

# Shaping a Flap Using a Bioabsorbable Mold—A Preliminary Report

Akimitsu Nishibayashi, MD,  
PhD\*†  
Koichi Tomita, MD, PhD\*  
Mifue Taminato, MD\*  
Kenji Yano, MD, PhD\*‡  
Ko Hosokawa, MD, PhD\*

**Background:** We previously reported that good surgical outcomes can be obtained with breast mold made by 3-dimensional printing. However, detailed breast shape is often difficult to create. Accordingly, we aimed to determine whether transplanting a flap and bioabsorbable mold in vivo would yield better results by retaining the flap shape inside the mold during the scar formation period.

**Methods:** Vascularized adipose flaps were elevated in the bilateral inguinal region of male Sprague-Dawley rats ( $n = 7$ ). A cone-shaped, bioabsorbable mold (Lacto-Sorb mesh) was created using a template. On the experimental side, the flap was inserted into the mold and fixed. On the control side, a conical flap was created using absorbable sutures, based on a template.

**Results:** The flaps were harvested 3 months postoperatively, and flap volume, base area, and projection were measured with 3-dimensional imaging. Volume and base area on the mold side tended to be smaller than those on the control side ( $P = 0.18$  and  $0.13$ , respectively) and close to the values of the template. In addition, the ratio of projection and base area value was significantly greater on the mold side than on the control side ( $P = 0.04$ ). Histology revealed little inflammatory cell invasion, and scar tissue thickness around the flap showed no significant difference between the 2 groups ( $P = 0.76$ ).

**Conclusions:** This study demonstrated that soft-tissue morphology can be controlled to some extent with a bioabsorbable mold. Its clinical application in breast reconstruction requires further investigation. (*Plast Reconstr Surg Glob Open* 2018;6:e1890; doi: 10.1097/GOX.0000000000001890; Published online 6 August 2018.)

## INTRODUCTION

We have reported good surgical outcomes (left–right symmetry) of a breast mold created using 3-dimensional (3D) imaging and a 3D printer.<sup>1,2</sup> These methods are very useful when deciding the appropriate size of a flap and direction of placement. However, when the flap is buried below the skin during breast reconstruction, detailed breast shape is often difficult to create. Moreover, ingenuity and experience are needed to fix the flaps to the chest wall.

Thus, we considered that transplantation of a flap and bioabsorbable mold into the body would likely yield better results by retaining the flap shape inside the mold during the scar formation period (within 1–2 months postoperatively). This would enable more detailed construction and simplify the procedure for fixing the flap onto the chest wall. We performed a study using rats to evaluate the efficacy and safety of this method for future clinical application of the mold.

From the \*Department of Plastic and Reconstructive Surgery, Graduate School of Medicine, Osaka University, Osaka, Japan; †Department of Plastic and Reconstructive Surgery, Osaka General Medical Center, Osaka, Japan; and ‡Department of Plastic and Reconstructive Surgery, Osaka Breast Clinic, Osaka, Japan.

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## MATERIALS AND METHODS

All animal experiments were approved by the Ethics Review Committee for Animal Experimentation of Osaka University.

### Preparation of Bioabsorbable Mold

An acrylonitrile-butadiene-styrene copolymer template was prepared using a personal 3D printer (MakerBot Replicator 2x, MakerBot Industries, Brooklyn, N.Y.). To simplify the evaluation, the base radius of the template was set at 15 mm and the height at 20 mm, making it conical. With the prepared template as the base, a 0.5-mm thick

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bioabsorbable mesh (LactoSorb, Walter Lorenz Corp Jacksonville, FL, USA) was heated to mold the shape, and a conical bioabsorbable mold was prepared (Fig. 1A).

