

BRIEF COMMUNICATION

International Confederation for Cleft Lip and Palate and Related Craniofacial Anomalies Task Force Report: Palatoplasty in the Speaking Individual With Unrepaired Cleft Palate

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Introduction: The benefits or otherwise of late palate repair in older children or adults are uncertain. The outcomes, particularly without appropriate speech therapy, are often disappointing. The issue is of special importance in the poorer countries where these patients are most commonly seen and where limited capacity and facilities may have to be rationed.

Method: A task force was set up to report back to the International Congress in Orlando in May 2013. The chairman and some members were nominated by the organizers and further members were added during the discussion process. Some of the members had considerable experience of late palate repair. The task force compiled a report after 9 months of e-mail correspondence. The report includes reports of some previously unpublished studies. A summary of the report was presented at Cleft 2013 in Orlando.

Conclusions: There was a general consensus that late palate repair is of benefit for many patients and that, even if normal speech is not attained, outcomes are positive. Outcomes depend on the age of the patient (the younger the better), on the skill of the surgeon and, ideally, on the availability of appropriate speech therapy. A protocol for a prospective international multi-center study is proposed.

KEY WORDS: *adult cleft palate, cleft palate, late palate repair, palatoplasty, speech therapy after late palate repair, unrepaired cleft palate*

ASSIGNED OBJECTIVE OF THE TASK FORCE

This task force was charged with assessing the evidence regarding late palate repair, giving recommendations based on this evidence and the experience of task force members and suggesting future directions for research.

TASK FORCE FUNCTIONING

Membership Acquisition and Demographics

The membership of the task force reflected the countries where most older patients present with unrepaired palates but included some other members who, it was felt, could add useful advice. It included surgeons and speech pathologists. Initial membership was suggested by the Scientific Committee of the Congress, and additions were made after discussion within the membership and approval by the task force co-chairs.

The final task force included members from Brazil, Canada, China, India (three), Israel, Taiwan (two), the U.K. (two), the United States, and Yemen. There were 10 surgeons and three speech pathologists.

Method(s) of Interactivity

A series of questions was posed and the task force communicated by e-mail for a period of 7 months prior to the submission of a report for the transactions for the International Congress in Orlando, Florida, in May 2013. A presentation was made to the Congress and a meeting held after the presentation for those interested.

Issues Addressed

After some preliminary discussion, the task force addressed the following issues:

1. The significance of age
2. Speech assessment
3. Records
4. Investigations
5. The role of speech therapy before and after repair
6. Late palate repair where no speech therapists/pathologists are available
7. Hearing

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8. A cost/benefit analysis of late palate repair
9. Is there a maximum age above which palate repair is inappropriate?
10. Is late palate repair a priority in a centre which cannot cope with its workload?
11. Surgical technique for palate repair for the late unrepaired palate
12. Palate repair with simultaneous pharyngoplasty in the older patient
13. Postoperative speech therapy
14. The role of prosthetic management
15. Predictive factors for successful treatment
16. Outcome measures
17. Secondary surgery after unsuccessful primary surgery in the older patient
18. Visiting mission teams and late palate repair
19. Possible future international studies

CONCLUSIONS OF THE CLEFT 2013 TASK FORCE

1. The Significance of Age

It is widely accepted that the palate (at least the soft palate) should be repaired by the age of 2 years and probably by the age of 12 months. Early speech is usually developed by the age of 2 years. Individuals whose palates are repaired later than 2 years are, therefore, at a potential disadvantage for two reasons: They are likely to have developed articulation errors that have to be corrected if speech is to be fully intelligible; and the soft palate may not have grown and the palate muscles may not have developed as they would have if an appropriate palate repair had been performed at an earlier age. These disadvantages multiply as the age of repair increases.

Patients with unrepaired palates, therefore, can be subdivided into the following age groups: 2 to 6 years (preschool in many countries); 6 to 12 years (primary school); 12 to 18 years (secondary school); and over 18 (tertiary education/marriage/work). Each age group poses different problems, and each country presents different challenges. The chance of obtaining a competent sphincter and achieving normal speech seems to decrease progressively with age.

2. Speech Assessment

An accurate assessment of speech is important in evaluating the likely benefits of repair of the cleft palate and the need for speech therapy.

