

Consent to Craniofacial Plastic and Reconstructive Surgery

(Template)

Patient's Name: _____ Patient's Date of Birth: _____

Medical Record No. : _____ Name of Responsible

Physician: _____

I. Surgery to be implemented (please add a brief explanation for any complicated medical term)

1. Recommended Surgery (Site):

2. Recommended Reason for the Surgery:

(please note the specific side for the part with difference of left and right)

II. Statement of the Physician (please mark "V" for an item that has been notified to the patient and "X" for an item that hasn't been notified to the patient)

1. I have tried my best to explain the information relevant to the surgery in a way that the patient can understand, particularly involving the following items:

- Reason for the surgery, steps, range, risk and success rate of the surgery and possibility of blood transfusion
- Surgical complications and possible treatments
- Possible consequence of not implementing the surgery and other alternative treatments
- Any temporary or permanent symptom that may occur after the surgery
- I have delivered the additional surgery-related descriptive information the patient if any

2. I have left sufficient time to allow the patient to ask questions related to the surgery and have answered the questions too:

(1) _____

(2) _____

(3) _____

Signature of the Physician Responsible for the Surgery:

Date:

Time: ____ (h) ____ (m)

III. Statement of Patient

1. The physician has explained to me and made me fully understand the information relevant to necessity, steps, risk and success rate of the surgery.
2. The physician has explained to me and made me fully understand the risks of other alternative treatments.
3. The physician has explained to me and made me fully understand the possible prognosis of the surgery and the risk of not implementing the surgery.

4. I've understood blood transfusion may be necessary during the surgery; **I agree disagree with blood transfusion.**

(Except for an emergent case as specified in Article 63 of the Medical Care Act.)

1. I have put up my questions and doubts regarding my condition, the surgery and treatment etc. and received replies.
2. I understand in case it is necessary to incise an organ or tissue during the surgery, the organ or tissue may be kept for a period of time in the hospital for the purpose of pathological analysis and report and the organ or tissue will be disposed discreetly as per relevant laws and regulations by the hospital.
3. I understand the surgery may be the most appropriate option at present but it cannot be ensured that the surgery would improve my condition definitely.

I agree with implementation of the surgery based on the statement above.

Signature of the Consenter:

Relation with the Patient: _____

Tel: (0) _____

Address:

Date: _____

Time: ____ (h) ____ (m)

Signature of the Witness:
unnecessary, Signature:

Witness is

Date: _____

Time: ____ (h) ____ (m)

Remarks: _____

I、General Surgical Risks

1. Except for surgeries with local anesthesia, a small part of lungs may collapse and lose function during a surgery, resulting in an increase of the possibility of chest infection, which may require antibiotics and respiratory therapy.
2. Surgeries except for those with local anesthesia may cause vascular embolization accompanied by pain and swelling in legs. And coagulated blood clots may disperse and enter into lungs, causing a deadly danger; but such situation is not common.
3. Since the heart is under stress during a surgery, a heart disease or stroke may be induced.
4. Medical institutions and medical staff will try their best to provide a treatment and surgery to a patient; but the operation will not be necessarily successful and an accident that may even cause death still might happen.

II、The patient shall sign the field of "Signature of the Consenter" personally; but if the patient is a minor or unable to sign in the field personally, the person provided in Item 2, Article 13 of the Medical Care Act shall sign in the field <The Civil Law provides: an adult is a person whose age is 20 or above.>.

III、In case the consenter is not the patient, the relation between the consenter and the patient shall be filled in the field of "Relation with the Patient".

IV、As for the witness, the field may be left blank when there isn't any witness; but the box in front of "Witness is unnecessary" should be ticked and the person who ticks the box should leave a signature.

V、**Any medical activity relevant to a plastic or cosmetic surgery that is not necessary medically must not be executed for minors under the age of eighteen in accordance with Item 4.1 of Article 28, Physicians Act of Republic of China, Taiwan.** ◦

Description of Craniofacial Plastic and Reconstructive Surgery (Template)

The description explains conditions of concerned patients and the purpose, method, benefit, possible complications, success rate and alternatives of craniofacial plastic and reconstructive surgery (hereinafter referred to as CPRS), possible problems during recovery and possible consequences without implementing the surgery, which can be used as reference for discussions between patients and physicians. Please discuss with your physician if you still have any doubt after the physician gives his/her explanation before you sign on the consent.

