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Dorota Cudziło[1], *Teresa Matthews-Brzozowska*[1,2]

LONG-TERM FOLLOW-UP AFTER DISTRACTION OSTEOGENESIS WITH FACE MASK IN CLEFT LIP AND PALATE PATIENTS – PRELIMINARY REPORT

ODLEGŁE WYNIKI PO ZASTOSOWANIU METODY OSTEOGENEZY DYSTRAKCYJNEJ Z UŻYCIEM MASKI TWARZOWEJ U PACJENTÓW Z ROZSZCZEPEM WARGI I PODNIEBIENIA – DONIESIENIE WSTĘPNE

[1]Orthodontic Clinic of the Institute of Mother and Child in Warsaw
[2]The Chair and Clinic of Maxillofacial Orthopaedics and Orthodontics of the Poznań University of Medical Sciences

Abstract

Introduction: *Patients with cleft lip and palate are often diagnosed with maxillary deficiency, i.e. the reduction of maxillary measurements in three dimensions. The method of distraction osteogenesis (DO) remedies the disorder caused by bone insufficiency by generating new bone tissue. Despite the fact that DO has long been considered an effective method to treat significant bone deficiencies, it is still not a standard treatment applied by clinicians to manage underdevelopment, especially in the maxillary area. There is only a small number of publications concerning the long-term follow-up results of the use of that method to treat patients with cleft lip and palate.*

The objective: *Long-term analysis of dentoskeletal changes in cleft lip and palate patients treated with distraction osteogenesis and the use of a facial mask.*

Material and methods: *In 2001-2004, 30 patients with cleft lip and palate and related maxillary deficiency were treated by means of distraction osteogenesis and a facial mask. However, due to incomplete documentation, only 15 persons, having full medical documentation and a set of cephalometric radiographs taken in three specified time periods, were qualified for the study. The cephalometric analysis was performed on the following lateral head radiographs: pre-distraction images (T0), images taken after active distraction (T1) and 5 years after the completion of the distraction process (T2). A group of 12 persons participated in the 5-year follow-up measurements (T2).*

Results: *Cephalometric assessment indicated that after the use of distraction osteogenesis, the maxilla advanced by the mean of 3.84 mm and the SNA angle increased by the mean of 2.76° (statistically significant data). The maxillary advancement was accompanied by downward mandibular rotation. Long-term assessment after 5 years indicated that the SNA angle was reduced by 0.64°.*

Conclusions: *The use of distraction osteogenesis with a facial mask to manage maxillary deficiency deserves more attention. It requires a close cooperation of the orthodontic and surgical team, as well as high motivation on the part of the patient. In order to provide the final assessment of the long-term results, further studies need to be conducted on larger clinical material.*

Key words: distraction osteogenesis, maxillary distraction osteogenesis, maxillary hypoplasia, cleft lip and palate patients

Streszczenie

Wstęp: *U pacjentów z rozszczepem wargi i podniebienia często diagnozowany jest niedorozwój szczęki polegający na zmniejszeniu jej wymiarów w trzech płaszczyznach przestrzennych. Metoda osteogenezy dystrakcyjnej (DO) niweluje zaburzenie spowodowane niedoborem kostnym poprzez generację nowej kości. DO pomimo tego, że od lat uznana jest za efektywną metodę w leczeniu znacznych deficytów* *kostnych nadal nie jest metodą standardowo wybieraną przez klinicystów do leczenia niedorozwojów zwłaszcza w obrębie szczęki. Niewielka liczba publikacji dotyczy odległych wyników po zastosowaniu tej metody w leczeniu pacjentów z rozszczepem wargi i podniebienia.*

Cel pracy: *Odległa analiza zmian szkieletowo-zębowych u pacjentów z rozszczepem wargi i podniebienia, leczonych metodą osteogenezy dystrakcyjnej z użyciem maski twarzowej.*

