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Production of 3D-Printed Ribs with a Novel Material (Nylon 680 Co-Polymer) for Chest Wall Reconstruction on a Pig Model: Preliminary Results of an Experimental Study

Domuzlarda Göğüs Duvarı Rekonstrüksiyonu için 3D Printer ile Kaburga Üretimi: Yeni Bir Malzeme (Nylon 680 Co-Polymer) Deneysel Çalışmanın Preliminer Sonuçları

Nezih Onur ERMERAK[1], Mustafa YÜKSEL[2], Barış YÜKSEL[3], Tunç LAÇİN[1], İpek ERBARUT SEVEN[4], Berna KARAKOYUN[5]

[1]*Marmara University Faculty of Medicine, Department of Thoracic Surgery, İstanbul, Turkey*
[2]*Bilim Demiroğlu University Faculty of Medicine, Department of Thoracic Surgery, İstanbul, Turkey*
[3]*Google Company, Department of Computer Engineering, New York, USA*
[4]*Marmara University Faculty of Medicine, Department of Medical Pathology, İstanbul, Turkey*
[5]*University of Health Sciences Turkey, Hamidiye Faculty of Medicine, Department of Physiology, İstanbul, Turkey*

ABSTRACT

Aim: Three-dimensional (3D) printing has gained popularity among all fields of science in recent years. New research studies about the utilization of 3D printing in the medical field, in terms of medical devices and implants, have been published recently. We tried to adapt this technology into thoracic surgery by implanting 3D produced ribs following chest wall resection with a novel material called Nylon 680 Co-Polymer. We, hereby, present the preliminary results of this experimental study.

Materials and Methods: We ordered multi detector computerized tomography of the chest for 2 pigs. We measured the area that we planned to resect on chest wall and used the data for printing custom-made rib for the reconstruction of the resected area. Then, we produced ribs with a USA Food and Drug Administration approved material called Nylon 680 Co-polymer (Taulman 3D, Saint Peters, MO, USA) by using 3D printer (Afinia H480, Chanhassen, MO, USA). Pigs were operated under general anesthesia and the resected areas were reconstructed with custom-made 3D printed ribs.

Results: One of the pigs passed away due to myocardial infarction while waking up from anesthesia. We followed up the other pig for 45 days. Then, we sacrificed the animal and resected the operated part for histopathological evaluation. Histopathologic evaluation revealed moderate chronic inflammation with few giant cells containing pigmented foreign bodies.

Conclusion: Although we need more studies, it is an important step for adapting 3D-printing into thoracic surgery. Additionally, it is important to identify a potential new material (Nylon 680 Co-polymer) for the future studies. We can use this new material for 3D-printed implant and mesh production, which enables us to produce custom-made products with lower cost in shorter time.

Keywords: 3D printing, thoracic surgery, Nylon 680 Co-polymer, chest wall resection and reconstruction, novel technology

ÖZ

Amaç: Üç boyutlu (3D) baskı son yıllarda tüm bilim dalları arasında popülerlik kazanmıştır. 3D yazıcılarda kullanılabilen Nylon 680 Co-polymer adlı yeni bir malzeme ile kaburga üreterek, domuzlarda göğüs duvarı rekonstrüksiyonu için kullanmayı amaçladık. Bu yeni malzeme ile gerçekleştirilen deneysel çalışmanın ön sonuçlarını sunmaktayız.

Gereç ve Yöntem: Göğüs duvarında rezeke etmeyi planladığımız iki domuza çok kesitli bilgisayarlı toraks tomografisi çektirerek rezeke edeceğimiz alanı ölçtük. ABD Gıda ve İlaç Dairesi onaylı Nylon 680 Co-Polymer (Taulman 3D, Saint Peters, MO, ABD) ile 3D yazıcı kullanarak kaburgalar

Address for Correspondence: Nezih Onur ERMERAK MD, Marmara University Faculty of Medicine, Department of Thoracic Surgery, İstanbul, Turkey
Phone: +90 533 714 14 63 **E-mail:** onur.ermerak@marmara.edu.tr **ORCID ID:** orcid.org/0000-0003-1939-3222
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ürettik (Afinia H480, Chanhassen, MO, ABD). Denekleri opere ederek göğüs duvarı rezeksiyonu sonrası yeni üretilmiş kaburgalar ile göğüs duvarı rekonstrüksiyonu gerçekleştirdik.