I 、 Patient's Conditions:

The surgery is used to treat craniofacial abnormalities as following commonly:

1. Mandibular protrusion (commonly known as hopper-type jaw): mandibular protrusion is clinically the most common dentofacial anomaly. Serious dentofacial anomaly may keep the front row of upper teeth from contact with the front row of lower teeth, cause malocclusion and affect the patient's appearance and clarity of articulation.
2. Double-jaw protrusion (commonly known as bucktooth): the patient's teeth are prone to exposure, upper and lower lip close incompletely during relaxation, too much part of the gingivium may be exposed during smile and the jaw seems small and retrusive; so the patient has to close his/her lips tightly to prevent exposure of teeth, making the patient's expression seem serious.
3. Maxillary retrusion: mandibular prognathism always is complicated with minor maxillary retrusion. And simple and severe maxillary retrusion is often found in patients with cleft and some congenital craniofacial deformity, mainly caused by poor development of upper jaw. Occlusal conditions of maxillary retrusion are similar to that of mandibular protrusion and sunken nose is apparent in terms of appearance for such patients.
4. Mandibular retrusion: such conditions is often found in patients with double-jaw protrusion. Jaw looks small and short and the whole face is short in terms of appearance for such patients. Mandibular retrusion is complicated with anterior open bite and commonly both jaws need surgical treatments so as to reconstruct a normal face for such patients. Some patients also are affected a problem of temporomandibular joint and the serious one may cause stenosis of respiratory tract, snoring and even obstructive sleep apnea syndrome.
5. Maxillary/ Mandible Asymmetry: facial bones and dental midline incline to the underdeveloped side and affect facial contour, symmetry and occlusal surface due to inconsistent maxillary/ mandible development.

II 、 Purpose & Benefit:

Correction of relative maxillary/ mandible position. The surgery is most commonly used in treating the occlusion problem that cannot be improved with straightening of teeth simply due to some skeletal abnormality. CPRS can move the bones and teeth together to the most ideal position.

III 、 Method:

The following procedures may be implemented individually or jointly. A orthodontist will formulate a surgical program and a craniofacial surgeon will implement the surgery after they have discussed and reached a consensus with the patient.

1. In order to modify the relative position of maxilla/ mandible, maxilla and/or mandible will be sawn

and repositioned after being adjusted to the proper position depending on the specific conditions.

Common procedures of CPRS include:

- 1) Bilateral Sagittal Split Osteotomy (BSSO): a sagittal split is made to the mandible ramus to readjust its position and mini titanium nails will be used for fixation. The mandible may be moved (turned) for adjustment of occlusion and facial contour.
 - 2) LeFort I: the maxilla is cut open horizontally and fixed with mini titanium nails after its position is adjusted. Facial length and teeth position can be modified by moving the maxilla.
 - 3) Wassmund: it is an osteotomy for the front end of maxilla. Generally the first premolar of maxilla will be taken out at first; next some bone of the distema and bone of maxilla will be ground to allow the front teeth to move backwards.
 - 4) Kole: it is an osteotomy for the front end of mandible. Similar to Wassmund, the first premolar may be removed to move the front teeth backward.
 - 5) Osseous Genioplasty: the position of jaw will be changed after adjustment of position of maxilla/ mandible. And osseous genioplasty may be used to move the jaw forward or backward and adjust its length.
2. Tooth Extraction: in general, premolars or molars may be extracted during CPRS.
- 1) Extraction of premolar teeth generally is adopted for the purpose of Wassmund and Kole. Since premolar teeth are transitional teeth between anterior teeth (incisors, canines) and posterior teeth (molars); extraction of premolars will not affect the masticatory function.
 - 2) Extraction of wisdom teeth: wisdom teeth of almost 60% - 70% of persons need to be extracted due to insufficient space or incorrect tooth position no matter whether they would accept the a cranial plastic and reconstruction surgery. Wisdom teeth will be extracted in order to prevent mutual interference between wisdom teeth and the foregoing surgery (e.g. a metal bone nail that is knocked into a wisdom tooth or a wisdom tooth that may sink into the bone after the surgery cannot be taken out). Intraoperative removal of wisdom teeth during a cranial plastic and reconstruction surgery can reduce the number of anaesthesia and surgery for a patient.

IV 、 Expected Benefits:

Improvement of maxillary/ mandibular protrusion, retrusion and asymmetry complicated with bucktooth, hopper-type jaw and malocclusion due to some congenital factor, trauma or skeletal development. At the same time, as CPRS may move bones and teeth together to the most ideal position and make relative positions and symmetry of lip, tongue and face normal; related functions of the jaw and oropharynx may be improved and facial contour may be significantly improved. CPRS can also be used to treat severe obstructive sleep apnea and improve sleep respiratory disturbance caused by airway stenosis.

