

DISEASES of the CHEST

VOLUME XXIX

JANUARY 1956

NUMBER 1

Direct Vision Intracardiac Surgery in Man Using a Simple, Disposable Artificial Oxygenator

C. WALTON LILLEHEI, M.D., RICHARD A. DEWALL, M.D.,
RAYMOND C. READ, M.D., HERBERT E. WARDEN, M.D.
and RICHARD L. VARCO, M.D.
Minneapolis, Minnesota

It has been long recognized that the successful curative treatment of certain congenital malformations and acquired diseases of the heart in man would require an effective method for performing reparative surgery in the open heart under direct vision.

The advent of controlled cross circulation as a successful method for totally by-passing the heart and lungs in man^{1, 2} has removed the barrier to intracardiac corrective surgery for many of these congenital defects of the heart heretofore considered inoperable or subjects for palliative procedures only. The malformations which have been successfully corrected by open cardiectomy during the interval while the heart and lungs were totally by-passed using a donor circulation are: ventricular septal defects, atrioventricularis communis, isolated infundibular pulmonic stenosis, tetralogy of Fallot, and pentalogy of Fallot defects.^{3, 4}

The ability to carry out definitive reparative procedures inside the human heart under direct vision and at a reasonable risk, promises the early development of curative surgery for other congenital cardiac conditions at present still incurable. Moreover, the scope of expansion both necessary and likely in this field of open heart surgery is impressive. It has been estimated⁵ that 50,000 infants are born in the United States each year with congenital heart malformations and since more than one-half of these have components to their defects which will require total by-pass of the heart if they are to be cured, it is evident that a sizable new field of surgical endeavor is in the making. This is not to ignore the additional thousands who have acquired defects of the coronary arteries or cardiac valves of types which are not now curable by existing surgical techniques not involving temporary heart by-pass.

The magnitude of these demands emphasizes the need for techniques widely applicable to the maintenance of the patient's circulation during that interval while his heart and lungs are totally by-passed. The essence

From the Department of Surgery and Variety Club Heart Hospital, University of Minnesota Medical School, Minneapolis, Minnesota.

This research has been supported by the following contributions and grants: (1) Paul Mathieu Fund, (2) Graduate School of the University of Minnesota, (3) Minnesota Heart Association, (4) Life Insurance Medical Research Fund and (5) National Heart Institute, U.S.P.H.S. (Grant No. 830).

of wide applicability is simplicity combined with effectiveness. An important dividend of simplicity is safety. These criteria have received sustained emphasis in our investigative work.

For short intervals, simple mechanical pumps of several types are capable of effectively substituting for this function of the heart. The obstacles to success in this field have been due to the apparent intricacies of developing an efficient arterialization of the venous blood by an artificial or extracorporeal oxygenator which does not irreparably damage the

