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# Mandibular effects of maxillary distraction osteogenesis in cleft lip and palate☆

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*Abstract.* Maxillary distraction osteogenesis (DO) is a reliable treatment for severe maxillary deficiency in cleft lip and palate (CLP). The objective was to analyze its long-term effects on the mandible. A retrospective study of 24 CLP treated with maxillary DO using the Polley and Figueroa technique was done; patients were followed for more than 4 years. Preoperative (T0), 6–12 months postoperative (T1), and ≥4 years postoperative (T2) cephalometric radiographs were evaluated. A classical cephalometric analysis was used to assess treatment stability, and a Procrustes superimposition method was used to assess local changes in the shape of the mandible. The mean age of patients at T0 was $15.4 \pm 4.1$ years. SNA increased at T1 and T2 ($P < 0.001$), with no significant relapse between T1 and T2, indicating stability at 1 year after treatment (T0 = $72.4 \pm 5.3°$; T1 = $81.3 \pm 6.2°$; T2 = $79.9 \pm 6.1°$). SNB, facial angle, gonial angle, and symphyseal angle remained stable. Long-term analysis of the mandible demonstrated a minimal counter-clockwise rotation of the body (mandibular plane = $-0.2 \pm 3.2°$) and ramus ($-0.6 \pm 4.3°$). Maxillary DO in CLP had no significant effect on the shape or rotation of the mandible. The maxillary advancement remained stable after 1 year.

Key words: cleft palate; cleft lip; growth; distraction; mandible; maxilla.

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Maxillary retrusion is a common problem affecting children with cleft lip and palate (CLP). The prevalence of this skeletal class III relationship requiring surgery has been estimated to be around 25%.[1,2] The aetiology is multifactorial, and includes the severity of the initial deformity and the iatrogenic effects of the primary surgical treatment. These patients were initially treated with conventional orthognathic surgery, but the introduction of distraction osteogenesis (DO)[3,4] allowed the cleft surgeon to treat severe maxillary hypoplasia with other modalities.[5,6]

Maxillary DO has been used successfully in CLP for many years. This reliable treatment of severe maxillary deficiency has been proven to have good long-term stability.[7–13] When this technique is used for significant maxillary advancement, some studies have reported a mandibular autorotation (clockwise), due to the forward and downward movement of the maxilla and/or due to the counter-clockwise rotation of the palatal plane, increasing the posterior vertical dimensions.[7,11,12,14,15] Despite this initial mandibular movement, to the best of our knowledge no published studies have focused directly on the long-term mandibular effects of maxillary DO in CLP.

The purpose of our study was to evaluate the long-term effects on the mandible of external maxillary DO in CLP. Specific aims were to evaluate the mandibular shape, rotation, and position. We hypothesized that the effects would be minimal.

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## Materials and methods

This retrospective study reviewed cleft patients treated with maxillary DO in a paediatric cleft/craniofacial and plastic surgery unit. The cases of all complete CLP patients treated consecutively between January 2001 and January 2008 were reviewed. This research was carried out in accordance with the principles outlined in the Declaration of Helsinki.

The inclusion criteria were: complete unilateral CLP (UCLP) or complete bilateral CLP (BCLP) patients with severe maxillary hypoplasia and class III malocclusion (requiring a horizontal maxillary advancement ≥7 mm), operated on by the same surgeon with the same primary treatment protocol,[16] and distracted externally in accordance with the Polley and Figueroa technique.[17] Cephalometric radiographs taken preoperatively (T0), at 6–12 months postoperatively (T1), and more than 4 years postoperatively (T2) were required for the chart to be complete (Fig. 1). Patients with incomplete files, internal distraction patients, and syndromic cleft patients were excluded from the study.

### Maxillary distraction osteogenesis technique

The maxillary DO was always carried out externally using the KLS Martin Rigid External Distraction system (RED; KLS Martin, Tuttlingen, Germany) or the Walter Lorenz Blue device (Walter Lorenz Surgical, Jacksonville, FL, USA). First, a custom-made intraoral orthodontic appliance was inserted preoperatively in each patient to link the maxillary skeleton to the distraction apparatus. The system consisted of a double arch (vestibular and palatal arch) and a transpalatal arch, all cemented with bands on the first permanent molars and the first primary molars or permanent premolars. Two external traction hooks were welded to the vestibular arch at the level of the lateral incisors, and were bent under and in front of the upper lip with the end of the hook ending at the level of the palatal plane.