Materiał i metody: *W latach 2001-2004 u 30 pacjentów z rozszczepem wargi i podniebienia oraz towarzyszącym niedorozwojem szczęki poddanych zostało leczeniu metodą osteogenezy dystrakcyjnej z użyciem maski twarzowej. Jednak z powodu niepełnej dokumentacji do badań zakwalifikowano 15 osób z pełną dokumentacją medyczną oraz z kompletem zdjęć cefalometrycznych. wykonanych w trzech określonych przedziałach czasowych. Analizie cefalometrycznej poddano telerengenogramy boczne głowy: z okresu przed zabiegiem dystrakcji (T0), po aktywnym procesie dystrakcji (T1) oraz 5 lat od zakończenia procesu dystrakcji (T2). Do badań odległościowych wykonywanych po 5 latach (T2), zgłosiła się grupa 12 osób.*

Wyniki: *Ocena cefalometryczną wskazywała, że po zastosowaniu metody osteogenezy dystrakcyjnej osiągnięto wysunięcie szczęki średnio o 3,84 mm, wartość kąta SNA wzrosła istotnie statystycznie średnio o 2,76°. Wysunięciu szczęki towarzyszyła rotacja żuchwy ku dołowi. W ocenie odległej po 5 latach wartość kąta SNA zmalała o 0,64°.*

Wnioski: *Metoda osteogenezy dystrakcyjnej w leczeniu niedorozwoju szczęki z użyciem maski twarzowej jest godna większego zainteresowania, wymaga ścisłej współpracy zespołu ortodontyczno-chirurgicznego i dużej motywacji ze strony pacjenta. Do ostatecznej oceny wyników odległych konieczne jest prowadzenie dalszych badań na większym materiale klinicznym.*

Słowa kluczowe: osteogeneza dystrakcyjna, osteogeneza dystrakcyjna szczęki, niedorozwój szczęki, pacjenci z rozszczepem wargi i podniebienia

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INTRODUCTION

Cleft lip and palate patients with diagnosed maxillary deficiency suffer from the disturbed growth of bone structures in three dimensions. Observations of other authors based on own research indicate that the maxilla in cleft patients is shorter and retruded in comparison to patients without a cleft (1, 2, 3). Effective treatment is possible only with the use of surgical procedures. The end of the last decade of the 20th century saw publications assessing the outcomes obtained with the DO method in patients with maxillary deficiency. The method eliminates malformation caused by bone insufficiency by generating new bone tissue. No clinical signs of a relapse into maxillary deficiency after distraction osteogenesis weighs in favour of using that method in cleft patients (4, 5, 6). Distraction osteogenesis was predicted to become an alternative to classical orthognathic procedures in maxillary deficiency management, especially in patients still in the growth period (4, 7, 8).

The objective of this report is a long-term analysis of dentoskeletal changes in cleft lip and palate patients treated with distraction osteogenesis and a facial mask.

MATERIAL AND METHODS

In the report, lateral head radiographs of 30 patients with (nonsyndromic) cleft lip and palate taken in 2001-2004 were analysed retrospectively. However, only 15 persons were selected for the study, as the criterion was full medical documentation and a set of cephalometric radiographs taken in three specified periods: pre-distraction (T0), after the completion of active distraction (T1) and a 5-year follow-up (T2). The mean age of the patients at the moment of distraction fluctuated between 14 years 6 months and 24 years 11 months, which gave the mean age of 17 years 4 months.

Medical interviews indicated that patients were under the care of orthodontic clinics in their place of residence from early childhood. As maxillary deficiency management solely by orthodontic methods showed no progress, they were referred for further interdisciplinary treatment in the specialist centre for congenital craniofacial defects of the Institute of Mother and Child in Warsaw (IMID).

The clinical extraoral examination revealed that the patients were characterised by a sunken sub-nasal area, shorter upper lip, convex lower lip and dominating chin outline, whereas intraorally negative overjet of the incisors was identified.