However, the majority of older patients presenting with unrepaired cleft palates are in the less developed and poorer parts of the world. This further adds to the challenges. There are few, and sometimes no, appropriately trained speech therapists in these countries. Even in countries where there has been recent development of

speech therapy, experience may be limited. Many surgeons have a poor understanding of speech and may not be able to differentiate between velopharyngeal incompetence, which may be corrected by surgery, and articulation errors (compensatory articulation), which may not be altered by surgery and intelligibility not significantly improved.

There is, therefore, an urgent need to establish speech therapy schools and to train more speech pathologists/therapists, some of whom will work in cleft teams. In the meantime, cleft surgeons need to learn more about speech so they can distinguish among hypernasality, nasal emission, and cleft-type articulatory errors. A teaching DVD and/or online tutorial on speech for surgeons would be a good start.

There is also a need to develop speech stimuli across languages so outcomes are measured appropriately and can be compared across studies. The guidelines suggested by the universal reporting parameters group (Henningsson et al., 2008) could be adapted across languages for this purpose. These were further extended (Henningsson and Willadsen, 2011).

3. Records

Before surgery on the late unrepaired palate, it is important to document the following: the age of the patient; whether the patient is syndromic; the educational status of the patient; any speech therapy that the patient has had; the extent of the cleft (e.g., 3/3, 2/3, and 1/3 hard palate and 3/3, 2/3, and 1/3 soft palate); and an attempt to score palatal and pharyngeal muscle activity on oral examination with the patient saying /a/ (if possible, with a video recording). We suggest a scoring system of 1, *poor*; 2, *fair*; and 3, *good*. In addition, audio and, if possible, video recordings of speech provide a record against which the surgeon can objectively assess the outcome of surgery and may provide the basis for an international study.

If a speech pathologist, speech and language therapist, and/or phoniatician is part of the team, an assessment of the following aspects of speech and language is recommended: language development (i.e., does the patient have age-appropriate development of expressive language?); nasal emission; nasal turbulence; nasality; articulation; speech understandability and intelligibility; and voice. Moreover, using internationally agreed scoring systems (see paper on universal parameters below as one example, although it should be noted that this is not validated), conduct an audiological assessment (see section 7 below) and an assessment of general development.

At surgery, the details of the cleft should be documented, including the width of the cleft at the back of the hard palate (if the hard palate involved); the soft palate length, both absolute and in relation to the pharynx (Randall et al., 2000); and an assessment of the cleft musculature.

The details of the surgery should include whether magnification was used (loupe magnification or microscope) and surgical procedures relative to the hard palate (e.g., von Langenbeck, two-flap, Veau/Wardill/Kilner, or no hard palate incisions) and/or the soft palate muscles (e.g., intravelar veloplasty—with details—or Furlow).

Documentation of postoperative complications should include bleeding and especially the need for blood transfusion; infection; fistula; and major breakdown.

Outcome records should include the patient's and relative's views of the benefits of the operation (e.g., can the patient be better understood on the telephone?); any postoperative speech therapy; the assessment of speech outcome by a speech pathologist, speech and language therapist, and/or phoniatrician if part of the team (as preoperatively); a speech audio and, if possible, video recording (as preoperatively); and audiological assessment.

This information will allow the surgeon to evaluate the results of the surgery. Ideally, this information could become part of a multicenter, multinational study (see section 19 below).

4. Investigations

Investigations such as videofluoroscopy and nasendoscopy are of most value in the assessment of velopharyngeal incompetence (VPI) and velopharyngeal dysfunction (VPD) following repair. However, before and after late palate repair, they may give some information about the length of the palate (difficult to assess in an unrepaired palate); mobility of the palate; the size and configuration of the pharynx, especially of the posterior pharyngeal wall (as seen on lateral videofluoroscopy); and the position of the levator knee in the velum (as seen on lateral videofluoroscopy). However, the value of these investigations in patients having late primary repair is questionable.

Nasometry gives an objective measure of nasal resonance but may not be available in poorly equipped centers, and interpretation requires establishment of language- and population-specific norms. It will probably not affect decision making.