V 、 Possible Complications, Probability of Sequelae and Treatments (including but not limited to the following):

1. Risk of General Anesthesia:

- 1) The commonly used classification of anesthetic risk is defined on the basis of classification of physical condition as recommended by the American Society of Anesthesiologists. According to the definitions provided in 2001, the mortality rate during surgery is about 0.08% for Class I (normal healthy patients).
- 2) Hypotensive anesthesia with high-degree difficulty of implementation often is used to reduce intraoperative blood loss as it will take a long time to finish CPRS. In order to decrease unexpected risks during general anesthesia, a preoperative visit for anesthesia must be schedule

for all patients so as to allow the the anesthesiologist to assess the patients' physical status and confirm the classification of anesthetic risk. In case a patient is suffering from any systemic disease or dysfunction, he/she must inform his/her physician of such condition.

2. Intraoperative blood loss: CPRS may cause significant bleeding for structures of head and neck have rich blood circulations. The volume of intraoperative blood loss (depending on different operative sites and methods) is generally about hundreds of milliliters or more than 1,000 ml. In addition to adoption of hypotensive anesthesia for reducing intraoperative blood loss, preoperative blood donation can be taken into consideration in advance so as to execute an intraoperative autologous blood transfusion if necessary.
3. Injury of inferior alveolar nerve :
 - 1) As the nerve is located in the site where BSSO may be implemented; it is impossible to avoid injury of the nerve completely. If rupture of the inferior alveolar nerve is found and may be restored during the surgery, a microsurgery may be adopted to suture the nerve.
 - 2) According to a clinical follow-up made by our hospital, ____% of patients may suffer from paralysis of inferior alveolar nerve after the surgery, among whom ____% of patients may recover within 6 months, the remaining patients may continue to recover or cannot recover completely. Inferior alveolar nerve is responsible for the sensation of lower lip, lower face and bottom row of teeth; so impaired function of the nerve will lead to dysaesthesia or imperception; but facial appearance and expression will not be affected by the impairment.
4. Unexpected bone fracture (incidence rate is 1% around):
 - 1) The incision of upper/ lower jaw bone should be kept away from nerves, teeth roots and other structures; but sometimes fracture may happen to an unusual position of upper/ lower jaw bone due to individual anatomical structure and nature of the bone, which is called as "unexpected fracture".
 - 2) If unexpected fracture will not affect the operation at all or may be fixed with bone nail; then the surgery can be performed as planned. If the fracture cannot be restored and may affect the surgery (incidence rate less than 1%); a steel wire will be used to fix the upper/ lower jaw after the surgery. So the patient will be unable to open his/ her mouth for 4 to 6 weeks and can only take completely liquid food after the surgery and the removal of trachea cannula will be extended to postoperative day 1 or 2. Application of bone nails in fixation of unexpected fractures may leave a wound on cheeks of patients, which generally is no more than 1 cm long.
5. Facial nerve injury (incidence rate less than 0.1%): according to medical records, such injury may occur in patients who have accepted BSSO. A temporary facial neural paralysis may recover slowly in 3 months. In case of a permanent neural injury, patients whose facial expressions still deform due to facial neural paralysis in 6 - 12 months after the surgery may need another surgery for treatment.
6. Optic nerve injury (incidence rate less than 0.02%): according to relevant medical records, such injury may occur in patients who have accepted LeFort I. Partial sight of patients with temporary optic neural paralysis may recover slowly in 6 months. But a permanent optic nerve injury may result in ablepsia.
7. Ischemia and necrosis of bone: such symptom is caused by poor blood circulation due to osteotomy (incidence rate less than 0.02%). If there is any sign of bone necrosis and still chance to restore the bone, the patient may need a hospitalization to accept medication or hyperbaric oxygen treatment. In the event that the bone is totally necrotic; a surgery is required to take any sequestrum out and a

subsequent CPRS may be needed too.

8. Fracture or loosening of a tooth, root damage, falling of a fixed denture or dental braces: since CPRS is conducted in the oral cavity; it is unavoidable that teeth and appendages are damaged or loose during the process; but surgeons will minimize the damage to teeth and avoid leaving any falling foreign body in the wound.
9. Postoperative residual facial asymmetry or centerline offset: the incidence depends on individual conditions and mostly occurs in patients with original maxillary/ mandible asymmetry. In some cases, the differences between the left and right face are more apparent due to skeletal shape and asymmetric position when upper and lower teeth are aligned, which requires a balance between dental midline and facial symmetry to achieve both functional and aesthetic satisfaction. Many patients with seemingly simple bucktooth or hopper-type jaw have minor facial asymmetry actually, which may be more obvious after the surgery. The judgment on midline and symmetry may be affected by factors such as intubation and tissue swelling during the surgery. In addition, the postoperative position of temporomandibular joint may be different that when the surgery is conducted as muscles are completely relaxed during general anesthesia, which may cause postoperative facial contour is deviated from inoperative judgment.

