# **Original Article**

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# Presurgical management trends and nasoalveolar molding usage for infants with cleft lip and palate in the capital of a developing country

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#### Abstract

**BACKGROUNDS:** Nasoalveolar molding (NAM) application is among presurgical management (PSM) techniques used for infants with cleft lip and palate (CLP). It helps to approximate the palatal cleft and to reshape the nasoalveolar complex prior to primary lip repair. This study aimed to explore types of PSM and the dental speciality provision for infants with CLP in Baghdad. The status of NAM usage and surgeons' perceptions toward NAM usage were assessed.

**MATERIALS AND METHODS:** This is a cross-sectional paper-based questionnaire study that collected responses of surgeons perform primary lip and nose repair regarding PSM. The questionnaire was distributed amongst public and private hospitals in Baghdad. Twenty surgeons were enrolled (only those surgeons who perform primary repair for infants with CLP); two females and eighteen males.

**RESULTS:** The majority of participants' responses suggested that the majority of infants with CLP were provided with baby feeding plates and lip straps. Six surgeons reported that a percentage of their patients who have been provided with NAM. PSM in Baghdad was mostly supplied by orthodontists and plastic surgeons, and the next most likely providers were prosthodontists. 82.35% of the surgeons found that primary surgical repair procedures were easier with NAM than for the other infants. The rest have not perceived any differences.

**CONCLUSIONS:** Orthodontists, surgeons and prosthodontists were involved in providing PSM. Baby feeding plates and lip straps were the most common PSM in Baghdad, although NAM is not uncommon. Most surgeons believe that using NAM made surgical procedures easier and permitted the prediction of surgical outcomes.

### **Keywords:**

Cleft lip, cleft palate, NAM therapy, nasoalveolar molding, orthopaedics

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# Introduction

Cleft lip and/or palate (CLP) is a common developmental birth defect affecting the craniofacial region<sup>[1,2]</sup> and seen in 1/700 live births globally.<sup>[3,4]</sup> The management of CLP is complex and life-long for the affected individual, with the affected structures pivotal for basic functions such as swallowing, feeding and speech, in addition to normal facial aesthetics. The long-term effects of CLP can cause psychological problems for patients and their parents and whilst not life-threatening, CLP can affect quality of life and impact on physique and health.<sup>[5]</sup>

Management of patients with CLP is a long journey, requiring the collaboration and

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interaction of multiple specialities (feeding specialist, nurse coordinator, plastic/maxillofacial surgeon, otolaryngologist, dentist, orthodontist, prosthodontist, paediatric dentist, geneticist, speech therapist and social worker). The process of treatment includes various steps starting with a feeding plate for the newborn, then going through surgical procedures, management of the developing dentition, speech therapy and many other steps, as well as psychotherapy sessions for affected individuals and their parents.<sup>[6,7]</sup> What makes this journey worth the time, expense and effort is achieving a good functional and aesthetic result for the patient. During this multidisciplinary process each procedure is aimed at solving a present problem, preventing the development of further potential problems, or preparing the patient for the next step of treatment. Unsuccessful management at any step will negatively affect subsequent steps of the treatment process and the final outcomes, and additional corrective procedures are likely to be required. This can have a detrimental impact on treatment outcome.

Management of patients with CLP starts from birth; new infants struggle during feeding and construction of a feeding plate achieves isolation between the oral and nasal cavities which helps to establish feeding. That is followed by primary lip repair at four to six months of age and palatal surgery within 12-18 months.<sup>[8]</sup> However, additional surgeries are not uncommon due to the severity and malalignment of the clefted shelves. In the 1950s, presurgical infant orthopaedics (PSIO) was first introduced<sup>[9]</sup> to approximate the clefted palatal and alveolar shelves before initial surgery. Use of PSIO maximises the success of successive surgeries and improves the ultimate outcomes of treatment, and furthermore it maintains the isolation between oral and nasal cavities during suckling. It can be passive or active.<sup>[10]</sup> Early in the 1990s, more attention was given to nasal asymmetry, wide alar bases, reduced nasal projection and the flattened dome of the nose, especially in severe unilateral cleft lip and palate (UCLP) and diminished columella especially in bilateral cleft lip and palate (BCLP).<sup>[11,12]</sup> A secondary rhinoplasty after puberty is often necessary,<sup>[13]</sup> and acceptable nasal appearance is difficult to restore. Nasal cartilage shows a tendency to relapse after re-contouring, and nasal stigma is characteristic of cleft patients.<sup>[13]</sup>