5. The Role of Speech Therapy Before and After Repair

The speech pathologist or speech and language therapist, if part of the team, is pivotal in assessing the patient's speech and advising the surgeon of the likely outcome if velopharyngeal competence can be achieved by surgery.

Most patients having late palate repair will have acquired cleft articulation errors. Opinion is divided as to whether speech therapy (if available) should be offered before surgery or delayed until after surgery

when, it is hoped, palatal function will have improved and, ideally, velopharyngeal competence achieved.

The consensus was to first repair the cleft if it is believed that the patient will benefit.

Appropriate speech therapy, if available, will almost always be necessary after late palate repair. If not available, the outcome is likely to be less favorable.

Unfortunately, in spite of stressing the importance of speech therapy, follow-up for postoperative evaluation is poor in many countries and compliance may be even worse for therapy, complicated by the fact that families need to commit and understand that it is usually a long-term, ongoing process, in contrast to one-off surgical procedures.

6. Late Palate Repair Where No Speech Therapists/Pathologists Are Available

As outlined in previous sections, a speech therapist/pathologist is very important in preoperative assessment and recording of speech; a prognosis for the likely outcome if surgery is effective; postoperative speech therapy; and postoperative assessment and recording of speech.

If a speech therapist/pathologist is not available, the surgeon needs to acquire a basic understanding of speech—and, in particular, the effects of hypernasality and articulation errors on intelligibility. Many surgeons who do not work with speech therapists do not understand the difference between nasality and articulation and the effect on intelligibility. An older patient with established glottal articulation may obtain little benefit (at least as far as speech is concerned) from repair. Surgeons need to understand this when they are making decisions. As suggested previously, a teaching DVD and/or online tutorial on speech for surgeons would be a good start.

7. Hearing

Many patients with late unrepaired cleft palates will have hearing deficits. An audiological examination, including threshold estimation and assessment of status of the middle ear, is an important part of the patient's preoperative assessment.

If hearing loss is identified, measures to improve hearing should be instituted if possible. This may involve the insertion of ventilation tubes or the provision of hearing aids. Hearing should be optimal to give the patient the best chance following surgery. It may be that correcting the abnormal velar muscle anatomy improves eustachian function and hearing. Preoperative and postoperative audiology may help answer this question.

In a study in Hyderabad, India, hearing deficits were less common than expected (<30% overall) and severe losses requiring hearing aids were rare. The results in postoperative patients were similar. The surgeons did

not insert any ventilation tubes because they were not convinced of their efficacy in older patients and were not confident about follow-up (Reddy, unpublished data).

8. A Cost/Benefit Analysis of Late Palate Repair

In a country with limited resources and facilities, priorities need to be set and a cost/benefit assessment should be considered for each patient and for late palate repair in general.

The benefits include potential improvement in speech (which may be less than expected); benefits in eating and drinking; possible improvements in hearing; increased self-confidence and feelings of self-worth; and improved prospects for education, employment, and marriage.

However, there may be costs: negative outcome with no speech improvement—or even deterioration; possible complications; and the use of facilities might deny surgery for patients who could receive more benefit.

In the opinion of surgeons working in countries where many patients present with late unrepaired palates, the benefits usually outweigh the risks (Murthy et al., 2010). In the study in Hyderabad, India, in no case did speech deteriorate. None of the adults said they would have refused surgery if they knew beforehand what they would be going through, and all would recommend it to anyone with similar problems. Many adults with unoperated palates had surprisingly intelligible speech. The worst speech was in patients with very poor earlier surgery with scarred, immobile, and fistulous palates. Having no surgery is better than undergoing poor surgery (Reddy). There was more operative blood loss, but complications such as postoperative bleeds, fistulae, and breakdowns were similar to those in younger patients.

9. Is There a Maximum Age Above Which Palate Repair Is Inappropriate?

There is evidence that speech outcomes are significantly less satisfactory when palate repair is performed after the age of 10 years (Sell, 2008).

Much depends on the patient's articulation. An older patient with established glottal articulation may benefit very little from surgery—even if appropriate speech therapy is available. However, some older patients have surprisingly good articulation despite hypernasality, and speech may be markedly improved by surgery. Sell (1992), however, reported that in her study of 24 Sri Lankan adults there were poor outcomes when palate repair was undertaken in adulthood, with a high incidence of poor preoperative and postoperative articulation, postoperative fistulae, and VPI.