### Animal Experiments

Male SD rats (200–250 g,  $n = 7$ ) were anesthetized using an intraperitoneal injection of a mixture of midazolam (2 mg/kg), medetomidine (0.15 mg/kg), and butorphanol (2.5 mg/kg). Following a bilateral inguinal incision, vascularized adipose flaps nourished by the superficial circumflex iliac artery were elevated. On the experimental side, the flap was inserted into the mold and fixed with absorbable sutures (Fig. 1B). On the control side, a conical flap was created with absorbable sutures on the basis of a template (Fig. 1B). The wounds were closed in 2 layers.

At 12 weeks postoperatively, animals were killed, and bilateral flaps were harvested. The 3D morphology of the specimens was assessed using a David Structured Light Scanner SLS-1 (David Visions Systems GmbH, Koblenz, Germany). Image data were analyzed using 3D image data analysis software developed specifically for breast reconstruction procedures (Breast-Rugle, Medic Engineering, Kyoto, Japan). The volume, base area, and projection of specimens were evaluated.

### Histomorphometric Analysis

Thinly sliced sections of flap were prepared for hematoxylin–eosin and Masson trichrome stains. To evaluate the degree of scar formation around the flap, the widest area of each sample was sliced, and scar thickness was measured at 5 random sites.

### Statistical Analysis

All data are expressed as means  $\pm$  SD. Differences between the 2 groups were examined for statistical significance using paired Student's *t* tests. Statistical significance was set as  $P < 0.05$ .

## RESULTS

At 3 months postoperatively, when the surgical wound could be assessed, the mold had been completely absorbed in all animals. On both the mold and control sides, the sub-

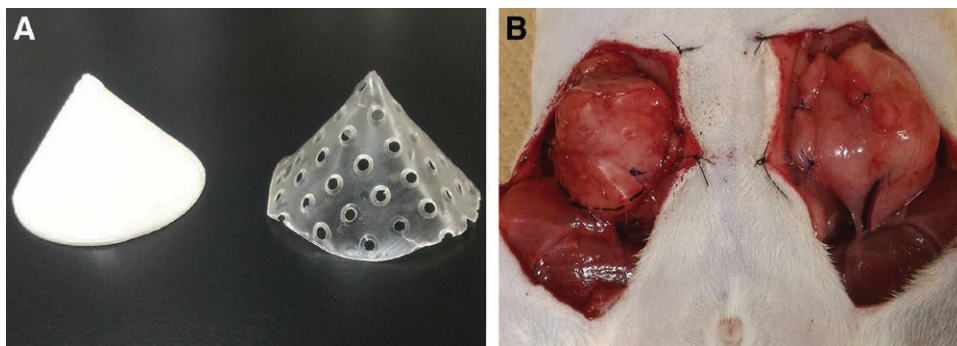
cutaneous adipose flap could be easily identified, regardless of site (Fig. 2). In addition, the adipose flap on the mold side retained softness similar to that on the control side. The sampled flap volume, base area, and projection (the distance from the base of the flap to the highest point) were evaluated. Both the mold and control sides showed larger flap volume and base area regardless of site compared with the template (4.7 cm<sup>3</sup> and 7.1 cm<sup>2</sup>, respectively; Fig. 3A, B). Meanwhile, projection was smaller on both the mold and control sides than on the template (2 cm; Fig. 3C). Comparison between the mold and control sides showed that the flap volume and base area tended to be smaller on the mold side than on the control side ( $P = 0.18$  and  $0.13$ , respectively; Fig. 3A, B). There was no significant difference in projection between the 2 groups ( $P = 0.56$ ; Fig. 3C). Furthermore, evaluation of the ratios of the projection and base area (when the template was assumed to be the breast, the larger the value, the better the shape maintained) showed that the value on the mold side was significantly larger than that on the control side ( $P = 0.04$ ; Fig. 3D).

On histological examination of the isolated specimens, good grafting of the adipose flap was seen in both the mold and control groups, regardless of site; moreover, there was no clear infiltration of inflammatory cells (Fig. 4A, B). In the evaluation of scar tissue thickness around the flap using Masson trichrome stain (Fig. 4C, D), there was no significant difference between the 2 groups ( $P = 0.63$ ; Fig. 5).