Bulgular: Deneklerden bir tanesi anesteziden uyanırken miyokard enfarktüsü nedeniyle kaybedildi. Diğer domuz 45 gün boyunca, deney hayvanları için barınak olan merkezde 45 gün boyunca takip edildi. Sonrasında sakrifiye edildi ve opere edilmiş olan alan histopatolojik inceleme için rezeke edildi. Histopatolojik değerlendirme, pigmente yabancı cisimler içeren dev hücreler ve orta derecede kronik enflamasyon olarak yorumlandı.

Sonuç: Bu çalışma 3D yazıcı teknolojisinin göğüs cerrahisi alanında kullanımı açısından önemlidir. Ayrıca yeni bir malzeme olan Nylon 680 Co-polymer'in tanımlanması yeni bir çalışma alanı oluşturmaktadır. Bu yeni malzeme ile hastalara özel tasarlanmış implantlar veya meşler kısa süre içinde üretilebildiği gibi çok daha ucuza mal edilebileceği ön görülmektedir.

Anahtar Kelimeler: 3D baskı, göğüs cerrahisi, Nylon 680 Co-polymer, göğüs duvarı rezeksiyon ve rekonstrüksiyonu, yeni teknoloji

INTRODUCTION

Three-dimensional (3D) printing has gained popularity among all fields of science in recent years[1-4]. New research studies about the utilization of 3D printing in medical field in terms of medical devices and implants for the body have been published recently. 3D printing gained attraction also in pharmaceutical field, illustrated by USA Food and Drug Administration (FDA) approval of 3D-printed drug product in August 2015. Owais et al.[5] produced mitral annulus by 3D printing using echocardiographic data and experienced the potential use in cardiac surgeries. Thawani et al.[6] presented a 3D-printed model of arteriovenous malformation and demonstrated arterial and venous phases separately. Moreover, in orthopedic field, use of this technology in the aspect of surgical view is getting much more popular. Zhang et al.[7] constructed a 3D-printable, bioceramic articular spacer assembly and used it in arthroplasty surgeries. In addition, Mulford et al.[8] published a review article for defining current and future applications used in orthopedic surgery.

Surgical management of chest wall defects after oncological resection is a common situation in thoracic surgery. Management of this entity requires creativity and flexibility. The material used for the reconstruction of the chest wall can vary from mesh, methyl methacrylate to prosthetic systems like titanium plates or bars[9-11].

We tried to adapt this technology into thoracic surgery by using Nylon 680 Co-polymer, which is a novel material with lower cost.

MATERIALS AND METHODS

The research was reviewed and approved by Acıbadem University Local Ethics Committee for Animal Experiments (ACU-HADYEK), İstanbul, Turkey (decision no: 2015/17, date: 02.03.2015). This research supported by the Scientific and Technological Research Council of Turkey (TUBITAK-115S797).

All animals received care formulated by the National Society for Medical Research and the Guide for the Care and Use of Laboratory Animals prepared by National Academy of Sciences and published by the National Institutes of Health, NIH publication no. 80-23, revised 1985.

The mean body weight of two male domestic pigs was 32.5 kg and the mean body surface was 1.02 m^2. Multidetector computerized tomography (MDCT) scans of the thorax were performed and 3D reconstruction images were developed for better evaluation (Figure 1). We planned to perform 5 cm incisions in the midaxillary line and 5 cm partial resection of the 5^{th} ribs (Figure 2). Measurements of the resection were made by using MDCT and all data were transferred to AutoCAD software system (Autodesk, Inc. California, USA). All mesh models were produced by AutoCAD.

We used the data for printing custom-made rib for replacing the resected part. We produced ribs in different size with Nylon 680 Co-polymer/FDA approved material (Taulman 3D, Saint Peters, MO, USA) by using 3D Printer (Afinia H480, Chanhassen, MO, USA). The 3D-printed implants were sterilized with ethylene oxide.

Pigs were operated at Acibadem University Center of Advanced Simulation and Education (CASE) Laboratories, İstanbul, Turkey. General anesthesia was induced with intravenous ketamine (1 mg/kg per body weight) and propofol (4.0 mg/kg per body weight), and was maintained by volatile anesthetics (isoflurane 1.5-2.5%). The animals were equipped with a femoral arterial catheter and rectal probe for hemodynamic, thermal monitoring and five-lead electrocardiogram.

