# A Stepwise Guide for Easy, Rapid and Accurate Oral Impression Taking for Newborn Cleft Lip/Palate Infants

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**Abstract:** In developing countries, awareness for proper management of newborn cleft lip/palate (CL/P) is not widely spread. Many CL/P infants arrive to clinic few weeks or sometimes months after birth and may need naso-alveolar moulding (NAM) therapy. NAM is an important treatment modality that should be initiated as early as possible after birth. Intraoral impressions are required for the fabrication of NAM devices. Therefore, rapid un-stressful cost effective intervention is crucial. **Aim:** To present an efficient and cost-effective method of impression taking to CLP infants. **Material and methods**: Cost of each impression of the three materials used, rubber base, alginate and impression compound was calculated in USD. Effectiveness was evaluated on the basis of the total number of impressions needed, by each type of material all through treatment and the number of dental models produced by each impression material. **Statistical analysis:** One-Way ANOVA and the One-Way ANOVA Post Hoc Tests were used to calculate difference between study groups and significance between study groups' means. **Results:** Rubber base showed the least cost-effectiveness ratio (6.2), compared to alginate (23.41) and impression compound (23.36). Although all three materials produced similar number of dental models, yet the use of rubber base required the least number of impressions thus saving time and total cost. **Conclusion:** Intraoral impressions taken for CLP infants could be less stressful, rapid, accurate and cost effective using the described procedure and material.

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***Key words**:* Oral impression technique, Cleft lip and palate, naso-alveolar moulding therapy.

## 1.Introduction:

Infants born with cleft lip and palate (CL/P) deformities always face many challenges in order to survive with their demanding condition. A fundamental treatment objective for these little patients is to restore normal anatomy and function. When major skeletal and soft-tissue aberrations in this craniofacial deformity are re-established pre-surgically, this allows for more favourable and stable post-surgical results.

Grayson et al.,(1999) This is achieved by naso-alveolar moulding (NAM) therapy which is being recognized as an important pre-surgical procedure[i].

NAM is essentially aimed to reduce the intensity of the initial alveolar cleft and nasal deformity in CL/P infants. Many NAM devices have been described in the literature but basically it is an intraoral plate that separates the oral and nasal cavities that may have nasal stents for moulding the nasal ala, nasal tip, and lengthening the columella. This plate also assists in restoring proper tongue position and function during feeding and swallowing, Grayson et al.,(2009).

Construction of such a plate requires an accurate impression of intraoral bony and soft tissue foundation and should by fast, requiring short steps that are safe and less annoying to the baby. Moreover, reducing the total cost of such procedure would be of great benefit. Proper tray selection and adjustment is fundamental for accurate and trouble free impression taking. This is usually achieved in well-developed cleft centres by using either ready-made infant size trays or special custom made trays that were previously fabricated for former CL/P patients and sterilized after use, Mylin et al.,(1968).

However, these are not always feasible in young growing cleft clinics, nor are ready-made infant sized trays available in the dental market. A variety of impression materials have been tried out in our clinic till a final approach has been set. Therefore, the aim of this article was to present a stepwise guide for a rapid, accurate, and cost effective impression taking of the upper jaw for newborn infants with CL/P using feasible and readily available aluminum stock trays and rubber base impression material.

## 2.Materials and Methods:

### 2.1.- Materials:

#### 2.1.1.Tray Selection:

At the Cleft Care Clinic, the smallest available size of an edentulous aluminum tray was selected. The tray was cut and trimmed to approximate the size of the dental arch using heavy duty or orthodontic scissors into a smaller size. A thin roll of softened pink wax was then adapted around the edges to cover any sharp metallic edges that might be harmful to the infant patient as in figure (1).

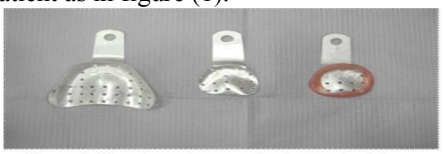

Figure 1: Showing a size one aluminum edentulous stock tray before and after being cut; pink wax added to the sharp edge for safety and to compensate for over-cut areas.

The adjusted tray was then inserted into the infant's mouth to check for proper extension. The tray should be wide enough to cover the lateral ridges and posteriorly should cover the maxillary tuberosities. Pink wax was added and adapted to cover any over-cut parts of the tray. It provided additional support to the impression material and prevented the material from overextending posteriorly.