In 1993, Grayson and Cutting proposed pre-surgical nasoalveolar molding (NAM). The concept of treatment with NAM is based on Matsuo's principle and depends on the residual plasticity of the cartilage which arises from the presence of maternal oestrogen during the first six weeks of life.<sup>[11,14-16]</sup> NAM has been modified over time, but the first protocol of treatment has been described by Grayson and colleagues.<sup>[17]</sup> It is preferable to start treatment with NAM within the first or second

week of life and continue for between four and six months. NAM is achieved using an active appliance that first approximates the clefted alveolus, and then reduces the size of the palatal cleft by adding soft acrylic to specific areas on the tissue side of the palatal plate during adjustment appointments. After this, a nasal stent extending from the palatal plate to the nostrils can help to reshape the associated nasal defects.<sup>[11]</sup> This device helps surgeons to restore nasaolabial aesthetics during primary lip and nose repair,<sup>[18]</sup> and to reduce the number of subsequent surgeries before early adulthood - this can reach 20 surgical procedures.<sup>[19,20]</sup> The shortcomings of nasoalveolar molding which have been reported in the literature include soft tissue trauma, a loss of compliance (as it requires weekly adjustment), potentially some relapse in the treatment made during the first year,<sup>[21]</sup> and one article suggests that NAM therapy has an adverse effect on facial growth other than nasal growth.<sup>[10]</sup>

Despite limited evidence in the literature confirming the benefits of NAM therapy, many centres and practices have adopted the use of it in the United States (US).[22] At this time, there are studies supporting the use of NAM therapy prior to primary repair surgeries to improve the nasolabial region aesthetic and reduce the need for revision surgeries.<sup>[23-25]</sup> However, potential harm to maxillofacial growth owing to active presurgical infant orthopaedics has also been reported.<sup>[10]</sup> Currently, the literature supports the effectiveness of the use of NAM on both nasal and alveolus asymmetry for UCLP patients.<sup>[26]</sup> Regarding BCLP, there was a promising preliminary study published in 2006 that was carried out at the Cleft and Craniofacial Clinic at the University of Texas at Houston Medical School, Texas by Spengler and colleagues. Spengler et al.[27] have found that the use of NAM even after the first month of age has a positive effect on the nose and the maxilla. Nasolabial asymmetry, deviation of the nose, nasal projection and columella length were all improved.<sup>[28]</sup> The typically protruded premaxilla in BCLP were brought into alignment with the maxillary alveolus.<sup>[27]</sup> There is also an interesting study that has confirmed the beneficial effect of NAM on the characteristic nasal deformity of patient with cleft lip and palate. This has demonstrated that at the age of 12.5 years of age, the nasal appearance of a patient with BCLP can be close to normal if the patient receives NAM followed by the primary lip surgery in time.[24]

In order to be able to develop and improve the status of therapies that are available for management of infants with CLP in Baghdad, research is needed to explore the commonly available managements in the city, find the ones with the best outcome and develop one proper protocol. This study aimed to distinguish the types of presurgical management (PSM) that are provided for infants with CLP, to probe whether NAM is one of the therapeutic options as a PSIO in Baghdad city and to recognise the dental specialities that are involved with providing PSM services. Assessing CLP surgeons' perceptions around the usage of NAM was one of our primary objectives. Our objectives were also to recognise whether NAM treatments have had an effect on surgical procedures, surgical outcomes and levels of parent compliance with treatment commencement.

