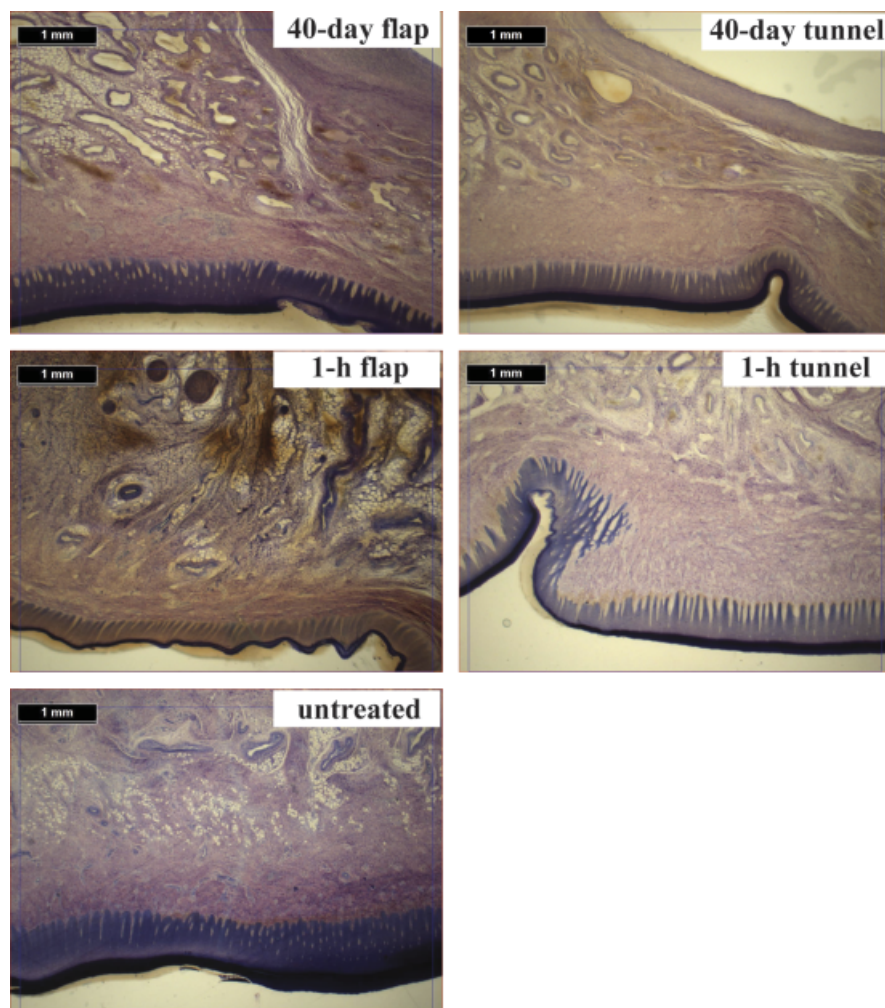


Fig. 5. The histological comparison of the epithelial structures between the five groups did not show distinct differences.