Some older patients in India have submucous fibrosis as a result of chewing pain, and this may be a contraindication to surgery.

As outlined in the previous section, apart from speech, there may be other benefits from surgery. Therefore, no absolute guidelines can be given regarding age.

10. Is Late Palate Repair a Priority in a Center That Cannot Cope With Its Workload?

It follows from the above that each cleft center must decide its policy about late palate repair. Ideally, each patient should be treated on his or her merits. In general, the older the patient, the less likely late palate repair be justified if resources are limited.

11. Surgical Technique for Palate Repair for the Late Unrepaired Palate

There is no universal consensus regarding palate repair techniques for any age group. In particular, there is ongoing debate on the relative merits of straight repair with varying degrees of muscle dissection versus Furlow palatoplasty. As for younger patients, there are advocates of both for late repairs, and good evidence as to which is best is still lacking. However, there are specific issues related to late palate repair. The older the patient, the less concerned the surgeon needs to be about the possible effects of surgery on maxillary growth. Cleft width often appears proportionately large in older patients—with less available tissue for closure. Whether this is real or apparent is uncertain. In addition, the soft palate musculature is often poorly developed, and operative bleeding is more often a problem in older patients.

Although there is variability in width and musculature, it is very rare for there to be insufficient tissue for closure (Reddy).

Saline hydrodissection with 1:500,000 adrenaline in saline has been advocated to reduce bleeding in the older patients (Lotha), but this may be more difficult in adults because the fluid tends to enter the submucosal rather than the subperiosteal plane (Reddy). It is important to wait (up to 10 minutes) after infiltration in these patients (Sadhu). There is much less bleeding if the dissection is carried out from the cleft edges and lateral releasing incisions avoided.

An unpublished study in Brazil (Alonso) of 50 patients having late palatal repair found good outcomes in those who had hypernasality only.

There may be a place for primary palate lengthening by oral and nasal buccinator myomucosal flaps in the hypoplastic palate in an older patient.

12. Palate Repair With Simultaneous Pharyngoplasty in the Older Patient

Because older patients have less satisfactory results from palatoplasty, simultaneous palate repair with pharyngoplasty has been advocated. A randomized

controlled trial (Reddy) was carried out in Hyderabad, India, comparing speech of patients aged 6 and older at the time of surgery. There were three groups: (1) routine palate repair with radical muscle dissection; (2) primary superiorly based pharyngeal flap added; and (3) modified orticochea pharyngoplasty added. Follow-up ranged from 6 months to 2 years. There was no statistically significant difference in speech. Many patients with pharyngoplasties had obstructive sequelae. This center has since discontinued the use of primary pharyngeal flaps in their protocol, and many flaps were later undone.

A study in Taiwan by Lun-Jo Lo and Clement Lin (unpublished data) evaluated 48 adolescent and adult patients with unrepaired cleft palate. There were 48 patients in two groups. One group received a one-stage operation (i.e., two-flap palatoplasty plus pharyngeal flap). The other group received a two-stage operation. In the two-stage protocol, a two-flap palatoplasty was used in the first-stage operation. The second-stage velopharyngeal surgery was selected based on nasopharyngoscope/videofluoroscope evaluation. They found the two-stage protocol is superior to the one-stage protocol.

In another Indian center, combined pharyngoplasty was performed in 10 consecutive cases and abandoned (Sadhu).

Experience in China was similar (G. Wang), where a primary pharyngeal flap was previously performed on some patients over 6 years of age based on the severity of the cleft. However, it was found that some patients can achieve velopharyngeal closure after palatoplasty, and a primary pharyngeal flap increased the risk of the surgery and had many complications. In this center, pharyngeal flaps are kept in reserve for a secondary procedure if necessary.

Therefore, there seems to be no evidence that outcomes are better when pharyngoplasty is combined with late palate repair, and complication rates are expected to be significantly higher.

13. Postoperative Speech Therapy

As emphasized in a previous section, postoperative speech therapy is essential in the majority of patients undergoing late palate repair if an optimal outcome is to be achieved. However, the therapy must be appropriate. Compensatory errors such as pharyngeal and glottal articulation may be very difficult to correct.