# **Materials and Methods**

This was a questionnaire-based study which was addressed to Iraqi surgeons who perform primary cleft surgeries, whether they do this at surgical departments of government-owned hospitals or of private hospitals. In this cross-sectional questionnaire study, a paper-based survey was distributed between five public hospitals and eight private clinics/centres, which are based in Baghdad. This questionnaire consisted of three parts; the first part was related to demographic data (age, gender) [Table 1]. The second part included the type of presurgical therapy used and who provides it [Table 2], with further questions regarding PSM. In the third part, surgeons' perceptions about the impact of NAM based on their experiences [Table 3] were gathered. This study was carried out over two months. The selection criteria for the surgeons who received it were that they were practicing primary lip and nose repair and palate repair for children with CLP under the age of two years in Baghdad. The design of NAM that is being used in Baghdad city is shown in [Figure 1].

### Results

The number of specialists who are performing primary lip, nose and palate repair in Baghdad hospitals' surgical departments is very low, and this is reflected in the small sample size of surgeons enrolled in the study. To address this, we included public and private sectors, but the sample size is still humble. Twenty surgeons were enrolled, two females and eighteen males. Their age

Table 1	ŝ.	Part	one	Demography
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Gender	Females	Males		Total
Number of surgeons	2	18		20
%	10%	90%		100%
Speciality	Maxillofacial surgeon	Plastic paediatric surgeon	Plastic surgeon	Total
Number of surgeons	4	1	15	20
%	20%	5%	75%	100%
		Minimum	Maximum	Median
Age (Years of age)	33	58	40.5	
Number of years of p primary repair	2	29	10	

range is between 33 and 58 years of age, with a median age of 40.5 years.

Results from the demographic section of the questionnaire show that the majority of surgeons who have performed the primary surgeries within the first two years of life for a child with CLP were plastic surgeons, a total 15 (75%). Surprisingly, only four surgeons (20% of our sample) were maxillofacial surgeons and only one (5%) was a plastic paediatric surgeon. Two out of the 20 surgeons (10% of the sample) were females and the rest 18 (90%) were males. The number of years of practicing primary repair surgeries for participants range between two and 29 years, and the median was 10 years [Table 1].

Each surgeon was asked about the types of presurgical therapy his or her patients had had before the primary surgeries were performed. Baby feeding plates and lip straps were the most common types of presurgical therapy that infants with CLP had had before primary surgeries, at 85% and 80% respectively. Only six surgeons (30%) had patients that had been served with NAM. Two out of the 20 surgeons (10%) had patients who had not had any type of presurgical therapy [Table 2].

Amongst respondents, we found that the majority of patients with CLP under maxillofacial surgeons (50%) have been served with baby feeding plates, then 25% are given lip strap and 12.5% given NAM. 12.5% of the cases have got no previous presurgical adjustments. The patients of plastic surgeons, on the other hand, have been mostly served with lip strap at 41.94%, and then baby feeding plates in 38.71% of cases. 16.13% have been served with NAM and 3.22% have no treatment before the primary lip and nose surgery is performed. The plastic paediatric surgeon who was involved in this questionnaire did baby feeding plates and lip straps for his own patients with CLP before

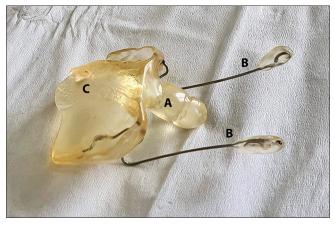


Figure 1: Nasoalveolar molding appliance. A retentive button, B nasal stent, C hole

Presurgical therapy*	Feeding plate	Lips strap	NAM	None	
Maxillofacial surgeon	4	2	1	1	
%	50%	25%	12.5%	12.5%	
Plastic paediatric surgeon	1	1			
%	50%	50%			
Plastic surgeon	12	13	5	1	
%	38.71%	41.94%	16.13%	3.22%	
Total	17	16	6	2	
%	85%	80%	30%	10%	
Number of years of practicing primary repair surgery		2-5 Years	6-10 Years	11-20 Years	21-29 Years
Use NAM in their treatment		0	4	0	2
Speciality <sup>†</sup>	Orthodontist	Prosthodontist	Maxillofacial surgeons	Plastic paediatric surgeon	Plastic surgeon
Maxillofacial surgeon	1	2	2		
%	20%	40%	40%		
Plastic paediatric surgeon				1	
%				100%	
Plastic surgeon	8	6			9
%	34.8%	26.1%			39.1%
Total	9	8	2	1	9
%	45%	40%	10%	5%	45%
Timing for primary lip and nose surgery with and without the use of NAM <sup>1.8</sup>			Same	Different	
Grand Total			10	6	
%			62.5	37.5%	
Timing for primary palatal repair with and without the use of NAM**. <sup>††</sup>			Same	Different	
Total			11	5	
%			68.75%	31.25	