#### 2.1.2.Impression Materials:

Polysiloxane; condensation-type of putty consistency was used to take the impression. This material offered good tear strength and adaptable setting time that made it an ideal impression material for infants. The setting time could be adjusted according to manufacturer's instructions by adding more catalyst to deliver a rapid set. After the material was loaded into the pre-adjusted tray, it took 10-15 seconds intra-orally to set. In cases of wide clefts or when external nasal anatomy was required to fabricate a nasal molding device, more material was added in this area to allow for accurate recording of the anterior nares. Care should be taken not to apply too much material that might block nasal passages.

The impression was taken out and another mixture of medium bodied elastomeric material was added on top of the heavy body that to obtain the fine details for good retention of the appliance.

### 2.2.- Methods:

All impressions were taken with the infant fully awake without anesthesia. Instructions were given to the parents in the visit prior to impression taking not to feed their baby for at least two hours. If the impression will be taken in the first visit, it was advised to wait about two hours after the last meal to prevent the infant from vomiting during the procedure. For safety and prophylactic purposes, the attending personnel and/or clinician should be adequately qualified to manage in case of air way obstruction or regurgitation of gastric contents that might be occurred during the impression procedure. Moreover, the facility was equipped with high volume suction apparatus and oxygen portals.

The infant was held on the parent's lap where his/her back was against the parent's chest. The clinician's position to the infant during insertion was at ten o'clock position; behind the patient's head, as shown in figure (2). The impression material was not inserted until partial setting of the material has been observed. The impression was inserted intra-orally at a ten o'clock position for 10-20 seconds. Immediately after insertion, the infant was turned forwards and downwards on to his belly where the face was facing the floor but the head was held upright as shown in figure (3). This allowed for any fluids to spill out of his/her mouth without blocking the airway. After the material set, the impression was taken out and inspected for proper extension.

After dryness of the impression, the medium bodied material was added. An amount similar to the size of a medium-sized marble ball was applied and the amount of catalyst was adjusted to deliver rapid setting. The loaded tray was ready for insertion when material strands pulled out by the mixing spatula at about 1 cm long. It was applied over the whole surface of the putty impression but care was taken not to increase the material posteriorly to prevent gagging and discomfort to the infants. Same position and timing were repeated once again.

Figure 2, Infant position during try in of the tray and inserting the impression. The clinician stands behind the patient's head at a 10 o'clock position.


Figure 3: Photographs showing (A); infant was immediately turned onto his/her belly after insertion of the impression. Note the extension of the impression material facially to record the anterior nares. B; head should be supported all through the procedure

The impression was taken out of the patient's mouth and carefully inspected. It should cover all the cleft areas, dental arches and reached the depth of labial and buccal vestibules. It should be extended posteriorly to cover the tuberosities and recorded the nasal septum in bilateral CL/P cases (Figure 4).
Moreover, during the impression procedure, an eye should be kept on the baby's face to check for airway patency for fear of obstruction. A crying infant revealed a patent airway. If for any reason the child could not cry or was cyanotic, the impression was removed immediately and the air way was checked for patency.


Figure 4: Photographs showing (A); final impressions for unilateral complete CL/P and (B); bilateral complete CL/P. Note: the medium body rubber base wash is pink in colour and the heavy body rubber base is green.

**2.2.1. Cost Effectiveness Analysis:**

Several materials were tried out in accordance to the technique previously described. The impression materials used were rubber base; heavy and medium body, fast set alginate and impression compound. Consequently, a cost effective analysis was performed based on those three materials according to the procedure described above.

The cost of each impression was estimated in USD. Among calculated cost were the price of trays; both stock and special trays used during procedure. In addition to laboratory fees to fabricate custom made special trays. Moreover, the cost of dental stone used to pour the impression to obtain dental models and cost of each material per weight in grams was also estimated. The average cost of working days lost by the parents for skipping work to attend to the clinic with their baby was calculated. This was calculated from start of treatment till three months post palatal surgery. In addition the average cost of transportation for these parents to and from our clinic was also calculated.

It was worthy to mention that no extra fees or profit were charged, as our clinic belongs to a teaching facility where services were offered with cost price only. Effectiveness was calculated on the basis of the total number of impressions needed with each material to produce the study and the working models on which the appliance was fabricated in all phases of treatment till three months after primary palatal repair.

It was estimated that models were needed for seven timeframes during primary treatment for documentation and assessment purposes especially in teaching academic facilities. Before the device fabrication; at least two devices for each child prior to primary lip repair depending on cleft width and time at which treatment started. Then at the end of NAM therapy just before primary lip repair, one month post primary lip repair, three months post lip repair. Again just before primary palatal repair, one month and three months post palatal repair. Then, collected data was tabulated and statistically analyzed. Means and standard deviations for each variable were calculated. One-Way ANOVA test and One-Way ANOVA Post Hoc tests were used to assess the statistical significance of the differences between the study groups.