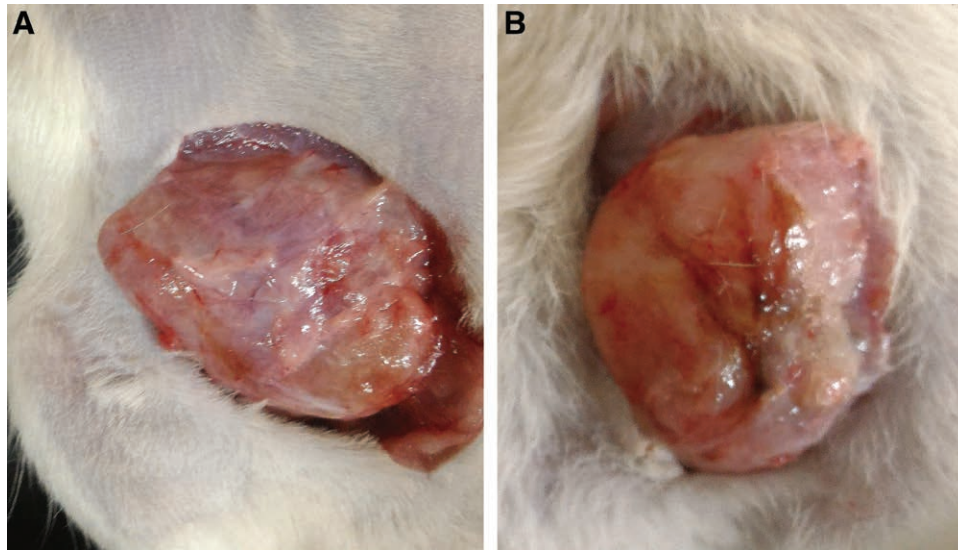
## DISCUSSION

The results of this study showed that transplanting an adipose flap and a bioabsorbable mold inhibited to some extent an increase in flap volume and base area because of weight gain in rats and postoperative compression. This demonstrated that adipose flap shape could be controlled by using a bioabsorbable mold. Moreover, results of histological evaluation indicated that the thick scar formation and hardening of the flap due to inflammatory cell invasion did not occur during the absorption of the bioabsorbable mold, suggesting its safety in clinical application.

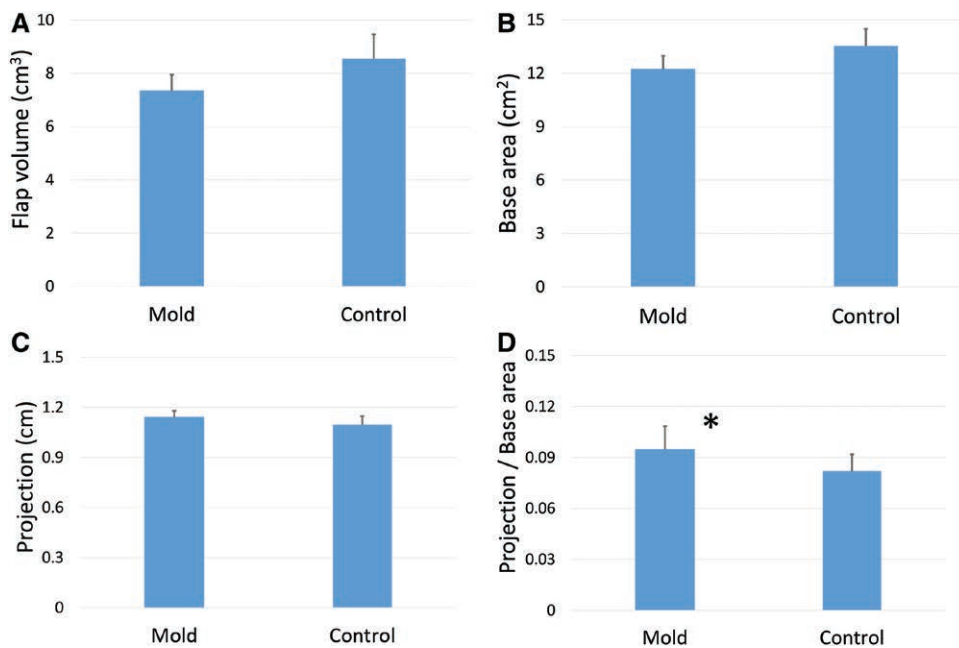
At present, breast shaping in autologous reconstruction, breast reduction, or mastopexy is performed through