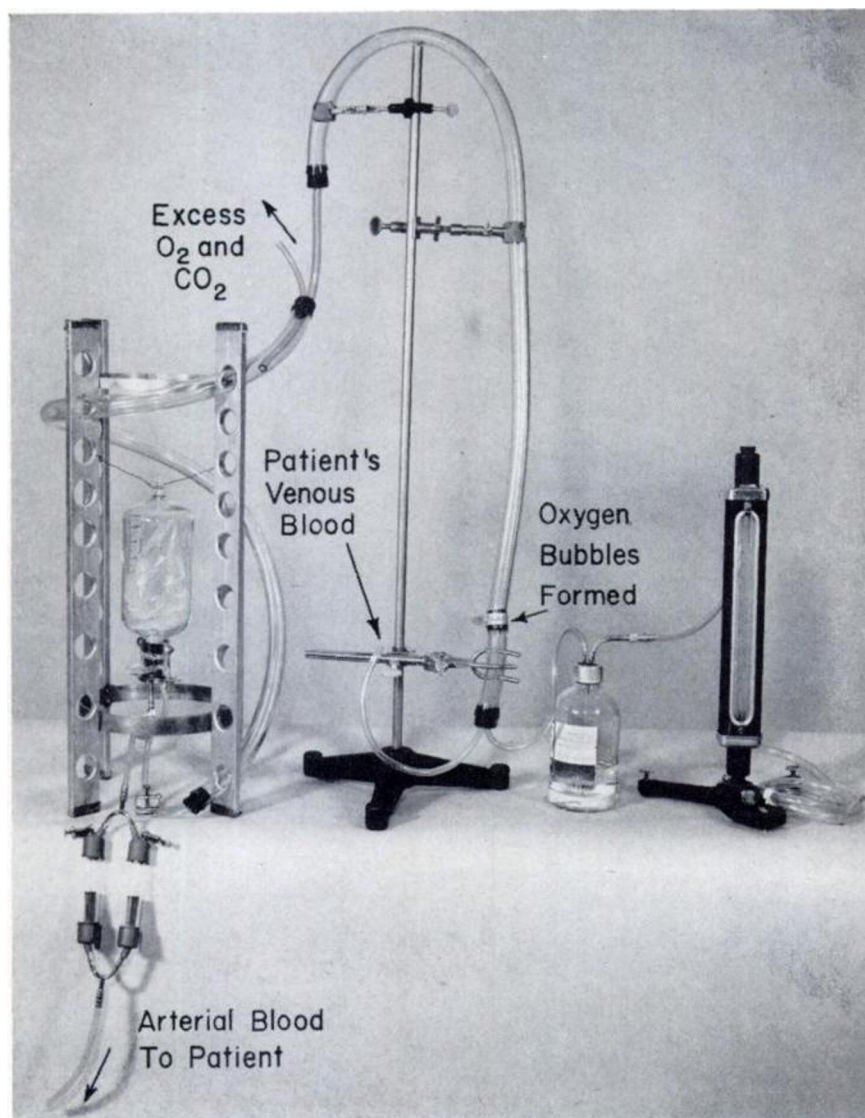


FIGURE 1: The extracorporeal oxygenator utilized for the operative procedures herein reported. From left to right may be noted: the oxygen flow meter (Fisher-Porter), oxygen humidifier, the vertical mixing tube emptying into the spiral settling tube, and the central reservoir from which the blood is perfused through filters to the patient's arterial system.

blood, particularly its clotting mechanisms. The simple oxygenator herein described serves as temporary replacement for the human lungs, and appears to be a significant step forward in the fulfillment of this concept of wide applicability by demonstrating not only the possibility but also the effectiveness of the principle of arterialization of venous blood by the direct introduction of oxygen.

For these operative procedures, this oxygenator was used in combination with the same pump† previously described for use in controlled cross circulation.³ The low flow principle,^{1,4} previously emphasized, has been an important adjunct here also to the successes obtained.

The extensive experimental investigations involved in the development of this oxygenator have been described elsewhere.⁷ The oxygenator (Figure 1) has no moving parts, is assembled entirely from commercially available plastic (pure polyvinyl) food hose,* and is sterilized by autoclaving. Because of its simplicity and the fact that the total cost of the component parts is less than five dollars, we have preferred to dispose of it after each clinical case rather than to clean and reuse it. The utilization of plastic is believed important since experimentally it has been found that extensive contact of blood with glass surfaces has deleterious effects upon its clotting mechanisms.

Oxygenation of the venous blood occurs by the direct introduction of 100 per cent oxygen in the form of large bubbles in the vertical plastic tube (mixing tube). The bubbles are obtained by allowing the oxygen to enter the blood near the base of the mixing tube through 18 number 22 standard intravenous needles (with their nub cut off) which have been inserted circumferentially through an ordinary rubber laboratory stopper. The blood-oxygen contact at the surface of these bubbles as they rise in the column of venous blood circulating through the mixing tube presents the large surface area necessary for efficient oxygen uptake and carbon dioxide elimination without the intervention of a foreign substance for filming. The bubbles are then largely dissipated by momentary contact with a potent non-toxic silicone antifoam substance** sprayed or painted on the distal (U shaped) portion of the walls of the mixing tube and the smaller plastic connecting tube.

Any remaining bubbles, because of their relatively large size, rapidly rise to the surface and are eliminated carrying off the carbon dioxide as well as the blood descends by gravity flow in the plastic settling tube (in the form of a helix). From the settling tube the now arterialized blood enters into the central collecting reservoir (an ordinary Kelly flask lined by a polyethylene bag) from which it is perfused through the patient. The oxygenated blood leaving the central reservoir is filtered through standard blood filters.***

During the interval from May 13 to August 9, 1955 there were seven patients, all seriously ill, operated upon by this method for the correction

†Sigmamotor Co., Model T-6S, Middleport, New York.