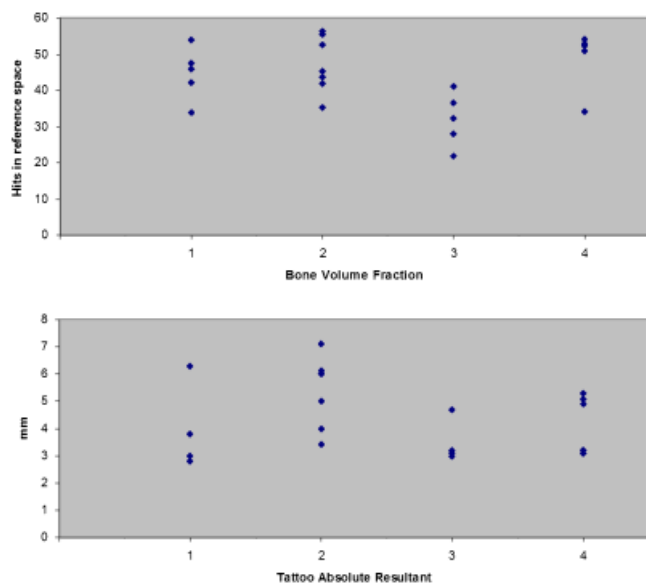


Fig. 6. Scatter plots of 25 operated goats showing the spread of the average values in one goat for each group. On the horizontal axis the groups: 1, 1-h flap; 2, 40-day flap; 3, 1-h tunnel; 4, 40-day tunnel. On the vertical axis the counted hits in the reference space according to Cavalieri principles for the bone volume fraction and the absolute calculated resultant in mm for the stereographic measurements.

the surrounding tissues. In the tunnel procedure, a lack of view and freedom of manipulation was experienced, and so the placement and fixation was less easy as compared with the flap procedure. The tissue expander starts to swell as soon as it comes into contact with a fluid, and so the manipulation and operation time is limited in a moist environment. The amount of fluid in contact with the expander is easier to control in a flap procedure. Therefore, from a practical clinical point of view, a flap procedure is recommended. Screw fixation is important, because the expander could otherwise wander due to chewing or expanding forces. The extension of the silicon envelope and its screw fixation could be at the relaxation incision side. Because the extension part with the screw has no swelling, the tension on the sutured relaxation incision will be less. The last part of the pocket can be tunnelled, allowing easily placement of the end of the tissue expander whereby the incision length is reduced.

**Soft tissue**

After 40 days, the soft tissue in all the groups was in excellent shape. There were no perforations and a volume increase of the lacuna, created by the tissue expander between bone and soft tissue. The volume increase did not cause stretching of the overlying soft tissues. Before treatment, the shape of the soft tissue of the palate is arched; it has a concave form. When a tissue expander is placed during surgery, the soft tissue is elevated from the palatal bone. The soft tissue shape flattens. It transforms into a convex shape during expansion. Changing from a concave form to a flat form results in a decrease in the surface area. The transformation from a concave form to a convex form does not alter the surface area. The volume between bone and soft tissue may increase, even though the surface area of the soft tissue has not increased. Expansion of the tissue was observed clinically, and proven by the weight of the tissue expanders. Hence, there has to be a volume increase. Therefore, the volume increase must have taken place between the bone and its covering soft tissue, without a change in the soft tissue surface area. Because of the above-mentioned reasons in the results, no vo-

lume increase was found histomorphometrically.

The dependence of the expansion speed on the shape of the expander has been shown before (Wiese 1998). A bowl expands less fast than a rectangular expander body. The expansion speed of the hydrogel depends inter alia on the distance to the centre of the expander body. The expansion speed is important because the higher the expansion speed, the less time the soft tissue has to adapt. If the expansion of the soft tissue is faster than the growth of the soft tissue, the soft tissue will stretch or the expander will even exoplate through the soft tissues. Stretching of the soft tissue means the soft tissue volume does not increase, although the soft tissue surface increases. The expanding time of the expanders in a 0.9% NaCl solution *in vitro* is 40 days. It was unknown to which level the Osmed<sup>®</sup> expanders would have been expanded in a goat's palate after 40 days. Assuming that the expanding times *in vitro* and *in vivo* are equal, no time in the study remained for the soft tissue without expansion. The expanded tissue could have a stretch component. The stereographic measurements did not show soft tissue surface increase; no soft tissue volume changes were found in the histomorphometric analysis. It can be concluded that there no stretch effect is visible after 40 days and there is no soft tissue increase. A shape turnover effect – the concave shape changing to a stretched or a convex shape – took place, creating a space between bone and soft tissue.