**Fig. 1.** Creation of an animal model for flap shaping using a bioabsorbable mold. A, The conical acrylonitrile-butadiene-styrene copolymer template (left, radius, 15 mm; height, 20 mm) is prepared using a personal 3D printer, with the template as base, and a bioabsorbable mold (right) using 0.5-mm thick LactoSorb mesh. B, Photograph of the flaps immediately after molding was completed. The flap was inserted into the mold and fixed with absorbable sutures (left, mold side). The flap was shaped into a cone with absorbable sutures while referring to the template (right, control side).



**Fig. 2.** At 3 months postoperatively, the subcutaneous flap could be confirmed easily on both the mold side (A) and control side (B). The mold was completely absorbed.

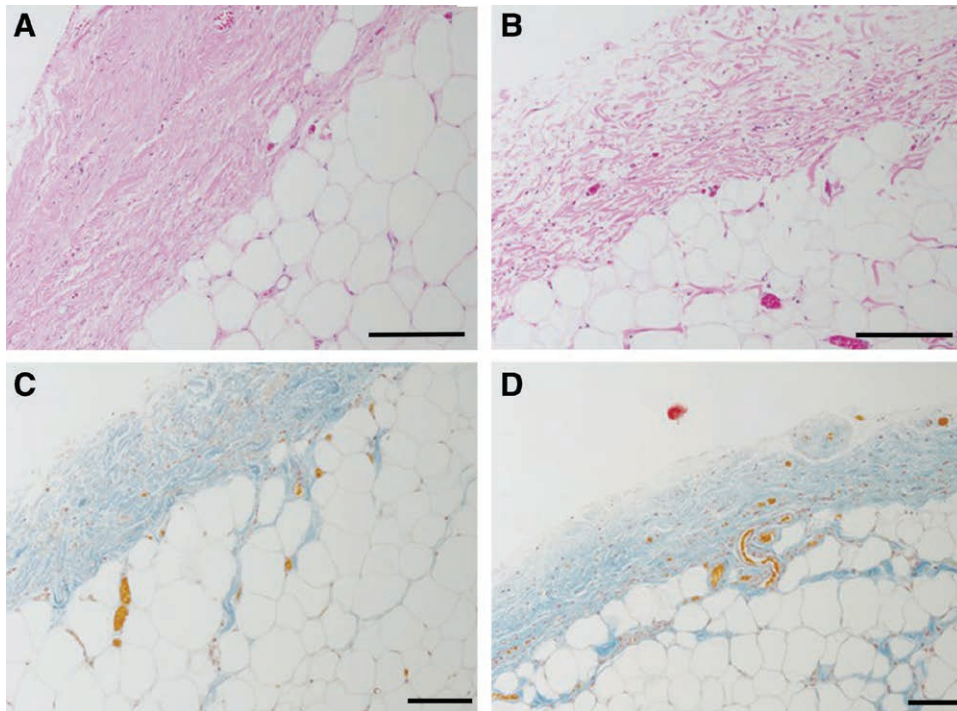


**Fig. 3.** The 3D morphology of the flaps was captured, and image data were analyzed using 3D image data analysis software. Data are expressed as mean ± SD, n = 7. \*Indicates  $P < 0.05$  compared with control.