The clinical data showed midfacial underdevelopment, which was confirmed by the cephalometric analysis. The value of the SNA angle defining the position of the maxilla to the cranial base was on average 73.42°, whereas the mean ANB angle defining the relative position of the maxilla to the mandible was -4.12° (T0). Cephalometric data confirmed the retruded position of the maxilla to the cranial base and mandibular base. Given the maxillary bone tissue insufficiency in all patients and skeletal immaturity in some of them, the decision was taken to implement the orthodontic and surgical treatment with the use of distraction osteogenesis. All the patients were orthodontically prepared for surgical treatment by means of fixed appliances. Orthodontic treatment prepared the dental arcades in such a manner as to ensure proper dental relations between the maxilla and the mandible after the distraction procedure. The surgical procedure was performed in every patient with the same technique, by an experienced surgeon (from the surgical team supervised by Z. Dudkiewicz) and consisted in high LeFort I osteotomy with complete maxilla mobilisation. After a latency period of 3 to 5 days, distraction was commenced with the use of a facial mask worn 24 hours daily. Thanks to elastics with the total force of 900g, the distraction vector could be modified on an on-going basis, so as to obtain the maximum possible overjet of the incisors at the end of the distraction osteogenesis (T1) in order to guarantee that the correct occlusion should be maintained. Active distraction lasted from 5 to 17 days (11 days on average). In all patients the correct relation of the incisors was obtained after the end of the period of active distraction. The outcome was stabilised by means of a further use of the facial mask only at night for 3 months – horizontal elastics with the force reduced to 450g were applied. The mean duration of the orthodontic treatment was 10 months prior to the surgical procedure and 25 months post-operationally. A group of 12 persons offered to participate in the long-term follow-up. i.e. more than 5 years after the completion of the distraction process (T2).

Methodology of the cephalometric examination

A detailed analysis of the lateral head radiographs was conducted in the case of every patient. The following were examined: 15 pre-distraction radiographs (T0), 15 radiographs taken after the end of the active distraction (T1) and 12 post-distraction images taken after more than 5 years (T2). In total, 42 lateral head radiographs were analysed in comparable conditions of the study (Fig. 1). The measurements were taken twice, one month apart, and the mean outcome of both measurements represented the final result. The pre-distraction measurements (T0) were compared with the values obtained directly after the maxilla distraction (T1) and min. 5 years after the distraction process was completed (T2). The results received after distraction osteogenesis were represented by the difference between the post-distraction and pre-distraction measurements (T1-T0). The long-term results were represented by the difference between the measurements obtained directly after the distraction and the 5-year follow-up (T2), i.e. T2-T1. The mean values in every patient for model measurements of the SNA and SNB angles were presented in table I.

Statistical analyses

The obtained results were analysed with the use of two non-parametric tests which differently evaluated the significance of changes in particular parameters.

Prior to selecting statistical analysis tests, the consistency of the cephalometric examination with the

Table I. The mean values in every patient for model measurements of the SNA and SNB angles were presented in table I.

Tabela I. Średnie pomiary wartości wybranych kątów SNA i SNB u badanych pacjentów.

Patient *Pacjent*	**SNA T(0)**	**SNA T(1)**	**SNA T(2)**	**T1-T0**	**T2-T1**	**SNB(T0)**	**SNB(T1)**	**SNB(T2)**	**T1-T0**	**T2-T1**
1	71.51	71.80	70.74	0.29	-1.06	77.84	75.89	77.86	-1.95	1.97
2	68.24	70.71	70.17	2.47	-0.54	73.98	73.29	74.00	-0.69	0.71
3	73.53	78.63	73.01	5.10	-5.62	81.49	78.42	80.07	-3.07	1.65
4	76.15	76.43	75.06	0.28	-1.37	77.09	76.35	76.65	-0.74	0.30
5	73.62	73.74	–	0.12	–	77.65	76.14	–	-1.51	–
6	72.13	76.61	77.66	4.48	1.05	75.27	73.47	75.15	-1.80	1.68
7	71.79	72.40	72.07	0.61	-0.33	71.88	69.99	71.10	-1.89	1.11
8	73.22	75.92	75.58	2.70	-0.34	78.03	78.11	78.06	0.08	-0.05
9	80.62	79.61	80.54	-1.01	0.93	82.69	81.92	82.78	-0.77	0.86
10	74.85	77.30	76.78	2.45	-0.52	74.59	72.42	74.54	-2.17	2.12
11	70.63	75.67	74.45	5.04	-1.22	75.51	74.08	78.40	-1.43	4.32
12	74.64	80.28	80.74	5.64	-0.14	77.00	75.84	77.40	-1.16	1.56
13	74.89	84.46	82.51	9.57	-1.95	85.32	84.05	85.89	-1.27	1.84
14	69.55	71.61	–	2.06	–	71.58	70.96	–	-0.62	–
15	75.60	77.08	–	1.48	–	81.78	85.00	–	3.22	–
Mean *Średnia*	73.42	76.15	75.51	2.76	-0.64	77.53	76.43	77.44	-1.06	1.01