We made a 5 cm incision in the midaxillary line and performed 5 cm rib resection for both animals. 3D-printed custom-made Nylon 680 Co-polymer rib was implanted into the resected area and stabilized with 2-0 polypropylene sutures on both margins. We checked the rib for stabilization and closed the anatomical structures according to proper anatomical manner.

Animals were wakened up from anesthesia and weaned off the mechanical ventilator. One of the animals passed away during the wakening up period due to a possible myocardial infarction. Second animal recovered uneventfully.

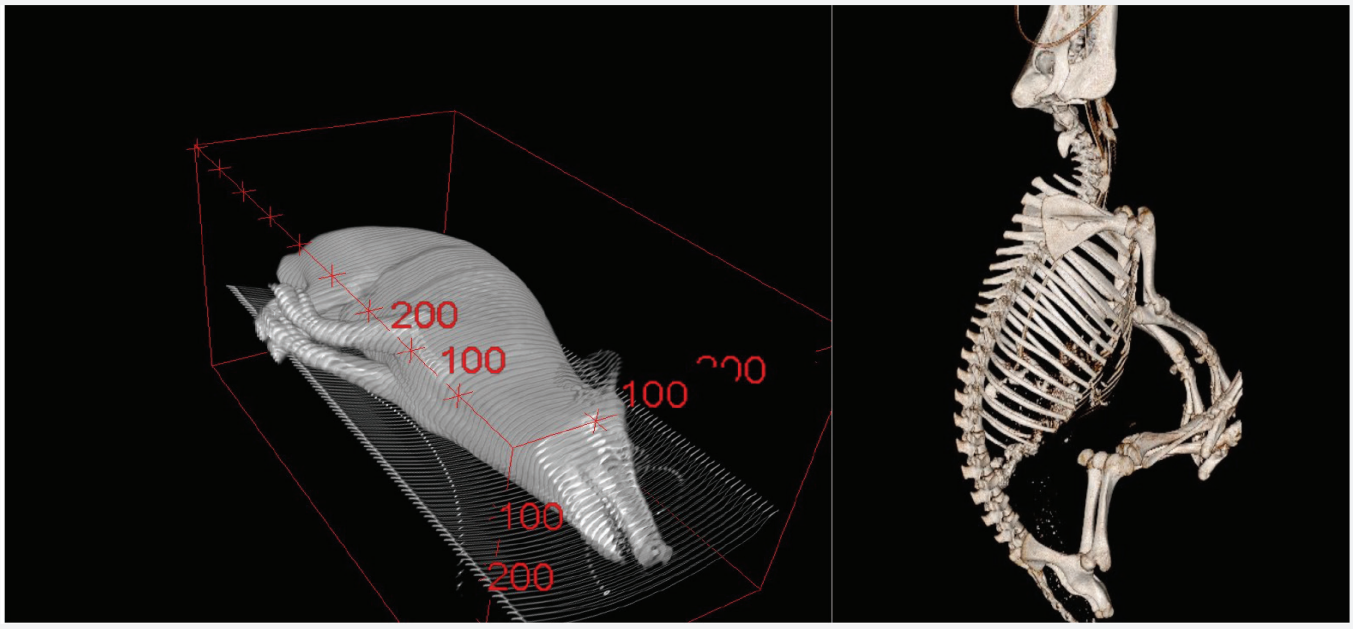

Figure 1. Multidetector computerized tomography scans and 3D reconstructed images of the animal before reconstruction
3D: Three-dimensional