VI 、 Success Rate:

Success rate of a craniofacial plastic and reconstructive surgery is about more than ____%. It is not successful for some patients due to postoperative skeletal misalignment or teeth correction and such patients need to accept a reoperation to achieve the ideal occlusion and appearance.

VII 、 Alternatives:

1. Orthodontic Treatment: a simple orthodontic treatment can change positions of teeth and surrounding alveolar bones; but the bones that can be modified in the treatment are only limited to those around the roots; so this approach is not applicable for serious malocclusion and cannot change misaligned occlusal surface with less effect on facial appearance.
2. Bone Contouring: the procedure can be used to improve problems of facial contour including square jaw or high malar; but it cannot change malocclusion.
3. Implantation of artificial bone: in a few cases (such as simple maxillary /mandibular retrusion without apparent abnormal occlusion), an artificial bone may be implanted to achieve the effect similar to that of bone moving.

VIII 、 Risk without Medical Procedure:

The main purpose of craniofacial plastic and reconstructive surgery is to improve occlusion and facial appearance; so it is not a necessary procedure for treating some kind of disease. The patient should evaluate the risk and benefit of the surgery discreetly so as to decide whether to accept the surgery. Most physicians will tell patients the alternatives to CPRS cannot achieve the expected result. Some patients may need CPRS due to obstructive sleep apnea syndrome as sleep-disordered breathing may result in a poor mental state and distraction even affect work performance and personal safety of the patients when it is serious.

IX 、 Possible problems during postoperative recovery period:

1. Please immediately notify the medical staff for examination if there is an obvious bleeding, pain and swelling at the wound or the patient is in a fever or feel chest pain and tightness, shortness of breath, heart palpitation or dizziness or shock.
2. The patient must have someone to accompany when he/she leaves his/her sick bed for the first time

after the surgery.

3. As the main wound of CPRS is inside the oral cavity; oral cavity should be cleaned to prevent infection based on instructions of the nursing staff.
4. The patient must swallow food without chewing in 4 to 6 weeks after the surgery and try to avoid any pressure on the upper/lower jaw before the bones heal completely, which may cause displacement of upper/lower jaw.
5. The following adverse effects and complications may occur in some patients who have accepted CPRS:
 - 1) Facial swelling: is generally most evident in postoperative day 2 to day 3 will improve significantly in a week. Swelling may be alleviated by ice compress and raising bedhead after the operation. Commonly it will take 3 months to deswell completely.
 - 2) Postoperative bleeding and wound hematoma: if the swelling continues to increase in a short period of time; it may be caused postoperative wound bleeding, which can be stopped with ice compress and moderate pressure. In case the bleeding continues; it may be necessary to carry out a surgery to stop bleeding; and if volume of heme is too low, it may be necessary to provide a blood transfusion to the patient. Postoperative hematoma may occur in a very few patients in several weeks after the surgery.
 - 3) Bone bone healing: bone healing requires a good fixation and poor bone healing may be caused by infection or loosening. Therefore, the patient must avoid severe activity, external impact and wound infection after the surgery. If the postoperative follow-up indicates that bone healing is unsatisfactory; a surgery may be needed to fix both ends of the bone concerned.
 - 4) Wound infection : because surgical incisions are inside the oral cavity; the wounds belong to the clean-contaminated wound. There is still a probability of wound infection less than 10% according to relevant reports of Centers for Disease Control and Prevention of U.S.. The possibility of infection may be reduced by keeping oral hygiene, correct wound cares, regular life style and quitting unhealthy habits after the surgery. Generally treatment for postoperative infection requires follow-ups at clinic and taking antibiotics. Pus in the wound needs to be abstracted or incision and drainage are needed in some cases. A very few patients may need to be hospitalized for administration with antibiotics or a surgical debridement.
 - 5) Bruise of skin around lips and oral cavity: because most of the surgical procedure is carried out inside the mouth; surgical devices may cause superficial damage to surrounding skin, which will usually heal in 1 to 2 weeks and will not leave any scar.
 - 6) Hypoesthesia of lower lip and skin at chin and gingival numbness: temporary paralysis including postoperative gingival numbness and hypoesthesia of lower lip and skin at chin may be caused by shock and pulling during the surgery even if no inferior alveolar nerves are injured. Generally it will take 3 to 6 months to recover. And in case a patient cannot recover from the symptoms, he/she will adapt to them in 1 or 2 years generally.
 - 7) Hypoesthesia of skin at cheeks: as the site of a maxillary surgery is very close to inferior orbital nerves; the surgery may cause a temporary paralysis that can affect facial sensation of the patient. Commonly such symptom will disappear completely.
 - 8) Slurred speech: CPRS will move positions of upper/ lower jaw bones and turn the relatively abnormal relation between tongue and teeth to a normal one. So the patient has to readjust his/ her way of speech plus some gingival abnormal sensation, causing some slurred speeches. But

articulacy of the patient commonly will be improved after the surgery when the patient adapts to his/ her new way of speech.