Intraoperatively, a classical Le Fort I osteotomy was performed using a reciprocating saw. Pterygomaxillary disjunction and a maxillary down-fracture were performed to mobilize the maxilla. Although not always done by some authors,[18] the down-fracture is useful to properly release the scar adhesions. No intraoperative repositioning of the maxilla was performed, and no bone grafting or internal skeletal fixation was utilized. The halo of the RED device was then fixated after closure of the intraoral wound.

After a latency period of 3–4 days, the maxillary distraction was started at a rate of 1.5 mm per day. All patients had a straight uniplanar horizontal advancement. Patients were evaluated once per week during the activation phase until the required advancement was obtained. The overjet between the maxillary incisors and the decompensated mandibular incisors was used as the clinical guide to determine the end of distraction. For the consolidation phase, the system was left in place for 4–6 weeks. At the end of the consolidation period, the halo was removed and a removable orthodontic facemask with elastic traction was used as a retainer at night for a further 6 weeks. No orthodontic alignment was performed before the distraction. All of the orthodontic alignment and levelling was done after the consolidation phase.

### Cephalometric analysis

The standardized lateral cephalometric radiographs analyzed for all patients enrolled in this study were taken shortly before the operation (T0) and postoperatively at 6–12 months (T1) and at more than 4 years (T2). A classical analysis was carried out using Procuste software 2007 (Procuste sarl, Caen, France). The bony landmarks used in this analysis included the following points: sella (S), basion (Ba), pterygoid (Pt), nasion (N), anterior nasal spine (ANS), posterior nasal spine (PNS), A-point (A), B-point (B), menton (Me), gnathion (Gn), gonion (Go), articulare (Ar), incisal edge and apex of the maxillary central incisor, incisal edge and apex of the mandibular central incisor, occlusal point (projection of the first maxillary premolar on the occlusal plane), distal of first maxillary molar, distal of first mandibular molar, porion (Po), orbitale (Or), and pogonion (Pog).

The angular measurements analyzed at T0, T1, and T2 were: SNA, SNB, ANB, Frankfort (Fr)–mandibular plane angle (FMA), facial angle of Ricketts (Fr/N–Pog), facial axis of Ricketts (Ba–N/Pt–Gn), occlusal plane–Fr angle (OP/Fr), inter-incisal angle, and superior incisor–Fr angle (Isup/Fr). The distance AoBo, representing the orthogonal projection of A-point and B-point on the occlusal plane, was also measured in millimetres (mm).

The Procrustes superimposition method[19–21] was then performed between T0 and T2 to evaluate the global morphological variations (Fig. 2). The superimposition was based only on the relatively stable cranial base points (N, S, Ba, Pt). This method allowed an analysis of the global changes in the maxillary and mandibular morphology and position, without introducing the size factor (eliminating the size differences between the radiographs). From these superposition images, the gonial angle (Ar–Go/Go–Me) and symphyseal angle (Go–Me/Me–B) were measured at T0 and T2 (Fig. 3). Rotations of the mandibular plane, ramus, and palatal plane were also calculated (Fig. 4). The value was negative when the rotation was counter-clockwise.

### Statistical analysis

Statistical analysis of the data was performed using SPSS version 17.0 software (SPSS Inc., Chicago, IL, USA). All variables were divided into continuous and categorical variables; categorical