**3.Results:**

The mean total material cost in USD from the start of treatment to three months post palatal repair when using the three different impression materials showed a highly significant difference as shown in (Table 1). The mean total cost ± SD of the rubber base impression material showed the least mean total cost (111.6 ± 10.0), followed by alginate (398.0 ± 33.1) and impression compound (408.8 ± 16.5).

The mean difference between rubber base and alginate or rubber base and impression compound showed high statistical significance. This was also true when comparing alginate and rubber or impression compound and rubber base. However, the mean differences between alginate and impression compound and vice versa were not statistically significant. The use of rubber base rather than alginate reduced the cost by 286.4$ and the use of rubber rather than impression compound reduced the cost by 297.2$.

The mean total weight of rubber base ± SD used was 162.8 ±14.6, while that of alginate was 385.9 ± 32.1 and that of Impression compound was 350.0 ± 14.1. Comparing these mean total weight difference

of the impression materials was statistically significant.

**Table (1): Comparison between different materials, regarding mean total cost of impression material**

| (I) material | (J) material | Mean difference (I-J) | P Value |
|---|---|---|---|
| Rubber base | Alginate | -286.4 | 0.000*** |
| | Compound | -297.2 | 0.000*** |
| Alginate | Rubber base | 286.4 | 0.000*** |
| | Compound | -10.8 | 0.353 NS |
| Compound | Rubber base | 297.2 | 0.00*** |
| | Alginate | 10.8 | 0.353 NS |

*NS non-significant,*low significant, ** significant, *** highly significant*

When comparing significance of total mean impression material weight; the mean difference between rubber base and alginate or rubber base and impression compound or alginate and rubber base or impression compound and rubber showed high statistical significance as shown in (Table 2). While mean differences between alginate and impression compound and vice versa were not statistically significant. The use of rubber base rather than alginate reduced the used weight by 223.1 gm and the use of rubber base rather than impression compound reduced the used weight by 187.2 gm.

**Table (2): Comparison between different materials regarding mean total weight of impression material**

| (I) material | (J)material | Mean difference (I-J) | P Value |
|---|---|---|---|
| Rubber base | Alginate | -223.1 | 0.000*** |
| | Compound | -187.2 | 0.000*** |
| Alginate | Rubber base | 223.1 | 0.000*** |
| | Compound | 35.9 | 0.16 NS |
| Compound | Rubber base | 187.2 | 0.00*** |
| | Alginate | -35.9 | 0.16 NS |

*NS non-significant,*low significant, ** significant, *** highly significant*

Regarding the total number of impressions needed from start of treatment till three months post palatal repair; the mean ±SD was 9 ±0.8 for rubber base, 17±1.4 for alginate and 18±0.7 for impression compound. Rubber base showed the least total number of impressions needed and this difference was statistically significant. The assessment between different material significance regarding mean total number of impressions was shown in (Table 3). Mean difference between rubber base and alginate, rubber base and impression compound, alginate and rubber base or impression compound and rubber base were highly statistical significant.

There was no statistically significant difference in the number of models produced through treatment by each impression material; rubber base showed a mean of 17.9±1.6, alginate had a mean of 17.0±1.4, while impression compound had a mean of 17.5±0.7.

**Table (3): Comparison between different materials regarding mean total number of impressions**

| (I) material | (J)material | Mean difference (I-J) | P Value |
|---|---|---|---|
| Rubber base | Alginate | -8 | 0.000*** |
| | Compound | -9 | 0.000*** |
| Alginate | Rubber base | 8 | 0.000*** |
| | Compound | -1 | 0.50 NS |
| Compound | Rubber base | 9 | 0.00*** |
| | Alginate | 1 | 0.50 NS |

*NS non-significant,*low significant, ** significant, *** highly significant*

Finally on evaluating the cost, effect, and cost/effectiveness ratio of the three materials; the rubber base impression material showed the least cost effectiveness ratio (Table 4).

**Table (4): Comparison between different materials regarding cost, effect and cost effectiveness ratio**

| Material | Cost {C}in $ | Effect {E} | Cost effectiveness ratio {C/E} |
|---|---|---|---|
| Rubber base | 111.6 | 17.9 | 6.2 |
| Alginate | 398.0 | 17 | 23.41 |
| Compound | 408.8 | 17.5 | 23.36 |

## 4. Discussion:

Intra-oral impressions taken for CL/P infants can be very challenging when compared to every day impression taking in the orthodontic clinic. Its difficulty can be described in terms of the smaller dimensions of the oral cavity, size of hard and soft tissue deformity, and respiratory demands of these

little patients that are obligatory nasal breathers. Trouble free impression taking requires the clinician to be aware of the complications that may occur and how to avoid them.