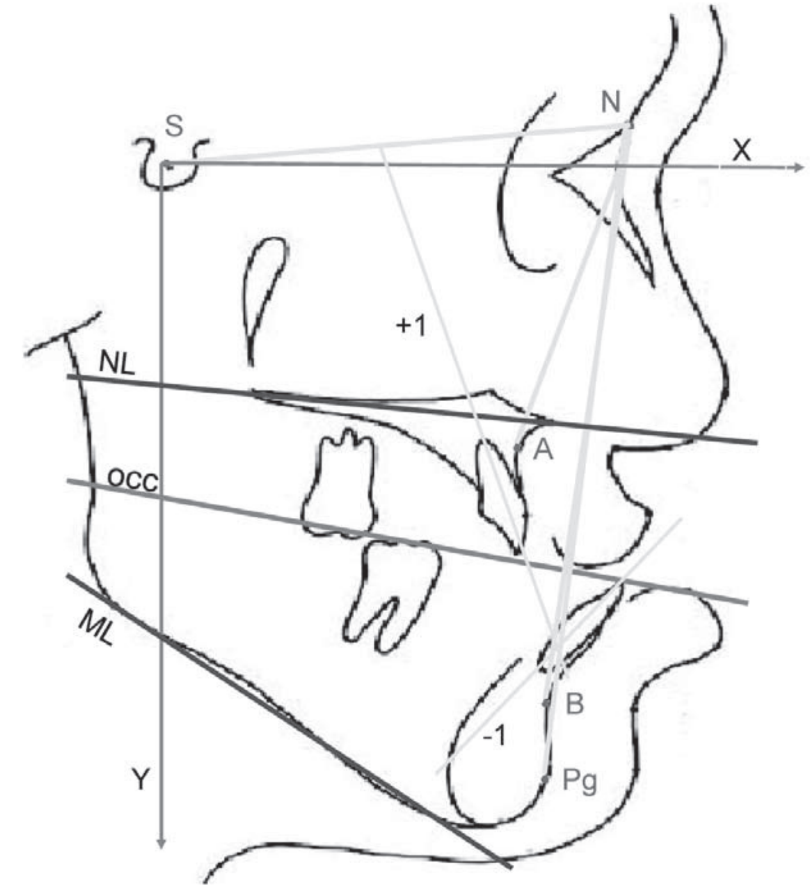

Fig. 1. Cephalometric landmarks used in the study: S – sella (center of sella turcica); N – nasion (junction of the frontal and nasal bones); A − point (anterior concavity of the contour of maxilla); B − point (Point B) – supramentale, sm; Pg – pogonion.

Cephalometric reference planes: SN – plane passing through S and N, anterior crania base; NL − maxillary line (plane); OCC − occlusial plane; ML − mandibular line (plane); +1- plane passing through the upper incisor; -1-plane passing through the lower incisor.

Cephalometrics angular measurments: SN/NL − angle to measure positional changes of the maxilla relative to the cranial base; SN/ML − angle to measure positional changes of the mandible relative to the cranial base; SNA − angle to measure the anterior position of the maxilla; SNB − angle to measure the anterior position of the mandible; NS/+1 − angle to measure inclination of upper incisor to the cranial base; 1/-1 − angle to measure inclination between upper and lower incisor.