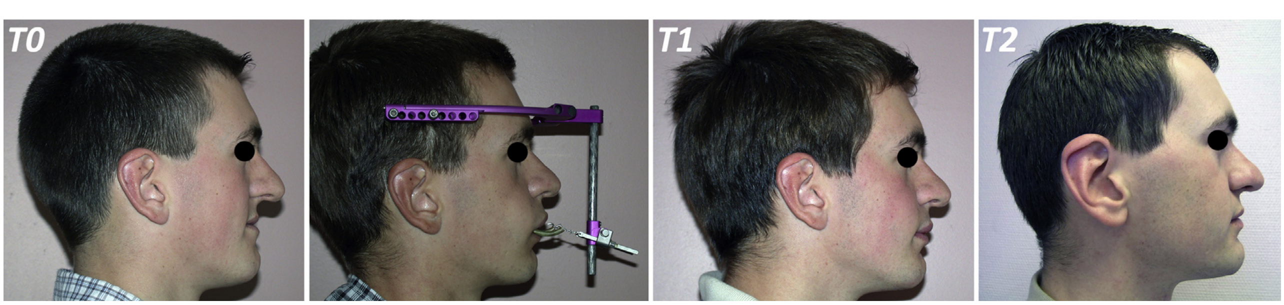


*Fig. 1.* Cleft lip and palate patient with severe maxillary hypoplasia preoperatively (T0), at 6–12 months post-distraction (T1), and more than 4 years post-distraction (T2).

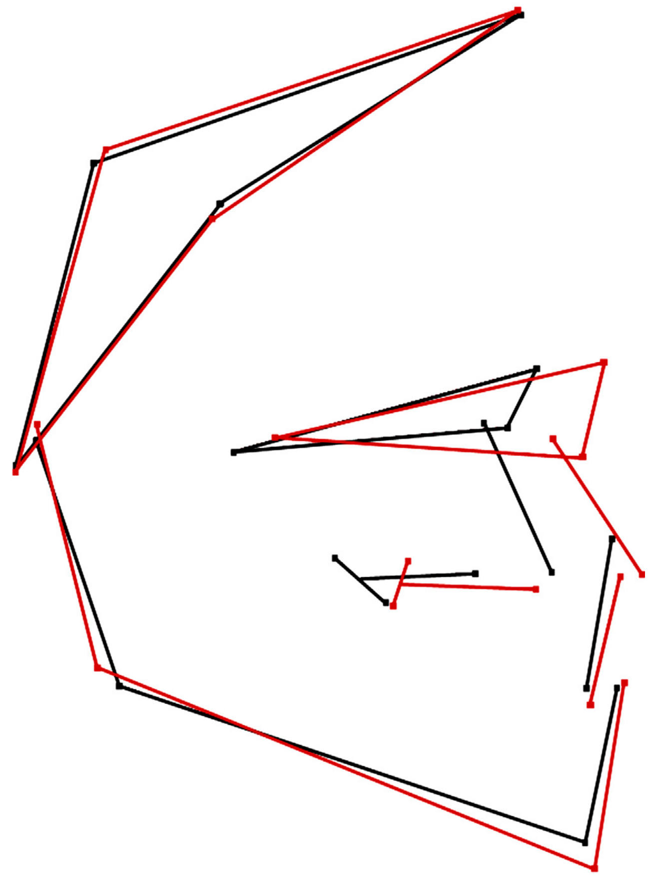

*Fig. 2.* Example of the Procrustes superimposition method [T0 in black, T2 in grey (red in online)].

variables were further subdivided into dichotomous and polychotomous variables. The changes between T0 and T1, T1 and T2, and T0 and T2 were compared for each of these variables. The Pearson $\chi^2$ test was used to analyze categorical variables. The *t*-test was used to evaluate a dichotomous categorical variable with a continuous variable. Analysis of variance (ANOVA) was chosen to study polychotomous categorical variables with continuous variables. Finally, Pearson correlations were used to evaluate two continuous variables. For all statistical tests, $P < 0.05$ was considered statistically significant.

## Results

### Patients

Thirty-three consecutive CLP patients with a severe maxillary deficiency were treated with external maxillary DO between January 2001 and January 2008. Of these, three syndromic patients, two patients with early complications (hardware loosening), and four patients lost to follow-up were excluded from the study.

A total of 24 complete CLP patients (17 UCLP and 7 BCLP) met the inclusion criteria and were reviewed (Table 1). The mean ± standard deviation (SD) age at the time of surgery was of 15.4 ± 4.1 years. The average follow-up time was of 0.7 ± 0.2 year at T1 and 4.5 ± 0.8 years at T2. The mean advancement was 16.2 ± 5.6 mm, with 58% of patients having advancements ≥15 mm.