\*Each participant can choose more than one management based on their experiences. \*Each participant has chosen more than one collaborator based on their most common collaboration. Only 16 participants had responded to the following question. The majority of participants agreed that 3 months is the best time for primary lip and nose repair. \*\*Only 16 participants had responded to the following question. \*The majority of participants agreed that 9-12 months is the best time for primary palate repair

primary surgery. Interestingly the surgeons who were more exposed to patients who had served with NAM were the surgeons with the median experience, 6-10 years [Table 2].

We have found that presurgical therapy for patients with CLP prior to primary repair surgeries was mainly provided by orthodontists and plastic surgeons specialists, at 45% each, followed by the prosthodontists at 40%. Maxillofacial and paediatric surgeons carried out only 10% and 5%, respectively [Table 2]. Table 2 showed that in 39% of the plastic surgeons' patients, plastic surgeons themselves were the ones providing the presurgical therapy. For the rest of the cases, orthodontists and prosthodontists were the ones providing presurgical treatments in 34.8% and 26.1% of cases respectively. Like plastic surgeons, maxillofacial surgeons provided presurgical treatment to 40% of their cases. Orthodontists and prosthodontists provided treatment in 20% and 40% respectively. The paediatric surgeon also provided the presurgical treatment for his patients.

For the majority of the recruited surgeons, timing for primary lip and nose surgery was about three months and between 9 and 12 months old for primary palatal repair. The type of PSM did not affect the timing of primary repair [Table 2].

Then we asked the surgeons if they have a sense of the effect of the use of NAM within the cases that they have worked with in simplifying the surgical procedures which followed and the short-term effect on children's appearance after the surgeries, as well as the effect of NAM on the compliance of care-providers for the children with CLP. Unfortunately, bearing in mind the small sample size, we found that three out of our sample had not dealt with patients who had been served with NAM; these were two plastic surgeons and one maxillofacial surgeon who mentioned that they did not work with cases that had been provided with NAM therapy prior to the primary surgeries. We noted that the surgeons who did not work with children with CLP who had been treated with NAM were either the youngest, at 33, or the oldest at 47 and 49 years of age. The former had the fewest years of practicing primary repair surgeries at two years, and the latter had the longest experience at 15 years.

A total of 82.35% of the surgeons have found that for children with CLP who have been treated with NAM before doing the first surgeries, surgical procedures

Speciality	No difference	Superior	Have adverse effect	Total
Maxillofacial surgeon	2	1		3
Plastic paediatric surgeon		1		1
Plastic surgeon	1	12		13
Total	3	14		17
%	17.65%	82.35%		100%
Is the use of NAM appliar	nce superior in comparison	to other modalities for	r the surgeon in terms of giving a b	etter result?
Speciality	No difference	Yes	Have adverse effect	Total
Maxillofacial surgeon	2	1		3
Plastic paediatric surgeon		1		1
Plastic surgeon	2	11		13
Total	4	13		17
%	23.53%	76.47%		100%
Is the use of NAM applian	ce superior in comparison	to other modalities for	the child parents in terms of their	compliance?
Speciality	No difference	Superior	Have adverse effect	Total
Maxillofacial surgeon		1	2	3
Plastic paediatric surgeon		1		1
Plastic surgeon	4	4	5	13
Total	4	6	7	17
%	23.53%	35.29%	41.18%	100%

were easier than they were for the other infants who received other means of presurgical modalities or no PSM provided at all. The other 17.65% of the surgeons had not detected any differences [Table 3].