Cephalometric linear measurements: X-A − maxillary anterioposterior position relative to the horizontal reference plane (X- axis); Wits − distance between perpendiculars drawn from the occlusal plane to points A and B (to assess anteroposterior jaw discrepancies).

Ryc. 1. Pomiary cefalometryczne stosowane w badaniu: S – sella (środek siodełka tureckiego); N – nasion (punkt pomiędzy kością nosową i czołową); A − punkt (największa wklęsłość w wyrostku szczęki); B − punkt (największa wklęsłość w wyrostku żuchwy) – supramentale; Pg – pogonion.

Linie wykorzystane w analizie: SN – linia łącząca punkty S i N, podstawa przedniego dołu czaszki;

NL − płaszczyzna podstawy szczęki; OCC − płaszczyzna zgryzu; ML − płaszczyzna podstawy żuchwy; +1 − linia przechodząca przez oś centralną zęba siecznego centralnego w szczęce; -1 − linia przechodząca przez oś centralną zęba siecznego centralnego w żuchwie.

Cefalometryczne pomiary kątowe: SN/NL − kąt określający położenie płaszczyzny szczęki względem podstawy czaszki; SN/ML − kąt określający położenie płaszczyzny żuchwy względem podstawy czaszki; SNA − kąt określający położenie szczęki względem podstawy czaszki; SNB − kąt określający położenie żuchwy względem podstawy czaszki; NS/+1 − kąt nachylenia osi siekacza centralnego do podstawy czaszki; 1/-1 − kąt zawarty pomiędzy osiami siekaczy centralnych szczęki i żuchwy.

Pomiary liniowe: X-A – położenie szczęki w wymiarze przednio-tylnym w odniesieniu do płaszczyzny poziomej (oś X); Wits − pomiar pomiędzy rzutem punktu A i punktu B na płaszczyznę zgryzu.

normal (Gaussian) distribution was verified with the use of the Shapiro-Wilk test. Most of the parameters proved inconsistent with the Gaussian distribution, therefore the statistical analysis was performed by means of two different non-parametric methods: the Wald-Wolfowitz runs test and Wilcoxon's test. The outcome of the statistical analysis was regarded significant with the significance level p<0.05. Statistical calculations were conducted by means of Statistica PL v. 8.0.

The study protocol was approved by the Bioethical Commission at the Institute of Mother and Child in Warsaw (Poland) and by the Bioethical Commission at the Poznań University of Medical Sciences (Poland).

RESULTS

The analysis of the cephalometric measurements indicated that specific bone structures shifted within the craniofacial part of the skeleton, i.e. the values of particular parameters changed (tab. II).

Post-distraction changes: T1-T0

After the use of distraction osteogenesis, the difference in the mean values between T1 and T0 was found. The maxilla advanced as a result of the distraction process, which was confirmed by a statistically significant increase in the SNA angle by the mean of 2.76° and the ANB angle by 3.83°, as well as the shift of point A by 3.84 mm forward. The maxilla advancement was accompanied by slight counter clockwise rotation and the angle of the maxilla inclination to the cranial base SN/NL was slightly reduced by 0.22°. The mandible was rotated clockwise and the angle of inclination of the mandible base to the cranial base SN/ML grew by 1.22°, yet its value remained within the average population range. The SNB and SNPg angles were reduced by 1.06° and 0.96°, which could have been caused by the pressure exerted by the facial mask on the chin. The values of the interincisal angle (+1/-1) and the angle of the inclination of the central incisors to the cranial base (1+/NS) were closer to the average population values (tab. II).

Long-term distraction changes: T2-T1

The long-term 5-year follow-up (T2) indicated specific changes in relation to the values obtained directly after the distraction process (T1). The SNA angle, defining the maxilla position, was reduced by 0.64°. The data may either confirm the tendency to a relapse into the pre-distraction maxilla position or prove the fact that, as a result of further physiological growth, the Nasion point (N) moved forward.