### Maxillary changes

The maxillary advancement was significant and remained stable after 1 year (Table 2). Indeed, the SNA, ANB, and AoBo increased significantly between T0 and T1 and between T0 and T2 (all $P < 0.001$), with no statistically significant decrease between T1 and T2. Vertically, the maxillary position remained relatively stable with no significant change in the OP/Fr angle ($P = 0.922$). The palatal plane showed a mean counter-clockwise rotation of $-2.8 \pm 3.8°$ (Table 3). This counter-clockwise rotation of the palatal plane was more significant in BCLP cases (UCLP = $-1.8 \pm 3.4°$; BCLP = $-5.3 \pm 3.7°$; $P = 0.035$). The inter-incisal angle decreased significantly ($P = 0.004$), and the Isup/Fr angle increased significantly ($P = 0.001$) mainly due to the proclination of the maxillary incisors. Age, sex, diagnosis, advancement, distraction time, and consolidation time had no other significant effect on the maxilla.

### Mandibular changes

The mandibular position remained relatively stable sagittally and vertically between T0 and T1, T0 and T2, and T1 and T2 (Table 2). No statistically significant change in the SNB ($P = 0.667$), FMA ($P = 0.806$), facial angle of Ricketts ($P = 0.980$), or facial axis of Ricketts ($P = 0.939$) was demonstrated. The gonial angle and the symphyseal angle also showed no statistically significant changes (Table 3). The mandibular plane showed an insignificant counter-clockwise rotation of $-0.2 \pm 3.2°$ (Table 3). Similarly, the ramus had a counter-clockwise rotation of $-0.6 \pm 4.3°$ (Table 3). When the advancement was ≥15 mm, the mandible had a tendency to rotate clockwise, with a mandibular plane rotation of $0.9 \pm 4.1°$ and a ramus rotation of $0.9 \pm 3.3°$. Age, sex, diagnosis, advancement, distraction time, and consolidation time had no other significant effect on the mandible.

## Discussion

Our results confirm that maxillary DO is a reliable and effective treatment for severe maxillary deficiency in CLP. The advancement remained stable after 1 year, with a statistically significant increase in the SNA, ANB, and AoBo at all follow-up times (all $P < 0.001$). Our results also demonstrated that maxillary DO had a minimal effect on the sagittal and vertical position of the mandible, with no significant changes in its shape or rotation.

The possible clockwise rotation of the mandible associated with maxillary DO in CLP was not shown in our study, which demonstrated no significant rotational change (minimal counter-clockwise rotations). The mandibular gonial and symphyseal angles did not change, and its sagittal and vertical position remained stable, with no significant differences in the SNB, FMA, facial angle of Ricketts, or facial axis of Ricketts at all follow-up times (all $P > 0.05$). This relative stability of the mandible has also been shown in other studies.[11–13,22] Aksu et al.[11]

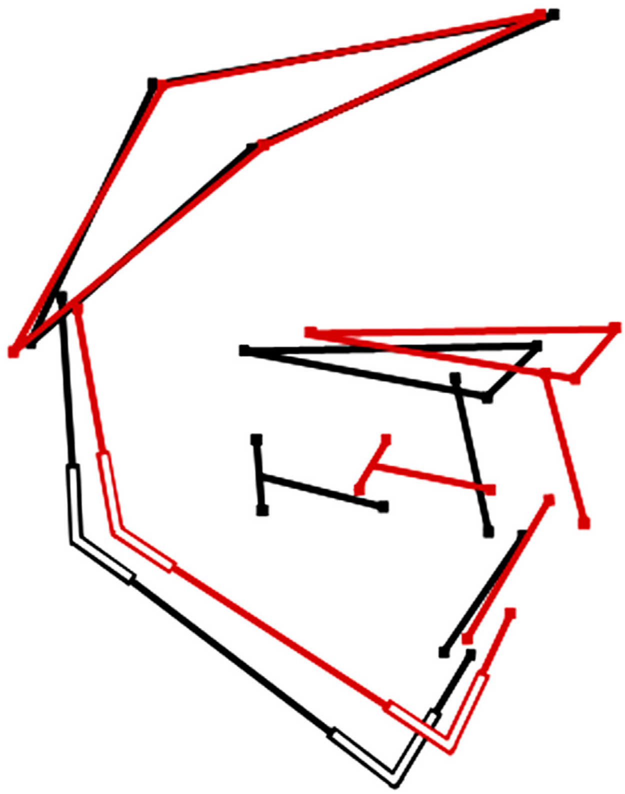

*Fig. 3.* Gonial and symphyseal angles [T0 in black, T2 in grey (red in online)].