In terms of the preference of the surgeons for the treatment by NAM appliances, Table 3 shows that 76.47% of surgeons had positive opinions and 23.53% surgeons were neutral. Finally, we asked our surgeons about the children's parents' compliance when NAM had been used in the treatment process of their child. 41.18% of surgeons found that the parents' compliance had been negatively affected, while 23.53% found that there was no difference in the compliance of the parents of a child with CLP, and 35.29% found that parents' compliance got even better.

# Discussion

Many surgical techniques have been developed to bypass the recorded complications following the primary repair operations.<sup>[29,30]</sup> However, some of the complications that compromise aesthetics and have an impact on individual psychology and behaviour, like surgical wound breakdown, scars and notches of the lip, have resulted from a lack of presurgical therapy to adapt and approximate the cleft segments.<sup>[29]</sup> PSM is a crucial step in the journey of CLP treatment. PSIO has a potential benefit on nasofacial aesthetics and stability; however, there is a big debate in literature about its long-term effects.

In Iraq, there are no special CLP centres. Instead, we have surgical departments at different hospitals that

provide surgical care for a variety of cases including CLP infants' healthcare. It is these specialists who have been first approached for the collection of data for this study. Generally, our questionnaire study has shown that the use of NAM is really limited in Baghdad. Going further, it was difficult for us to find surgeons who were providing primary lip and nose repair even in these surgical departments, so specialists in private individual clinics were then approached.

Although this was not one of the aims of this study, we found only 20 surgeons and the size of our sample is quite a humble number, especially when we consider that we have included six hospitals and eight private clinics or centres in our recruiting process. This reflects the fact that only a limited number of surgeons are developing a subspeciality in primary CLP repair.

This study showed that the majority of our sample participants (surgeons) were males, 90%, and only 10% were females [Table 1], giving a 1:9 female to male ratio. Similarly, in the United States (US) the proportion of female surgeons is less than that of males. Although since 1965 there was a dramatic increase in the number of female physicians graduating, between the years 2000 and 2013 the ratio of female surgeons to male was 1:5.<sup>[31,32]</sup>

Another observation of our study is that primary cleft surgeries in Baghdad have been performed mainly by plastic surgeons (75%), followed by maxillofacial surgeons (20%) and that paediatric surgeons made only 5% of the sample size [Table 1]. However, maxillofacial knowledge and training focuses on facial and oral areas and the jaws regions as well as the congenital abnormalities that affects those regions, like CLP. Craniofacial surgeries and CLP are considered familiar areas for maxillofacial surgeons.[33-35] Remarkably, the Eurocleft Project of 1996-2000<sup>[36]</sup> has highlighted that in Europe, at that time, it was not clear which speciality was eligible to do primary cleft repair. On the contrary, a wide variety of surgical specialities were involved. The Project reported that the top surgical specialities involved were plastic surgery (46.7%), followed by maxillofacial surgery (29.4%) and paediatric surgery (10%), then others. We cannot compare our finding with that report because of the sample size, and as our report reflected the trend of specialities performing CLP surgeries in Baghdad city only. However, we find it interesting as it is more or less like the experience in other countries like the UK during the nineties.<sup>[37]</sup> Whether those initial surgeries are under the umbrella of plastic or oral and maxillofacial specialities is not within the scope of our study, and the amount of surgical experience is what allows the surgeons to perform these surgeries.

According to the second part of our questionnaire [Table 2], feeding plate (palatal obturator) and lip strap, among other PSM procedures, are commonly used in the first few months before having the primary lip and nose repair, 85% and 80% respectively. In Europe, before organizing a management protocol for children with CLP, PSIO was routinely used (65%), mostly as a passive plate, and some teams were routinely using it as a feeding plate (70%).<sup>[36]</sup> An interesting finding in our study is that the PSM of infants with CLP with NAM is not uncommon, especially with all the controversy in literature about its long-term benefits.<sup>[22,23,38,39]</sup> Similarly in the US, though there is limited evidence on the advantages of starting with NAM before primary lip and nose repair, 37% of CLP special centres are providing this type of therapy.<sup>[22]</sup>

PSM is interdisciplinary. It could be provided by an orthodontist or by a prosthodontist.<sup>[40-42]</sup> Our finding was not far from this, as orthodontists and prosthodontists were the top specialists that were involved in PSM for infants with CLP, at 45% and 40% respectively. It was noted that the plastic surgeons were equally involved in providing PSM (45%), and so it is not all about speciality – instead, it is the training that is vital for successful management.