Selecting from commercially available infant size trays, Suri and Tompson (2004) is not something that is available at all times and in some developing countries as in Egypt, where such a tray does not exist abundantly in the medical and dental market. Moreover; special trays that have been fabricated from models of previous CL/P infants that have been collected over the years and choosing the most appropriate size for each new infant, Mylin et al.,(1968);Grayson et al.,(2009) is difficult to achieve in a young growing cleft clinic like ours. Another set back of this method is the unique configuration of each cleft that makes it rather difficult, time consuming and tiring for the little patient during the try in of different tray sizes.

An alternative suggested approach for impression taking in infants is the adaptation of a softened piece of pink wax in the infant's oral cavity to roughly obtain the size and anatomy. This is then poured into a primary model and a custom made special tray is fabricated and used for secondary impression taking. Again, this approach may be effective but time consuming. Grayson et al.,(2009) The fact that parents might skip working days and travel from far or rural areas in order to come to the clinic adds to the list of problems. Any procedure that will save time should be definitely employed, where time is a critical issue.

Positioning the infant on his/her parent's lap helps soothing the young baby and gives him/her a sense of security. It is preferred that a parent is involved in the process of impression taking. It allows them to psychologically understand what their child is going through. It gives them an idea of how the appliance is fabricated and offers them the ability to handle the insertion and removal of the appliance with capability later on. Some authors have also suggested that the surgeon holds the infant upside down to prevent the tongue and any fluids from blocking the child's airway, Grayson et al.,(2009). However, we have found positioning the infant and the clinician as previously stated to be easier, allows better control of removal and insertion of the tray, and reduces the baby's anxiety.

As regards the impression material; some authors have suggested alginate (irreversible hydrocolloids) as the impression material to be used, Mylin et al.,(1968); Jacobsen and Rosenstein (1984); Da Silveira(2003);Suri and Tompson (2004). This was also previously attempted in our earlier cases but is now strictly out of use in our clinic due to its very weak tear strength[ii] that allows it to be lodged into any of the many cleft undercuts that may produce serious repercussions. Also, setting time of alginate is not readily controlled or easily manipulated by the clinician and any posterior excess of the material may stimulate or exaggerate gagging reflex of the young patient.

Other prosthodontists may use impression compound, Suri and Tompson (2004) but has proven to be hurtful to the patient because of the many hotspots present in the material when inserted and was found to be time consuming in order to reproduce fine anatomical details. The impression needs to be adjusted several times which is annoying to the baby and the accompanying parents/guardians.

The use of heavy bodied elastomeric impression material (rubber base) as described in this paper has been recommended by several authors, Grayson et al.,(1999); Sabarinath et al.,(2008);Grayson et al.,(2009). It has shown to be a reliable material when used as described. It has better tear strength when compared to alginate. Its flow characteristics allow for good reproduction of the cleft and its undercuts without being inserted too deeply. This prevents its lodgment in these undercuts during removal of the impression which may result in inhalation of the residuals and serious respiratory complications. Setting time can be adjusted to allow for rapid set intraorally to avoid patient cyanosis or fatigue as it blocks the nasal passages allowing only for oral breathing. It has very high dimensional stability, Melvin et al.,(1969);Zarrinnia et al.,(1993);Kotbyet al.,(1997); Anusavice (2004);Sabarinath et al.,(2008) which allows it to be poured several times with high accuracy to obtain more than one model.

Although the three different materials were nearly similar in mean total number of casts obtained but rubber base impression material had the lowest cost and the cost effectiveness ratio; as rubber base was the lowest mean total number of impression taken and impression weight used. This can be attributed to the necessity of taking the impression in two visits when using the other two materials. A primary impression taken on the first visit, then a special tray is fabricated on the primary model and a secondary impression is taken on the second visit. This increases the cost of the material used by the double, in addition to lab fees. It also increases expenses on working parents having to skip more working days, in addition to transportation. Whereas the rubber base material when used, as we have described in this article, the impression is taken in one step with high accuracy saving material and time which is critical in the treatment of these babies.

## Conclusion

Intraoral impressions for infants with CL/P may be a challenging and stressful procedure for the infants, parents and clinician. The described procedure was safe, simple, efficient, time and cost-effective technique and minimizes any complication risk that might arise when employed as shown.

This approach for impression taking in infants or even children is recommended in regions where availability of special sized impression trays is limited and for cases which requires several impressions taken along different treatment phases.

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