*Mayon Plastics, Inc., Minneapolis, Minnesota. The plastic tubing used was $\frac{3}{4}$ " I.D. with a $\frac{1}{8}$ " wall.

**Antifoam A, Dow Corning Co., Midland, Michigan.

***Baxter Laboratories, Morton Grove, Illinois, Filter R-19.

of their cardiac septal defects. There have been five successes and two deaths in this series of patients as summarized in Table I. All of the survivors have been discharged from the hospital as normal children cured of their heart defects.

For these operative procedures the patients were heparinized with $1\frac{1}{2}$ mgs. per kilogram of body weight. Heparinized blood (18 mg. heparin mixed with 50 cc. five per cent glucose for each 500 cc. of fresh blood) was used for replacement of the patient's losses during operation. The operative techniques utilized have been described previously.¹⁻⁴

The flow of arterial blood from the pump-oxygenator system during the interval of total heart lung by-pass varied from 172 cc. per minute (D. C.) to 600 cc. per minute (J.N.W.). The patient's plasma hemoglobin levels drawn immediately after perfusion varied from 17 to 45 milligrams per cent.

TABLE I
REPARATIVE SURGERY IN THE OPEN HEART UTILIZING THE SIMPLE,
DISPOSABLE ARTIFICIAL OXYGENATOR

Patient	Weight (kg.)	Defect	Direct Vision Intracardiac Procedures	Duration Open Cardiomy (Min.)	Result
1. J.R. 3 yrs.	9.9	Ventricular septal defect, pulmonary hypertension (70/42), and endocardial fibroelastosis	Ventricular cardiomy, suture closure of septal defect*	17 $\frac{1}{4}$	Died 18 hours postoperatively
2. J.W. 21 mos.	10.5	Tetralogy of Fallot, daily anoxic convulsions	Ventricular cardiomy, suture closure of septal defect*, resection of infundibular stenosis	18	Living and Well
3. M.D. 2 yrs.	8.0	Atrial septal defect, pulmonary hypertension (75/30)	Atrial cardiomy, suture closure of septal defect, exploratory ventricular cardiomy	17 $\frac{1}{2}$	Living and Well
4. L.B.** 19 mos.	10.0	Ventricular septal defect, pulmonary hypertension (83/54)	Ventricular cardiomy, suture closure of septal defect	8 $\frac{1}{2}$	Living and Well
5. D.B. 4 yrs.	13.0	Ventricular septal defect, pulmonary hypertension (78/34)	Ventricular cardiomy, suture closure of septal defect	13 $\frac{1}{2}$	Living and Well
6. D.C. 19 mos.	5.3	Ventricular septal defect, pulmonary hypertension (62/35)	Ventricular cardiomy, suture closure of septal defect*	13 $\frac{3}{4}$	Died, 4 days postoperatively
7. J.N.W. 7 yrs.	19.0	Ventricular septal defect, pulmonary hypertension (80/50), cardiac arrhythmia	Ventricular cardiomy, suture closure of septal defect	12	Living and Well

() = The preoperative pulmonary arterial pressures in millimeters mercury.

* Closure stitches tied over a pledget of polyvinyl sponge.

** A plication of the pulmonary artery performed elsewhere at the age of seven months had been unsuccessful in preventing the progression of the pulmonary hypertension.

In patient two the preoperative femoral artery oxygen saturation was 44 per cent. The postoperative value is 92 per cent (Van Slyke analyses).

All seven patients awakened immediately postoperatively, and there was no evidence of neurologic, hepatic, or renal impairment of even a temporary nature. Likewise, there was no abnormal volume of hemorrhage observed in the postoperative interval.

Autopsies were performed in both patients who succumbed, and in each there was a convincing anatomic explanation for the death. At the time of autopsy the ventricular defects were found to be completely and correctly closed in both. Patient 1 (J.R.) had an associated severe endocardial fibroelastosis of the left ventricular muscle, and patient 6 (D.C.) had upon microscopic examination of the lungs widespread and advanced proliferative intimal arteriolar vascular lesions. In neither instance does this cause of death appear to be related in any way to the pump-oxygenator used.