*Table 1.* Patient characteristics.[a]

| Variables | |
|---|---|
| Patients, *N* | 24 |
| Age, years | 15.4 ± 4.1 |
| Sex | |
| Male | 16 (67%) |
| Female | 8 (33%) |
| Diagnosis | |
| UCLP | 17 (71%) |
| BCLP | 7 (29%) |
| Advancement, mm | 16.2 ± 5.6 |
| Advancement >15 mm | 14 (58%) |
| Distraction time, days | 13.7 ± 4.8 |
| Consolidation time, weeks | 4.7 ± 1.7 |

UCLP, unilateral cleft lip and palate; BCLP, bilateral cleft lip and palate.

[a] Data are presented as the mean ± stan-standard deviation, or number with percentage in parenthesis.

evaluated seven CLP patients treated with RED after their growth spurt (mean age 21.6 years), with an average follow-up of 37.3 months, and showed no significant change in the FMA or anterior facial height at the end of treatment. Similarly, Chen et al.[13] reported no significant change in the FMA or SNB at 5 years after external maxillary distraction in 12 growing CLP patients. However, they did show a significant increase in the mandibular volume calculated on three-dimensional computed tomography.[13] Gürsoy et al.[12] studied 13 prepubertal CLP patients treated with RED. At the 5-year follow-up, the mandible demonstrated minimal sagittal advancement (1–3 mm), but a significant downward movement (5–7 mm).[12] This sagittal stability (no change in SNB) but downward shift of the mandible was also reported by Honda et al.[22] after the long-term (5 years) evaluation of growing CLP children treated with maxillary DO.

The maxilla showed a significant sagittal advancement, with minimal vertical change, but some degree of counter-clockwise palatal plane rotation. Even with 58% of the advancement being greater than 15 mm, the maxillary movement remained relatively stable after 1 year, with no significant change in any of the variables between T1 and T2. Numerous authors have reported the effectiveness of maxillary DO in CLP,[7,9–13,23–27] with numerous studies also confirming the maxillary stability after the first post-distraction year.[7,9,13,23,24] In a three-dimensional computed tomography analysis, Chen et al.[13] demonstrated both linear and volumetric maxillary growth during the distraction phase and positional stability, with a significant stable increase in the overjet, SNA, and ANB, up to the 5-year follow-up. A counter-clockwise rotation of the palatal plane was also reported in the initial post-DO phase by Aksu et al.,[11] but this rotation of the maxilla had returned to its original position at the end of the 3-year follow-up.

Reports have also shown that maxillary DO in CLP results in better stability compared to a conventional Le Fort I

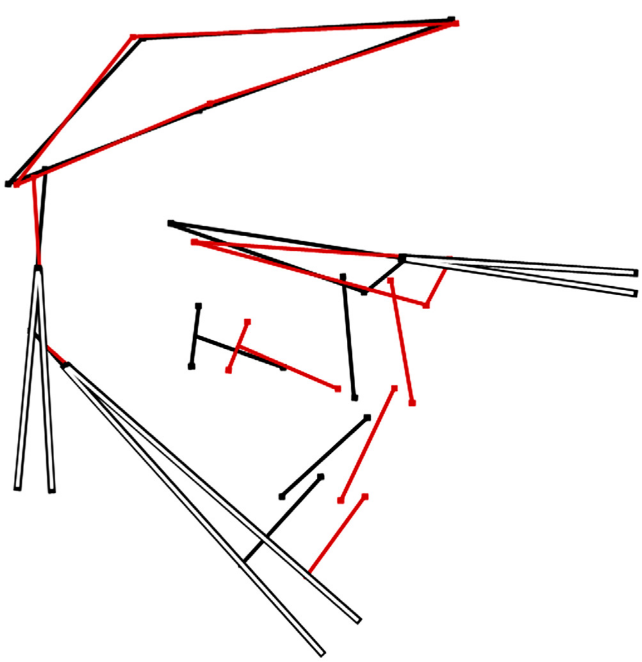

*Fig. 4.* Rotations of mandibular plane, ramus, and palatal plane [T0 in black, T2 in grey (red in online)].