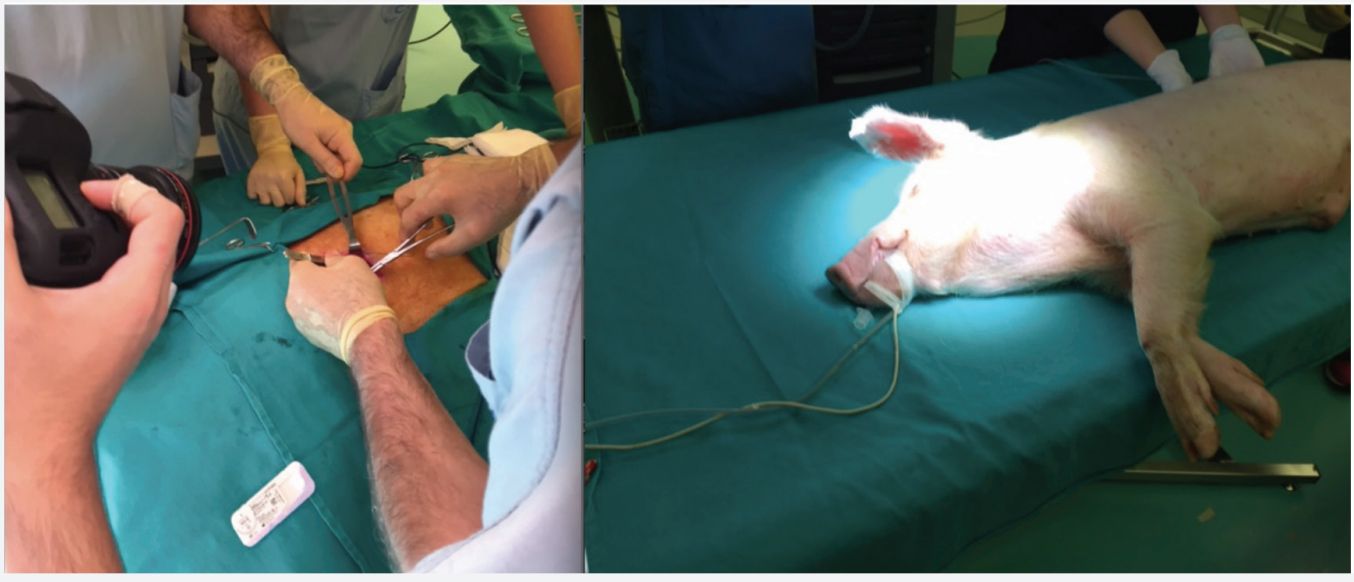

Figure 2. Procedure was performed under general anesthesia with a 5 cm incision

RESULTS

The animal received care for 45 days. He was followed up every day by one of the members from the research team. General condition, weight and appetite of the animal were recorded daily on regular basis. The pig was sacrificed on the 45th postoperative day and operated chest wall was resected totally. Specimen was delivered to the Marmara University Department of Pathology for histopathologic evaluation.

Tissue samples of implanted area were fixed in 10% formalin and processed for paraffin embedding. Sections of 4-5 µm thickness were processed for microscope slides. Slides were stained with hematoxylin and eosin. Histopathologic evaluation