Subsequent and continuing laboratory experiments with higher flow rates have not disclosed any problems concerned with increasing the output of this simple oxygenator sufficiently to supply the needs of adult patients.

Addendum:

To date, a total of 36 patients have had their hearts and lungs totally bypassed for periods of up to 50 minutes utilizing this simple pump-oxygenator system herein described. All of the patients have had a cardiectomy into one or more of their heart chambers for performance of direct vision reparative surgery. These patients have varied in age from 16 weeks to 21 years. Twenty-five patients have had curative surgery for ventricular septal defects associated with pulmonary hypertension with seven deaths. Six patients with the tetralogy of Fallot defects have had corrective surgery with two deaths. The remaining five patients have had direct vision intracardiac corrective surgery for atrial septal defect, atrioventricularis communis, or complete transposition of the great vessels. There has been no late mortality in any of these patients.

The last 19 consecutive intracardiac curative operations, all carried out in seriously ill patients with ventricular septal defects or tetralogy of Fallot, have been performed with only two deaths. This evidence of the efficacy of this simple oxygenator has resulted in its superseding completely the use of the human cross circulation donor for oxygenation which previously had set the standards in our clinic for safety and effectiveness because of its physiologic superbness.

SUMMARY

The successful curative treatment of many congenital malformations and acquired diseases of the heart requires an effective method for performing reparative surgery in the open heart under direct vision. The advent of controlled cross circulation as a successful method for totally by-passing the heart and lungs has demonstrated that intracardiac corrective surgery is both possible and feasible for certain of these congenital defects heretofore considered inoperable. This ability to carry out definitive reparative procedures inside the human heart under direct vision and at a reasonable risk has promised the early development of curative surgery for other congenital cardiac conditions as well as acquired diseases of the valves or coronary arteries which are not now curable by existing surgical techniques. The magnitude of these potential demands emphasizes the need for widely applicable techniques for maintenance of the patient's circulation during the by-pass interval. The essence of wide applicability is simplicity combined with effectiveness. The simple disposable artificial oxygenator herein described serves as a temporary replacement for the

human lungs and appears to be a significant step forward in the fulfillment of these concepts of safety and wide applicability.

This oxygenator has no moving parts, is assembled entirely from commercially available plastic tubing, and is sterilized by autoclaving. Oxygenation of the venous blood occurs by direct introduction of oxygen with coincident elimination of carbon dioxide. Because of its simplicity and the fact that the total cost of the component parts is only a few dollars, we have preferred to dispose of the oxygenator after each clinical use rather than to clean and re-use it.

Seven seriously ill children have had intracardiac corrective operations utilizing this artificial oxygenator in combination with a simple pump for total by-pass of the heart and lungs. There were five successes and two deaths in this series of patients. All of the five survivors have been discharged from the hospital as normal children cured of their heart defects. Their preoperative malformations included ventricular septal defects, tetralogy of Fallot, and atrial septal defect with pulmonary hypertension.

RESUMEN

El tratamiento curativo satisfactorio de muchas malformaciones congénitas del corazón así como de enfermedades adquiridas del mismo, requiere un procedimiento efectivo para realizar la cirugía reparativa en el corazón abierto a la vista directamente.

El advenimiento de la circulación desviada controlada como método que hace posible dejar de lado el corazón y los pulmones ha demostrado que es factible la cirugía correctora intracardiaca para estos defectos hasta ahora considerados inoperables.

Esta posibilidad de la cirugía cardiaca a cielo abierto con un riesgo razonable, promete el pronto desarrollo de la cirugía curativa para otras afecciones cardiacas congénitas así como adquiridas de las válvulas o de las coronarias que no son por ahora curables. La magnitud de estas demandas potenciales destaca la necesidad de técnicas de aplicación amplia para mantener la circulación durante la fase de desviación.

La esencia de la aplicabilidad extensa consiste en la sencillez combinada con efectividad. El oxigenador sencillo aquí descrito sirve para la substitución temporal de los pulmones humanos y parece que es un paso significativo hacia adelante hacia esos requerimientos de seguridad y de eficacia.