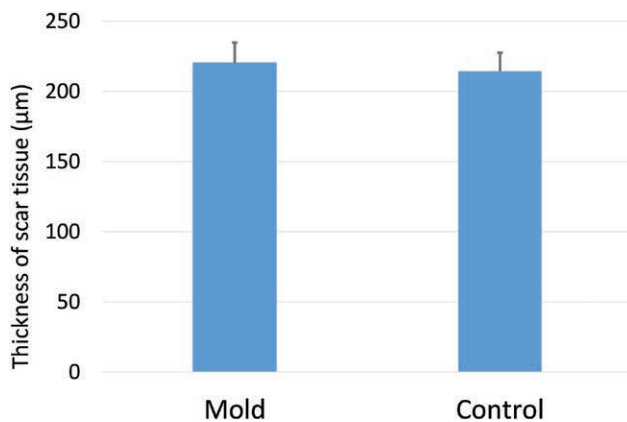
tissue fixation using absorbable or nonabsorbable sutures. Although these surgical outcomes have improved because of the recent advances in 3D imaging technologies and surgical procedures,<sup>1-4</sup> there is a limitation of fixation using sutures (ie, inaccuracy and postoperative slack). The advantages of using the absorbable mold in actual clinical practice are the fact that the flap shape is retained inside the mold during the scar formation, which occurs in approximately 1–2 months postoperatively, and that malposition and drooping of the flap due to inadequate fixation of the flap and postsurgical compression are likely preventable. Moreover, the time and effort needed to fix the

adipose flap to surrounding tissue during surgery can be decreased. On the other hand, retention of flap shape in fine areas by using the mold transplant was not observed in this study. However, in this animal model, compression of the flap was due to continuous stress under conditions that are different from those after actual breast reconstruction. Future investigation is required using animal model sites with some degree of postoperative rest, such as the back.

In addition, we assumed that for clinical application, the bioabsorbable mold will be prepared directly using the 3D printer; therefore, the chemical (hydrophilic character, crystallinity, and so on) and implant (surface/volume ra-



**Fig. 4.** Images of sliced sections of flap at 12 weeks postoperatively. Thin slices of the flaps were prepared for hematoxylin–eosin stain (A, B) and Masson trichrome stains (C, D). A and C: control sides, B and D: mold sides; scale bar: 100  $\mu\text{m}$ .



**Fig. 5.** There was no significant difference in thickness of the scar tissue around the flap between the mold and control sides. Data are expressed as mean  $\pm$  SD,  $n = 5$ .

tio, porosity, and so on) properties of the polymer must be investigated. These properties are predicted to affect the absorption speed of the mold in the body.<sup>5</sup> In breast reconstruction, the mold should remain strong for 1–2 months postoperatively during scar formation, followed by rapid absorption. According to the manufacturer, the LactoSorb (82% poly L-lactic acid and 18% poly glycolic acid) used in this study usually loses its strength in 5 months and disappears in 12 months. However, in this model, it disappeared in 3 months. As the absorption speed of LactoSorb has also been reported to be affected by the surrounding temperature,<sup>5,6</sup> a body temperature of rats, which is higher than that of humans,<sup>7</sup> may affect it. In addition, as site of implantation also influences the degradation of bioabsorbable ma-

terials,<sup>8</sup> absorption speed in the subcutaneous tissue of the chest needs to be taken into consideration.

The limitations of this study are the small sample size and nonoptimal animal model sites with continuous compression.

## CONCLUSIONS

This study demonstrated that soft-tissue morphology can be controlled by using a bioabsorbable mold. Further investigation is necessary to determine its clinical applications in breast reconstruction.

*Koichi Tomita, MD, PhD*

Department of Plastic and Reconstructive Surgery  
Graduate School of Medicine  
Osaka University  
2-2 Yamadaoka Suita, Osaka 565-0871, Japan  
E-mail: ktomita9@hotmail.co.jp

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