The values of the SNB and SNPg angles increased by the mean of 1.01° and 1.320°, which indicated further physiological growth of the mandible. In the long-term, the inclination of the maxilla to the cranial base decreased, similarly to the mandible inclination – the SN/NL and SN/ML angles were reduced by 2.24° and 2.49° respectively. The interincisal angle (+1/-1) decreased further and amounted to 139.58°, which was within the average population standard values. Similarly, the mean inclination of the central incisor axis to the cranial base was 100.19°, i.e. within the population standard.

As regards the statistical analysis of the pre-distraction (T0) and post-distraction (T1) measurements, only Wilcoxon's test showed statistically significant changes in the following angle parameters: SNA, ANB and linear

Table II. Selected parameters of cephalometrics results according Steiner`s analysis in T0, T1, T2.
Tabela II. Wybrane parametry analizy cefalometrycznej wg Steinera w T0, T1, T2.

Variables *Parametry*	Means population values *Średnie wartości populacyjne*	SD *Odch. Stand.*	T0 – before DO *T0 – przed DO*	T1 – after DO *T1 – po DO*	T2 – 5 years after DO *T2 – 5 lat po DO*	T1-T0 DO effect *T1-T0 – wynik po DO*	T2-T1 long term results after DO *T2-T1 – wynik odległy po DO*
SNA	82.00	3.50	73.42	76.15	75.51	**2.76***	-0.64
SNB	80.00	3.50	77.53	76.43	77.44	-1.06	1.01
SNPg	81.00	3.50	79.47	78.51	79.83	-0.96	1.32
ANB	2.00	3.00	-4.12	-0.29	-1.93	**3.83***	-1.64
Wits	0	2.00	-6.69	1.48	0.13	**8.17***	-1.35
1+/1-	127.00	8.50	150.85	145.39	139.58	-5.46	-5.81
1+/SN	104.00	6.50	90.85	96.38	100.19	5.46	3.81
SN/NL	8.00	4.00	11.9	11.68	9.44	-0.22	-2.24
SN/ML	33.00	6.00	35.83	37.05	34.56	1.22	-2.49
SGo/NGn	60.50	2.50	64.16	63.78	65.47	-0.38	1.69

*statistically significant according to Wilcoxon`s test p<0.05
**istotne statystycznie wg testu Wilcoxon'a p<0,05*

"Wits" appraisal. The Wald-Wolfowitz tests did not indicate statistical significance as regards the above parameters. Changes of the parameters in the long-term follow-up measurements were not statistically significant.

DISCUSSION

Patients with cleft lip and palate and identified maxillary underdevelopment have considerable deficiency of bone structures in three dimensions. That deficiency is particularly visible in the anterior-posterior dimension, which could be seen in the pre-distraction cephalometric analysis of the studied group. The application of distraction osteogenesis, availing of natural repair mechanisms and generating new bone tissue, seems to be worth consideration in cleft patients with significant bone deficiency. The generation of new bone tissue is accompanied by the gradual stretching of muscles and soft tissues, which mitigates the risk of relapse (4, 9). The above observation was decisive in selecting distraction osteogenesis as the treatment method in the above group of patients with cleft lip and palate.