Este oxigenador no tiene partes móviles, está hecho enteramente con tubos plásticos comerciales y es esterilizado al autoclave. La oxigenación de la sangre venosa se logra por la introducción directa de oxígeno coincidiendo con la eliminación del anhídrido carbónico. Por su sencillez y por el hecho de que el costo total de las partes componentes es sólo de pocos dólares, hemos preferido descartar el oxigenador después de cada uso en lugar de limpiarlo y volverlo a usar.

Siete niños seriamente enfermos han pasado cirugía intracardiaca correctiva utilizando este oxigenador artificial en combinación con una bomba simple para la desviación circulatoria completa del corazón y de los pul-

mones. Hubo cinco resultados satisfactorios y dos muertes en esta serie. Los cinco supervivientes se han dado de alta en el hospital como normales y curados de sus defectos cardiacos. Las malformaciones preoperatorias incluían defectos septales ventriculares, tetralogía de Fallot, y defectos septales atriales con hipertensión pulmonar.

RESUME

Pour obtenir un traitement curatif satisfaisant dans beaucoup de malformations congénitales et d'affections acquises du coeur, il est nécessaire qu'une méthode efficace permette la chirurgie réparatrice sur le coeur ouvert sous vision directe. La circulation croisée contrôlée permet d'isoler le coeur et le poumon. Ainsi a pu être démontrée la possibilité de la chirurgie intracardiaque curative dans certaines de ces anomalies congénitales auparavant considérées comme inopérables. Cette possibilité de mener à bien des procédés réparateurs à l'intérieur du coeur humain sous vision directe et moyennant un risque raisonnable, a permis le développement précoce d'une chirurgie capable de traiter les autres états cardiaques congénitaux, ainsi que les maladies acquises des valvules ou des artères coronaires, qui n'étaient pas curables avec les techniques connues jusqu'alors. L'emploi de ces possibilités augmentent la nécessité de techniques applicables sur une large échelle qui permettent de maintenir la circulation du malade durant le temps de l'intervention. Les principes d'une telle application sont la simplicité combinée à l'efficacité. Le simple dispositif d'oxygénateur artificiel décrit sert à remplacer temporairement les poumons humains et semble avoir permis un pas décisif dans l'application étendue et sans risque de ces conceptions.

Cet oxygénateur ne comprend aucune partie mobile. Il est assemblé entièrement avec des tubes plastiques que l'on peut trouver dans le commerce, et peut être stérilisé à l'autoclave. L'oxygénation du sang veineux se produit par introduction directe d'oxygène avec élimination simultanée de dioxyde de carbone. Etant donné sa simplicité et le fait que le coût total des parties qui le composent n'est que de quelques dollars, les auteurs préfèrent jeter l'oxygénateur après chaque emploi plutôt que de le nettoyer et de le réemployer.

Sept enfants gravement atteints ont subi des opérations correctives intracardiaques grâce à cet appareil en combinaison avec une simple pompe pour permettre l'exclusion totale du coeur et des poumons. Il y eut cinq succès et deux morts dans ce groupe de malades. Tous les survivants sont sortis de l'Hôpital comme des enfants normalement guéris de leurs malformations cardiaques. Il s'agissait de malformations ventriculaires septales, d'une tétralogie de Fallot, d'une malformation septale de l'oreillette avec hypertension pulmonaire.

ZUSAMMENFASSUNG

Die erfolgreiche curative Behandlung vieler angeborener Fehlbildungen und erworbener Krankheiten des Herzens verlangt eine wirksame Methode zur Durchführung reparativer Eingriffe am offenen Herzen unter direkter Sicht. Das Aufkommen eines Kreislaufes überkreuz unter Kontrolle als eines erfolgreichen Verfahrens zur völligen Umgehung von Herz und Lunge hat bewiesen, dass intracardiale korrigierende Eingriffe möglich