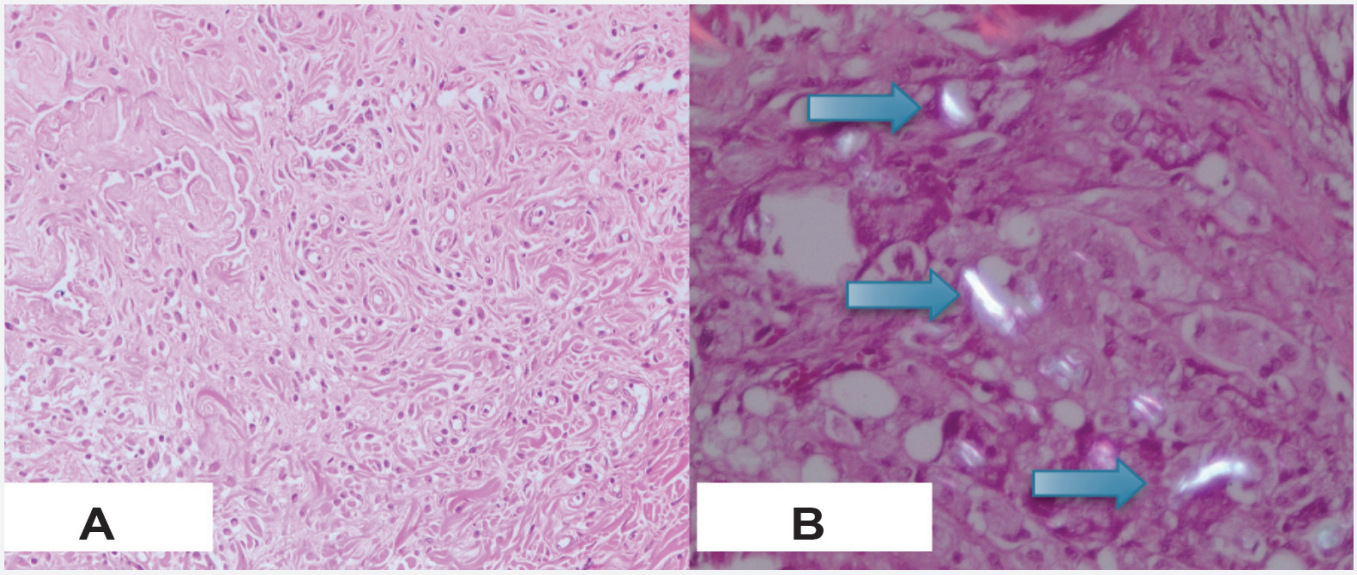

Figure 3. Histopathological evaluation showed moderate chronic inflammation with few giant cells containing pigmented foreign bodies. A) Chronic inflammation. B) Giant cells with pigmented foreign bodies in polarized light (blue arrow)

revealed moderate chronic inflammation with scattered giant cells. In polarized light, a few giant cells containing foreign bodies were observed (Figure 3).

One cartridge of Nylon-Co polymer weighs almost one kilogram, and it costs only 30 USD. Although total expense depends on the size of the implant, it is much more affordable than the regular implants produced with existing materials.

DISCUSSION

3D printing is a novel technology, and it is getting more involved in every scientific field each day. It is very important to adapt this technology in all fields of medicine. Especially in surgical branches, it is a valuable prospect in terms of medical devices, implants, and retractors. Couple of studies were published regarding the usage of 3D printing in thoracic surgery. Kurenov et al.[12] published their data about 3D-printed pulmonary artery models for patients receiving regional lung chemotherapy. They declared that 3D rapid prototyping allowed the replication of sophisticated anatomical structures that could be used to facilitate anatomic study, surgical planning, and device development. Biglino et al.[13] published an article about experimental cardiovascular modeling by 3D printing with a new rubber-like material for compliant arterial phantoms for in vitro studies and device testing. 3D-printed models save time in surgery planning as much as two thirds and help visualize complex pre-operative anatomical structures[14]. In thoracic surgery, 3D printing is being used to assess the invasion of vital structures by tumors and to assist in diagnosis and treatment of upper and lower airway diseases[15-17]. This technology provides a great opportunity to new technological developments and could be a game-changer in the surgical field[18]. By this technology, we can produce any kind of devices within the limits of our creativity. We can produce different types of custom-made surgical materials by ourselves with low cost in shorter time. Although we need more studies, this research is an important step for adapting 3D printing into thoracic surgery.

Study Limitations

Sample size is one of the limitations of the study. We need more studies with larger sample size to move into next steps. We did not compare the histopathologic results with the control group operated with the standard approved implants used in chest wall reconstruction. This is the second limitation of the study, but this study declares the preliminary results. In the light of these data, we can organize studies with larger sample size including control groups. This study is one of the pioneer data declaring the usage of implants with new material directly produced by 3D printing in thoracic surgery field. 3D printing technology is affordable and accessible, which mostly makes it possible to create accurate anatomic models, represents a new tool in thoracic surgery. These advances could aid physicians to personalize treatment approaches, improve surgical techniques, and reduce morbidity and mortality.

CONCLUSION

The application of 3D-printed materials enables precise planning for surgical procedures necessitating reconstruction or replacement. Although there has been progress in application

part of this technology, there are still limited data about the use and identification of new materials providing benefit in cost. We believe that the application of this new material in 3D-printing is going to help us for rapid prototyping with a lower cost for reconstruction in thoracic surgery in the future.

Ethics

Ethics Committee Approval: The study was approved by the Acıbadem University Animal Experiments Local Ethics Committee (ACU-HADYEK), İstanbul, Turkey (decision no: 2015/17, date: 02.03.2015).

Informed Consent: Animal experiment.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: N.O.E., M.Y., Concept: N.O.E., M.Y., B.Y., B.K., Design: N.O.E., M.Y., B.Y., İ.E.S., B.K., Data Collection or Processing: N.O.E., B.Y., İ.E.S., B.K., Analysis or Interpretation: N.O.E., M.Y., B.Y., T.L., İ.E.S., Literature Search: N.O.E., B.Y., Writing: N.O.E., B.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

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