### Bone

The tissue expander has bone on one side and mucosa on the opposite side, and so some bone resorption might have taken place. In accordance with the reactive force principles, the pressure needed to expand the soft tissue is equal to the pressure exerted on the bone. The matter with less resistance will move easier than the matter with more resistance. In the literature, different results, with different expanders, are reported on the reaction of the bone to the expanding forces of a tissue expander. Some authors reported bone resorption (van Damme et al. 1994), some multiple bony

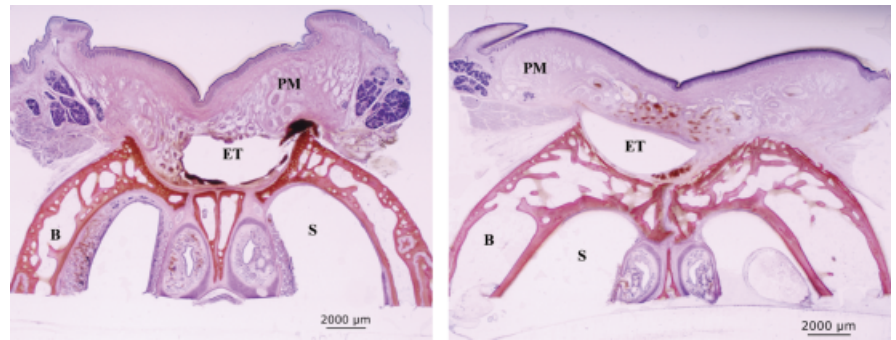


Fig. 7. Sections of the 1-h flap procedure (left) and the 40-day flap procedure (right) after removal of the tissue expanders. PM, palatal mucosa; ET, empty space tissue expander; B, bone; S, sinus maxillaris. It shows no bone resorption in one section when comparing the bone at the tissue expander side and the other side.

changes as well as changes at suture lines (El-Saadi & Nasr 2008), and others observed bone density decrease (Stuehmer et al. 2009). No bone resorption has also been reported (Abrahamsson et al. 2009). In a rat study (Sato et al. 1998) no bone resorption was observed when continuous compressive pressure was  $\leq 1.96$  kPa or when intermittent compressive pressure was  $\leq 9.8$  kPa. In contrast, continuous compressive pressure  $\geq 6.86$  kPa or intermittent compressive pressure  $\geq 19.6$  kPa caused significant bone resorption in all rats studied.

The tissue expanders generate a maximum expanding force of 243 mm mercury *in vitro* (Wiese 1998), which corresponds to 32.4 kPa. The pressure the hydrogel can generate is a continuous compressive pressure. Its maximum is 16.5 times higher than the critical pressure that causes bone resorption in a rat's palate. We expected the critical pressures for a goat's palate to be higher than in rats, because a goat is a larger animal. However, it is not inconceivable that the expander generates forces above a critical level that will result in bone resorption. One would expect a decrease in bone, due to resorption, on comparing the 1-h groups with the 40-days groups. However, only the 1-h tunnel procedure showed statistically less bone volume density. An explanation could be the damage of the bone due to the tunnelling procedure. After 40 days, it may have healed during the time of expansion. In case the tissue expander is in place for just 1 h, the healing time is much to a short.

The histological slides did not show bone resorption (Fig. 7). The form of the palate is arched; it is concave. This is an easy shape for expansion, as the soft tissue surface does not need to increase when it changes from a concave shape to a flat or a convex shape. If only small forces are needed for the expansion of the soft tissue, the reactionary expanding force generated by expansion of the tissue expander is also small. Bone resorption is unlikely to occur in such a case.

### Conclusion

All the Osmed<sup>®</sup> self-inflating tissue expanders expanded to their maximum size and created a space between soft tissue and bone as anticipated. The overlying soft tissue remains in excellent shape. The biocompatibility appears to be perfect. When placing a tissue expander in an intraoral site, a flap design is recommended. Further research is necessary to study the use of Osmed<sup>®</sup> self-inflating tissue expanders at another intraoral location (flat surface).

**Acknowledgements:** The authors would like to thank Osmed<sup>®</sup> GmbH, Ilmenau, Germany, for their generous gift of the tissue expanders as well as Straumann for the fixation screws. We would also like to thank Prof. Dr E. Hunziker for his histological advice and Ko van der Weijden for his mathematical support. This study has been made possible by ACTA.

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