Ideally, correction requires regular and continuing therapy from a specialist speech and language therapist/speech pathologist. Unfortunately, such therapy may not be available. Even where speech therapy is available, patients may live some distance from the center. In this situation, speech pathologists in Chennai, India, provide institution-based therapy for a week and then give the patients plans to practice at home. This is reviewed once in 3 months.

Among other factors, motivation of the patient for good speech has been an important indicator for outcomes (Murthy et al., 2010).

Attempts have been made to teach nontherapists who can work in the community with these patients. In Chennai, India, a community-based intervention program has been in effect over the last 9 years (funded by Transforming Faces, City, Canada). Here, community-based rehabilitation workers are trained to provide basic speech-correction services. The speech pathologist visits the community site, reviews each child, sets the objectives for speech correction, and discusses them with the community-based rehabilitation worker. Methods such as telemonitoring are implemented to monitor the quality of service provided at the community. Each child with a cleft in the community is reviewed by the speech pathologist at least once in 6 months (Sell et al., 2011) (Hariharan).

Opinion is divided about the usefulness of these approaches and good evidence for their efficacy is required.

14. The Role of Prosthetic Management

Prosthetic management, if available, should be considered as an alternative to surgery in situations such as the following: the patient is considered unfit for surgery; the patient is unwilling to consider surgery; it is considered unlikely that surgery will achieve velopharyngeal competence; and before surgery where it is uncertain if the patient will benefit—as a therapeutic trial. However, prosthetic management requires a skilled prosthodontist or other dental specialist; a motivated patient who is able to return regularly for appointments; adequate dentition for a prosthesis; ideally, availability of nasendoscopy and/or videofluoroscopy to evaluate closure and monitor adjustments; and speech therapy, as mentioned above.

15. Predictive Factors for Successful Treatment

It is important to assess the likely outcome before surgery is undertaken, particularly if priorities have to be established and choices made about who will benefit from treatment. Favorable predictive factors are a younger patient, preferably younger than 12 years and ideally less than 6 years—the younger the better; a motivated patient; articulation without persistent posterior errors; a patient with no hearing loss; a velum of good length and mobility; and appropriate, available postoperative speech therapy.

Sell (1992) found that when palate repair took place in individuals over the age of 8 years, the quality of preoperative articulation, age, cleft type, and school attendance were the independent variables associated with outcome.

16. Outcome Measures

The most important outcome measure is improvement in speech. As with preoperative evaluation, this involves an assessment of nasal emission; nasal turbulence; nasality; articulation; speech understandability and intelligibility; and voice. All should be measured using internationally agreed scoring systems (see paper on universal parameters below).

Other outcome measures may include improvements in eating and drinking; hearing; self-confidence and feelings of self-worth; prospects for education, employment, and marriage; and participation (World Health Organization, 2001).

17. Secondary Surgery After Unsuccessful Primary Surgery in the Older Patient

If primary palatoplasty fails to achieve velopharyngeal competence, further surgery may be indicated. The aim would be to improve velopharyngeal function without significantly impairing the nasal airway. Sleep apnea may be a bigger problem than hypernasality.

Investigations, such as nasendoscopy and/or video-fluoroscopy, are essential.

Many of the factors that compromise outcome in primary surgery in the older patient are also relevant for secondary surgery.

18. Visiting Mission Teams and Late Palate Repair

As stated above, late palate repair may be difficult and the complication rate higher. Teams of Western clinicians should be very cautious about undertaking such surgery unless they have appropriate experience and liaise closely with local surgeons and speech therapists.

19. Possible Future International Studies

Many questions could be answered if standard records are taken before and after surgery as described above. An international registry of late palate repairs would be a major step forward. A prospective study would be very helpful.

RECOMMENDATIONS FOR THE CLEFT 2017 TASK FORCE

Much of the previous information is anecdotal. The task force recommends that a prospective international controlled trial is conducted and reports to Cleft 2017 in Chennai, India.

The key recommendations for this study are as follows.

Surgeons and Technique

Information will be required about surgeons' techniques (particularly with regard to muscle dissection) and outcomes in younger patients. (A surgeon with poor

outcomes for younger patients will skew results against late palate repair.)