Following up, the majority of our surgeons agreed that there are advantages to using NAM therapy in terms of facilitating the easing of difficulty in surgical procedures and better surgical outcomes, 82.35% and 76.47%, respectively. The rest of the participated surgeons did not find any differences between children with CLP who received NAM and those who received

another PSM, 17.65% and 23.53%, respectively [Table 3]. Recently there was a similar questionnaire study that explored different dental specialists' opinions regarding primary lip and nose repair surgical outcomes. It targeted paediatric dentists, orthodontists, prosthodontists and oral surgeons. Interestingly, 99% of them suggested providing NAM to infants with CLP because of the positive effect on surgical aesthetic outcomes.<sup>[43]</sup> This is similar to our finding, although we aimed to include only surgeons in our study as they have the privilege of assessing the surgical outcome more precisely.

Compliance from the parents or the care provider is vital for successful treatment of patients with CLP. We found in the literature that lack of compliance negatively affected the use of NAM therapy as it requires weekly dental appointments for NAM adjustments and also daily care.<sup>[44,45]</sup> In our study, regarding the effect of using nasoalveolar molding on parents' compliance, we found inconsistency. Seven surgeons reported that it was negatively affected, six surgeons thought that it was positively affected and four surgeons did not report any effect [Table 3].

At the end of this questionnaire, we asked the participants "What was the benefit of using NAM over other measures of PSM that you have experienced?". The majority of answers were specific. The use of NAM prior to primary repair was expressed in molding nasal ala, getting better shapes of nostrils, approximating cleft shelves and molding the alveolus, better closure without tension and improvements of the nose, reduction of wide clefts, aligning alar cartilage and premaxillary set back alignments. On the other hand, some specialists' replies were more general and they reported that the surgical procedures were easier and that outcomes were aesthetically and functionally better.

At the end, it is worth mentioning that surgeons generally provide PSM for a considerable percentage of the patients with cleft lip and palate and most of them find that the use of NAM makes primary repair surgical procedures easier and have predictable outcomes. However, low percentages of infants with cleft lip and palate have been provided with NAM appliances. This highlights the fact that management of these patients is sophisticated and requires the collaboration of different specialities rather than surgeons alone. Treatment with NAM requires successive periodic appointments for adjustment. The adjustment visits include, in addition to monitoring the child, doing special practical procedures that will need time and skill. This is where other specialties like orthodontists, prosthodontist, pediatric dentists and so forth need to be involved more.

The difficulties in data collection during this study are a reflection of the health care of CLP patients in general, and the health services for PSM in particular. Launching the PSM protocol, organising and training CLP teams, and establishing CLP centres across Baghdad are necessary for improving the health care services. Making use of the European and US experiences in this field, especially that their experiences in the 90's are similar to ours now.

# Conclusion

Although there are limited resources from which to collect data about the PSM because of the lack of special CLP medical health centres, our questionnaire study has revealed that use of NAM is very limited here in Baghdad but it is still one of the PSM alternatives. Baby feeding plate (palatal obturator) and lip strap are the most common PSM. PSM is interdisciplinary; orthodontists, prosthodontists and surgeons are involved in providing this therapy.

In the majority of cases, surgeons believe that using NAM prior to primary repair made the surgical procedure easy in relative terms and permitted the prediction of surgical outcomes.

#### List of abbreviations

Cleft lip and/or palate	CLP
Presurgical infant orthopaedics	PSIO
Unilateral cleft lip and palate	UCLP
Bilateral cleft lip and palate	BCLP
Nasoalveolar molding	NAM
Presurgical management	PSM

#### **Authors' contributions**

(HA) designed the research study. (HA, DA, HM, and SS) performed the research. (HA, DA) analysed the data. (HA and DA) wrote the manuscript. (HM and SS) provided help and advice whenever needed during the process. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

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#### **Conflicts of interest**

There are no conflicts of interest.

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