*Table 2*. Cephalometric variables.[a]

| | T0 | T1 | T2 | *P*-value |
|---|---|---|---|---|
| SNA (°) | 72.4 ± 5.3 | 81.3 ± 6.2 | 79.9 ± 6.1 | <0.001[b] |
| SNB (°) | 76.5 ± 4.6 | 77.2 ± 4.7 | 77.7 ± 5.0 | 0.667 |
| ANB (°) | −4.0 ± 3.9 | 4.0 ± 3.4 | 2.3 ± 3.4 | <0.001[b] |
| FMA (°) | 30.2 ± 7.7 | 31.6 ± 6.7 | 31.0 ± 7.0 | 0.806 |
| Facial angle of Ricketts (Fr/N–Pog) (°) | 87.3 ± 4.9 | 87.6 ± 4.8 | 87.5 ± 4.6 | 0.980 |
| Facial axis of Ricketts (Ba–N/Pt–Gn) (°) | 86.1 ± 7.0 | 85.8 ± 6.7 | 86.5 ± 7.1 | 0.939 |
| AoBo (mm) | −8.2 ± 4.8 | 0.5 ± 4.3 | −0.7 ± 4.8 | <0.001[b] |
| OP/Fr (°) | 7.9 ± 4.6 | 7.5 ± 4.0 | 7.4 ± 4.9 | 0.922 |
| Inter-incisal angle (°) | 143.5 ± 12.7 | 133.9 ± 9.3 | 134.9 ± 9.0 | 0.004[b] |
| Isup/Fr (°) | 101.2 ± 10.3 | 109.3 ± 6.7 | 109.7 ± 6.4 | 0.001[b] |

[a] Data are presented as the mean ± standard deviation.
[b] Statistically significant.

*Table 3*. Long-term mandibular and palatal changes.[a]

| | T0 | T2 | *P*-value |
|---|---|---|---|
| Gonial angle (Ar–Go/Go–Me) (°) | 131.7 ± 6.3 | 132.4 ± 7.1 | 0.703 |
| Symphyseal angle (Go–Me/Me–B) (°) | 80.2 ± 7.7 | 78.1 ± 8.1 | 0.365 |
| Mandibular plane rotation (°) | −0.2 ± 3.2 | | |
| Ramus rotation (°) | −0.6 ± 4.3 | | |
| Palatal plane rotation (°) | −2.8 ± 3.8 | | |

[a] Data are presented as the mean ± standard deviation.

osteotomy.[10,25–28] Daimaruya et al.[26] compared six adult UCLP patients treated with RED to seven adult UCLP patients treated with a Le Fort I osteotomy. Their results showed that, although the total maxillary advancement in the DO group was significantly larger than that in the Le Fort I group, the relapse rate of the maxilla in the DO group was significantly lower in the horizontal direction (DO = 13.4%, Le Fort I = 25.5%).[26] Randomized controlled trials have also demonstrated internal distraction to be more stable after 5 years than conventional Le Fort I in the treatment of moderate (4–10 mm) maxillary hypoplasia in CLP.[10,25] A systematic review of long-term skeletal stability after maxillary advancement in CLP also reported a higher relapse rate with external DO than internal DO.[27]

Our study had several limitations. The number of patients evaluated was small, with a higher risk of sampling error. The design of this study was also retrospective, and not randomized. A prospective randomized clinical trial could have prevented the introduction of selection bias. Also, the study did not compare the effects of maxillary DO to a control group or a group treated with another modality (Le Fort I or internal distraction). Finally, our evaluation included both growing children and patients treated after their growth spurt, with the possible effect of showing or hiding certain treatment outcomes. Further research is required, ideally a randomized controlled trial with long-term follow-up comparing external distraction, internal distraction, and conventional Le Fort I.

In conclusion, maxillary DO in CLP induced no significant changes in the shape or rotation of the mandible. The sagittal and vertical position of the mandible was also affected minimally after 4 years of follow-up. The maxillary advancement was significant, with positional stability achieved after the first post-distraction year. This treatment modality should be proposed to CLP patients with severe maxillary hypoplasia requiring greater than 10 mm of advancement.

## Funding

None.

## Competing interests

None declared.

## Ethical approval

Exempted by the Comité de Protection des Personnes, Sud Mediterranée IV.

## Patient consent

Written patient consent was obtained for publication of the clinical photographs.

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