Patients

Inclusions will be all patients of 6 years or older who have late repair of unrepaired cleft palates. Exclusions will be patients who are unable to cooperate for preoperative video speech recording.

Patients having simultaneous lip and palate repair may be included but need to be assessed separately due to the potential effect of lip closure on the production of bilabial sounds.

Preoperative Assessments

Information collected before surgery should include patient details (i.e., name, age [date of birth], sex); hearing level (note any significant hearing problems); expressive language level; cognitive level/disability (note any significant learning problems/cognitive difficulties); cleft type (unilateral cleft lip and palate, bilateral cleft lip and palate, cleft palate only); date of lip repair if cleft lip and palate. The oral examination should include evaluating the extent of cleft (3/3, 2/3, and 1/3 hard palate and 3/3, 2/3, and 1/3 soft palate), as well as rating soft palate movement and pharyngeal wall movement (Passavant ridge) with the sound /a/ using a 1 (*minimal*) to 5 (*maximum*) scale. Another measure is an estimate of the soft palate length in absolute terms and in relation to the size of the pharynx using a 1 (*short*) to 5 (*long*) scale.

Furthermore, assessment of the patient's speech should be conducted by speakers of same language using the following descriptions: impossible to understand, very difficult to understand, moderately difficult to understand, or easy to understand. Individuals should answer questions about how cleft palate has affected their quality of life, such as the following: Has it interfered with your education? Has it stopped you getting a job? Has it stopped you from getting married?

A speech video recording should be undertaken in the patient's language, and a speech sample should be collected via a brief conversation. Use standard questions such as these: Who is in your family? What do you like to eat? What do you do at school? What work do you do? Also, ask the patient to count from 1 to 20, say the days of the week, and repeat single words and sentences (language dependent).

Speech Recording Method

To record a patient's speech, use a digital video camcorder and external tie clip microphone. Ensure that no shadow is cast on the patient's face and that light is not behind him or her. Place the microphone on the lapel of the patient's shirt or dress (or similar distance from mouth). Zoom in to include the whole head and

face and a little bit of the shoulder. When recording, use headphones to ensure that sound is being recorded, and remind the patient to keep looking at the camera.

Basic equipment to include are an audio-video recording device, external microphone (tie clip), mini tripod stand, and a set of earphones.

Operative Details

Document details of the surgery, including the hospital, surgeon, and date of operation. Record the findings of the operation: width (in millimeters) of the cleft at the back of the hard palate, front of the uvula; length (in millimeters) of the soft palate (measured from back of the hard palate to tip of the uvula with a sterile tape measure); estimated gap between uvula and posterior pharyngeal wall (in millimeters); position of uvula in relation to adenoid tissue, if present (i.e., upper third, middle third, lower third). Estimate the muscle bulk on dissection (from 1, *poor*, to 3, *good*). Conduct a suction test at the end of the procedure, scored as 1 (*only if helped with gentle finger pressure*), 2 (*spontaneously*), or 3 (*maintained when sucker removed from nose*). Also record the surgical technique, magnification used, hard palate incisions (pushback/Langenbeck/none), and details of muscle dissection (see operative protocol).

Follow-Up Assessment (Between 6 and 12 Months)

Examination of palate should include determining whether there is a fistula, and if so, site and size; rating of soft palate movement with the sound /a/ using a 1 (*minimal*) to 5 (*maximum*) scale; rating of pharyngeal wall movement (Passavant ridge) with the sound /a/ using a 1 (*minimal*) to 5 (*maximum*) scale; and estimating soft palate length in relation to size of pharynx using a 1 (*short*) to 5 (*long*) scale.

In addition, conduct a speech assessment, using individuals who speak the same language as the patient. Determine whether the patient is impossible to understand, very difficult to understand, moderately difficult to understand, or easy to understand.

Ask the patient questions about how the operation has changed his or her quality of life: Has it helped your education? Has it helped you to get a job? Has it made it possible for you to get married? Finally, video-record speech, as done preoperatively.

Assessment

Speech recordings would then be listened to and scored by an international panel of speech therapists, including, if possible, therapists who share the patients' first language.

Critique (Positive and Negative) of the Task Force Process

The functioning of the task force confirmed the value of e-mail communication among members of an international panel of experts.

Task Force Participants

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