The literature review showed that not many authors discuss the long-term results of the distraction method with the use of a facial mask as a distractor, as most of the reports focus on the Rigid External Device (RED) or intraoral distractors. Molina was the first to use distraction osteogenesis in the maxillary area with a facial mask as a distractor. He obtained the advancement of 7mm to 12 mm (the mean of 9 mm) in the cases of considerable maxillary deficiency. The ANB angle grew from 1.4° to 7.4° (4, 10), yet he did not present other cephalometric measurements confirming the maxillary advancement. After Molina, others were unable to repeat such a major maxillary advancement, i.e. up to 12 mm (7, 11). Among our patients, a similar outcome was recorded only in one person: the maxilla advanced by 11.5mm and the SNA angle grew by 9.57° (table I – patient 13); the outcome was maintained after 5 years. Swennen et al. obtained the correction of the maxillary position with a good aesthetic result in 6 patients aged 12 to 16 years after the use of a facial mask in distraction osteogenesis. They achieved the maxillary advancement of 1mm to 3.5 mm (the mean of 1.7 mm) (9). The results of our observations were more diversified: the maxillary advancement was from 1mm to 11.5 mm with the mean of 3.84 mm. In the cases of minor maxillary advancement we think that the forward movement of the maxilla was most likely limited by numerous scars left after earlier surgical procedures. In the results we presented, the use of a facial mask in the distraction process, apart from advancement of the maxilla and inclination of the incisors, also led to a concurrent clockwise rotation of the mandible.

The use of the Rigid External Device, which is more often described in the literature, is easier in technical terms, yet it is difficult to control the vertical movement of the maxilla. The above conclusion was reached by Emparazza et al. who assessed the use of a facial mask and RED as distractors. Moreover, as the above authors informed, it is uncomfortable for the patient to function throughout the distraction process with the device screwed to the skull and therefore it is difficult to suggest that solution. In their observations, the position of the mandible moved slightly backward with the use of a facial mask, which could have been the result of the pressure on the chin – the SN/ML angle increased (12). Given considerable disorders of the lower facial height, that phenomenon is regarded as positive (5, 12).

Another advantage of the use of a facial mask, similarly to other extraoral RED distractors, was the possibility to modify the distraction vector during distraction osteogenesis (4, 10, 12), which is impossible in the case of intraoral distractors.

The time of the surgery is shorter in distraction osteogenesis when compared to the classic orthognathic procedure, yet it requires more time devoted to the patient during the distraction process, which takes a dozen or so days. Patients also need to cooperate closely (8) as they play an important role during active distraction – wearing a mask is crucial to obtaining and preserving the expected outcomes. Moreover, as other studies have shown, the motivation to cooperate and correct one's oral hygiene is equally vital to ensure the long-term therapeutic success after the use of protraction osteogenesis (13, 14).

In the group of patients described, close cooperation within the orthodontic and surgical team was required at all stages of the active treatment in order to obtain correct occlusion conditions after the use of distraction osteogenesis and a facial mask. Other authors came to the same conclusion (4, 10, 15).

None of the authors using a facial mask as an extraoral distractor reported complications posing a risk to health and life. Neither did we record life threatening problems in our group of patients. Among the issues we identified there were: chin abrasion resulting from the pressure exerted by the mask and slight irritation of the vermilion zone caused by elastics. The use of another distractor, the RED system, also gives good results, however, there are reports on potential complications, such as epidural haemorrhage or intracranial migration of a pin (16, 17, 18). The risk of such complications is excluded in the case of a facial mask.

Contemporary orthognathic surgery comprises a high number of repair procedures which can be used in cleft patients – distraction osteogenesis should be recognised as one of them (19).

Based on own observations and literature review, it can be stated that distraction osteogenesis is a useful surgical procedure to manage maxillary deficiency in patients with cleft lip and palate. The method requires extensive experience from the team of surgeons and orthodontists, as well as strong motivation to cooperate on the part of the patient. The use of a facial mask as an extraoral distractor may be considered effective, however the final choice of the surgical technique and the distractor depends on the experience of the clinician who makes the decision after considering the advantages and limitations of each solution.

CONCLUSIONS

The use of distraction osteogenesis and a facial mask to manage maxillary deficiency deserves more attention.

It requires the close cooperation of the orthodontic and surgical team, as well as high motivation on the part of the patient. In order to provide the final assessment of the long-term results, further studies need to be conducted on larger clinical material.

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Address for correspondence:
Dorota Cudziło
Poradnia Ortodontyczna Instytutu Matki i Dziecka
ul. Kasprzaka 17a, 01-211 Warszawa
tel. (22) 32-77-128
e-mail: dcudzilo@gmail.com