und durchführbar sind für bestimmte dieser bisher als inoperabel bezeichneten angeborenen Fehler. Diese Möglichkeit zur Vornahme von endgültigen Wiederherstellungs-Massnahmen im Inneren des menschlichen Herzens unter direkter Sicht und mit verantwortbarem Risiko hat die Erwartung erweckt auf eine frühzeitige Entwicklung von curativen Operationen sowohl bei anderen angeborenen Herzleiden als auch bei erworbenen Klappenfehlern oder Erkrankungen der Coronar-Arterien, die bisher mit den bestehenden chirurgischen Techniken nicht zu heilen waren. Das Ausmass dieser möglichen Anforderungen verdeutlicht die Notwendigkeit eine allgemein anwendbaren Technik, um den Blutkreislauf des Patienten während des Umgehungs-Intervalls aufrecht zu erhalten. Das Wesen einer allgemeinen Anwendbarkeit ist Einfachheit in Verbindung mit Wirksamkeit. Der einfach zu gebrauchende, hier beschriebene künstliche Sauerstoffsättiger dient als zeitweiliger Ersatz für die menschliche Lunge und erscheint als ein bedeutender Schritt vorwärts in der Erfüllung dieser Planungen von Sicherheit und allgemeiner Anwendbarkeit.

Dieser Sauerstoffsättiger hat keine sich bewegenden Teile, ist ganz zusammengesetzt aus im Handel zur Verfügung stehendem plastischen Röhrenmaterial und wird im Autoklaven sterilisiert. Die Sauerstoffsättigung des venösen Blutes erfolgt durch direkte Einführung von Sauerstoff mit gleichzeitiger Ausscheidung von Kohlensäure. Wegen seiner Einfachheit und der Tatsache, dass die gesamten Kosten der Bestandteile nur wenige Dollar betragen, haben wir es vorgezogen, eher den Sauerstoffsättiger nach jeder Benutzung in der Klinik zu vernichten, als ihn zu reinigen und wieder zu benutzen.

7 schwerkranke Kinder wurden mit intracardialen Korrektur-Operationen behandelt unter Benutzung dieses künstlichen Sauerstoffsättigers in Verbindung mit einer einfachen Pumpe zur völligen Umgehung von Herz und Lunge. In dieser Gruppe von Patienten verliefen 5 erfolgreich und 2 endeten tödlich. Alle 5 Überlebenden wurden als normale Kinder aus dem Krankenhaus entlassen mit Heilung ihres Herzleidens. Ihre pre-operativen Missbildungen waren Kammerseptum-Defekte, Fallot'sche Tetralogie und Vorhofsseptum-Defekt mit Lungenhochdruck.

REFERENCES

- 1 Warden, H. E., Cohen, M., Read, R. C. and Lillehei, C. W.: "Controlled Cross Circulation for Open Intracardiac Surgery," *J. Thoracic Surg.*, 28:331, 1954.
- 2 Lillehei, C. W.: "Controlled Cross Circulation for Direct-Vision Intracardiac Surgery: Correction of Ventricular Septal Defects, Atrioventricularis Communis, and Tetralogy," *Postgrad. Med.*, 17:388, 1955.
- 3 Lillehei, C. W., Cohen, M., Warden, H. E. and Varco, R. L.: "The Direct-Vision Intracardiac Correction of Congenital Anomalies by Controlled Cross Circulation: Results in Thirty-Two Patients with Ventricular Septal Defects, Tetralogy of Fallot, and Atrioventricularis Communis Defects," *Surgery*, 38:11, 1955.
- 4 Lillehei, C. W., Cohen, M., Warden, H. E., Read, R. C., Aust, J. B., DeWall, R. A. and Varco, R. L.: "Direct Vision Intracardiac Surgical Correction of the Tetralogy of Fallot, Pentalogy of Fallot, and Pulmonary Atresia Defects: A Report of the First Ten Cases," *Ann. Surg.*, 142:418, 1955.
- 5 Lillehei, C. W., Baronofsky, I. D. and Varco, R. L.: "The Surgical Treatment of Congenital Heart Disease: Analysis of the Results in 388 Cases," *Bull. Univ. Minn. Hosp. and Minn. Med. Found.*, 24:75, 1952.
- 6 DeWall, R. A., Read, R. C., Warden, H. E., Gott, V., Varco, R. L. and Lillehei, C. W.: "A Simple, Disposable, Artificial Oxygenator for Use in Intracardiac Surgery," *Surgery*, submitted for publication.