- 9) Exposure of bone nail/ plate: a fixer inside a bone is exposed due to wound infection or poor healing and a surgery is needed to remove the fixer.
- 10) Facial soft tissue prolapse: when a bone is removed or retracted; its support to facial tissue will reduce accordingly, resulting in facial tissue prolapse. And such case may occur in older patients or patients with significant changes of skeletal position or insufficient skin elasticity. A further plastic surgery such as fat transplantation may be needed to improve the situation.
- 11) Change of facial contour is complicated with relevant psychological and social adaptation problems: CPRS will bring an obvious facial change to the patient. If families, relatives and friends of the patient can not get used to and recognize the patient's new face soon, they may cause some psychological pressure and social adaptation problems to the patient. And such situation will be more serious if the patient is old with a long-time social experience and complicated interpersonal relationships. Therefore the patient should have sufficient discussions with his/ her physician and good communications with his/ her families and make psychological preparations and constructions fully to reduce unnecessary disturbances.
- 12) Strong nasal sound when speaking: such case may occur in a patient who has the defect of gnathoschisis. Such patient may have too strong nasal sounds when speaking after accepting a maxillary antedisplacement surgery since the distance between his/her soft palate and throat is too wide plus original insufficient strength of relevant muscles, resulting velopharyngeal incompetence. Some patients may recover from the situation; some may need linguistic assessment and treatment and even some may need a surgical treatment.
- 13) Gingival atrophy, tooth discoloration and other oral lesions: some abnormality of teeth and peripheral structure may happen to a few patients after the surgery. The reason is yet not clear and no prevention has been found, even it hasn't been confirmed whether such abnormality is a direct result of CPRS.
- 14) Symptoms of temporomandibular joint: often can be seen in patients with serious mandible retrusion. In order to move the lower jaw forward as far as possible, the patients have to use mandibular condyles as the support, which may cause a temporomandibular joint discomfort or bone absorption for a long time.
- 15) Recurrence: refers to the bones of which positions have been changed returned to their original positions probably due to loose bone nails before bone healing, bone deformation and effect of surrounding muscles and soft tissues etc..

X 、 Supplementary Description:

1. Because relative position of the teeth will change along with modification of positions of upper/lower jaw bones; the surgeon of CPRS must closely cooperate with an orthodontist to ensure to adjust occlusion accurately to a desirable position and create an aesthetic faicial appearance at the same time.
2. If a patient accept such surgery for the purpose of improving his/her occlusion or facial contour; he/she will have to bear all relevant operation expenses by himself/herself as CPRS is not covered by National Health Insurance (NHI) of Taiwan. If a patient needs CPRS due to some congenital disease, cleft lip and palate, maxillary/ mandible deformity or underdevelopment caused by a trauma etc. and meets concerned regulations of NHI; NHI may help you and bear part of costs of the treatment.

3. The patient may use some self-paid medical materials depending on the actual situation during the surgery. And the surgeon will explain possible situations and recommend proper medical materials to families of the patient. A consent to adoption of self-paid medical materials will be signed if families of the patient agree with such adoption.

XI 、 Literatures:

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10. L.J.Lo,K.F.Hung,and Y.R.Chen,'Blindness as a Complication of Le Fort I Osteotomy for Maxillary Distraction',Plast Reconstr Surg,109 (2002), 688-98; discussion 99-700.
11. W.D.Owens,'American Society of Anesthesiologists Physical Status Classification System in Not a Risk Classification System',Anesthesiology,

XII 、 Questions from the Patient and Her Family:

- (1) _____
- (2) _____
- (3) _____

Patient (or Family/ Legal Representative): _____(Signature & Seal)

- I have understood the description stated above and agree to accept the craniofacial plastic and reconstructive surgery (please sign on the Consent to Craniofacial Plastic And Reconstructive Surgery).
- I have understood the description stated above and disagree to accept the craniofacial plastic and reconstructive surgery.

Relation with the Patient: _____(Required)

Physician for Explanation: _____(Signature & Seal)

Date & Time: