Review Article

Current status of pre- or subpectoral breast reconstruction in Japan

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Abstract: Breast reconstruction using silicone breast implants (SBIs) has been performed for many patients in Japan under the initiative of the Japan Oncoplastic Breast Surgery Society (JOBSS) since SBIs were first covered by insurance in 2013. A change in the lineup of available SBIs owing to the Allergan crisis caused a decrease in the availability of SBIs appropriate to Japanese breast contours. Recently, the number of immediate implant-based breast reconstructions (IBRs) was approximately 4,000 in one year and was slightly decreasing. The SBI is generally placed under the pectoralis major muscle. Because the number of patients with one-stage, implant-based operative indications is small, an acellular dermal matrix is not available in Japan, and the complication rate in one-stage, IBR is high, most immediate, IBRs are performed in two stages. The prevalence of immediate, one-stage, IBRs is approximately 10%. Fat grafting by injection using Coleman's technique is performed in many hospitals under the JOBSS initiative as a surgery combined with SBI insertion. Complications after SBI placement may be less common in Japan than those in other countries. Japanese breast reconstructive surgeons undertake preventive measures to lessen these complications according to guidelines and experts' opinions, which may contribute to the low complication rate after SBI placement. The total reported number of patients with breast implant-associated anaplastic large cell lymphoma is four, and no patients have died because of this disease. In Japan, procuring informed consent and diagnosing and treating this disease are performed according to the JOBSS guidelines.

Keywords: Breast reconstruction; breast implant; pectoralis major muscle

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Introduction

The quality of silicone breast implants (SBIs) has improved over time, making them more durable and safer. In addition, the ability to choose from many different types of SBIs, with respect to width, height, projection, shape, hardness, and texture, has made it possible to perform a wide variety of breast reconstructions. Breast reconstruction using SBIs is now routinely performed worldwide and is popular with patients due to its minimal invasiveness.

As breast reconstruction practices vary from country to country, understanding the approaches taken in different regions is vital for the continued development of this procedure. This review offers insights into the global landscape of immediate implant-based breast reconstruction (IBR), with a focus on Japan. It encompasses an overview of current trends, standard surgical techniques and procedures

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performed in combination with them, postoperative complications, and the occurrence and preventive measures of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

Overview of immediate IBR in Japan

In most cases of breast reconstruction worldwide, tissue expanders (TEs) and SBIs are used to improve the quality of life of patients suffering from mammary carcinoma or tumors after mastectomy. In Japan, TEs and SBIs have been covered by insurance since 2013, and breast reconstruction is performed under the initiative of the Japan Oncoplastic Breast Surgery Society (JOBSS) (1). Breast surgeons and plastic surgeons involved in breast reconstruction must acquire their own specialist qualifications by attending a lecture sponsored by the JOBSS. Breast reconstruction using these devices can be performed only in hospitals employing responsible full-time doctors (hospitals certified by the JOBSS). The hospitals certified by the JOBSS must abide by the rules regarding operative indications and methods according to the JOBSS guidelines and report on TEs and SBIs used in each hospital once a year.

I have summarized the operative indications and methods according to the JOBSS guidelines (1). Immediate IBR is indicated for patients with mammary carcinoma whose clinical stage is less than stage 2, without skin or muscle invasion or severe lymph node metastasis, who underwent mastectomy for mammary tumors, hereditary breast and ovarian cancer syndrome, and ovarian carcinoma, including those with a high risk for developing mammary carcinoma. Such reconstruction is not indicated for patients with active infection of the affected breast, local remnant tumor, pregnancy, breastfeeding, poor local circulation, severe wound dehiscence, or severe psychiatric disorder. One-stage IBR is indicated for patients undergoing nipple- or skin-sparing mastectomy with preservation of the pectoralis major muscle and no skin defects, and the SBI should be placed under the pectoralis major muscle. In contrast, two-stage IBR is indicated for patients with preservation of the pectoralis major muscle and a fully expanded pectoral skin envelope, in which case the SBI should also be placed under the pectoralis major muscle. In terms of informed consent before SBI insertion, the guidelines recommend that patients understand that SBIs are not semi-permanent, but may collapse at any time; they may need to undergo removal of a ruptured SBI and replacement with a new SBI or autologous tissue based on the situation, and they may suffer from various complications (infection, capsule contracture, abnormal positioning, and risk for BIA-ALCL). Furthermore, in the stable postoperative period, patients should undergo medical examinations once a year, and the SBI should be examined using magnetic resonance imaging or ultrasonography once every 2 years.

Three SBI manufacturers are currently approved in Japan: Allergan (Dublin, Ireland), Sientra (Irvine, USA), and Motiva (Alajuela, Costa Rica). A smooth, round SBI is produced by Allergan, Sientra, and Motiva, and a microtextured, round or anatomical SBI is also produced by Sientra. For SBI selection, one must consider that capsule contracture occurs less frequently with the textured type than that with the smooth type, whereas the risk for BIA-ALCL is much smaller with the smooth type than that with the textured type (2,3).

Using a round SBI has two disadvantages in view of the Japanese breast contour. First, many patients have breasts of moderate width, moderate height, and small projection; however, the appropriate round SBI is not available for these patients in Japan. Second, many patients have a mild to moderate thickness in the upper pole of the breast; however, that upper-pole fullness is prominent if a round SBI is used in such a patient (4). Therefore, anatomical SBIs are typically a better match for domestic patients than round SBIs. The appropriate anatomical SBI for patients with upper-pole thinness is the oval type (width larger than height); however, only five sizes of oval-type anatomical SBIs are available (210–350 cc). Resolving these problems may be the key to increasing the volume of IBRs.

Trends in immediate IBR in Japan

The annual changes in the number of immediate IBR surgeries in Japan from 2013 (the first year of insurance coverage) to 2022 are shown in *Figure 1A* (5). The number of surgeries increased rapidly to 5,497 by 2018; however, they decreased substantially to 3,483 in 2019. The reason for this is that Allergan performed a voluntary recall worldwide in July 2019 for a problem with BIA-ALCL, the so-called "Allergan crisis". In 2020, new SBIs produced by Allergan and Sientra were covered by insurance; however, the number of surgeries in 2020 decreased owing to the coronavirus disease pandemic (5). Accordingly, the number of SBIs appropriate for Japanese breast contours has further decreased; therefore, the most recent number of IBRs is still lower than that before the Allergan crisis.

The JOBSS has no official data on the ratio of the

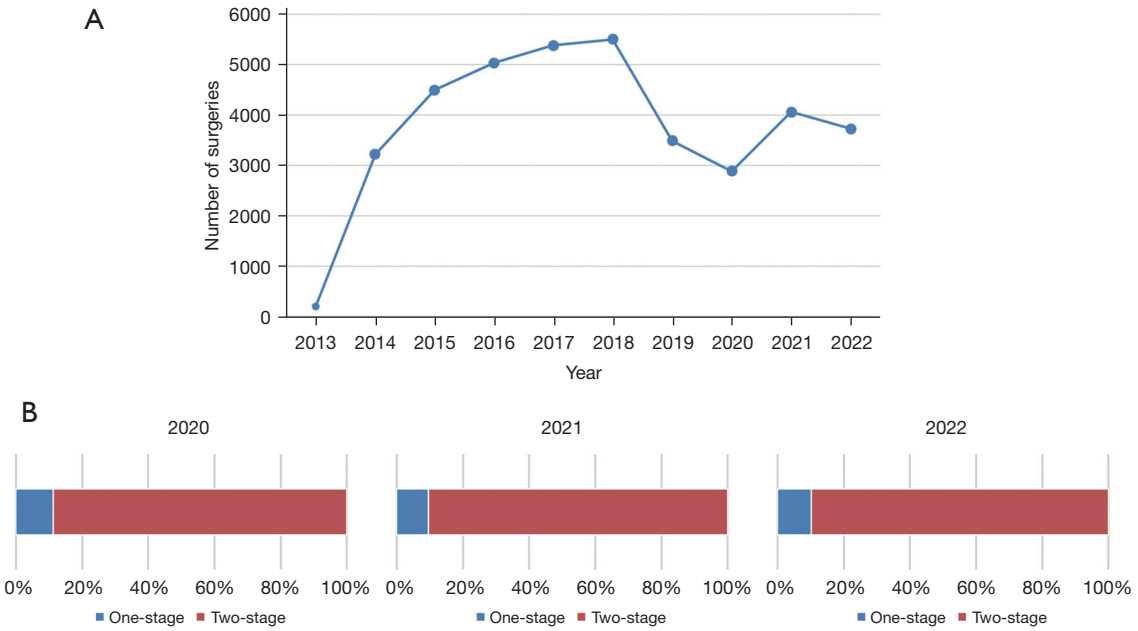

Figure 1 Trends of immediate implant-based breast reconstruction in Japan. (A) Annual change of number of surgeries of immediate implant-based breast reconstruction from 2013 (first year after insurance coverage) to 2022. (B) Comparison of number of surgeries in last 3 years between immediate one-stage and two-stage implant-based breast reconstructions.

number of IBRs to that of autologous tissue-based breast reconstructions in Japan. IBR was privately financed until 2013, and IBR as a percentage of all breast reconstructions was approximately 10%; however, this percentage increased by approximately 50% to 90% soon after SBIs were first covered by insurance (6). Thereafter, this percentage decreased by approximately 20% to 40% because of the Allergan crisis, and subsequently increased by approximately 30% to 70% (6). The annual JOBSS report for 2022 showed that the ratio of insertions of smooth SBIs to that of microtextured SBIs in Japan was about 2:1, and smooth SBIs have been used more than microtextured SBIs since the Allergan crisis (5).

The recent ratio of the number of immediate, one-stage IBRs to that of immediate, two-stage IBRs in Japan is shown in *Figure 1B* (5). This ratio may be lower than that in other countries. Several factors may explain the low number of immediate, one-stage IBRs in Japan. In Japan, simple mastectomy is the main type of mastectomy performed, and a few breast surgeons perform nipple- or skin-sparing mastectomies. This reconstruction is mostly indicated for patients with small, non-ptotic breasts (≤B cup) in Japan; however, such patients often have a low body mass index (BMI), and their mastectomy flaps tend to be thin and poorly vascularized. Furthermore, acellular dermal matrix (ADM) is not available in Japan as it is not covered by insurance, and many breast reconstructive surgeons may suppose that one-stage IBR has a higher complication rate and that satisfactory aesthetic results are difficult to achieve via this procedure.

Standard immediate IBR and its combination with major surgeries in Japan

The standard procedure for immediate, two-stage IBR in Japan is described below. The TE is completely covered by the muscular pocket, including the pectoralis major muscle, serratus anterior fascia or split-thickness muscle, and fascia of the rectus abdominis muscle (7). Thereafter, the lower pole of the affected breast is gradually expanded until the volume of the affected breast is approximately 1.2 times as large as that of the contralateral breast. SBI insertion is generally performed 3 to 6 months after the full expansion. SBIs are usually selected based on the height, width, and projection of the contralateral breast in the sitting or standing position and the weight of the resected tissue during mastectomy. Additionally, they are selected based on the type of mastectomy and the degree of ptosis in the contralateral breast (1,8,9). Manufacturer-produced SBI sizers are used in only a few hospitals because of their

Table 1 Number and incidence of postoperative complications in immediate one-stage and two-stage implant-based breast reconstructions in the last 3 years

Year	Number of surgeries	Infection	Hematoma/bleeding/ seroma	Skin necrosis/wound dehiscence	Capsule contracture/ malposition
2020	2,882	26 (0.9%)	51 (1.7%)	25 (0.8%)	44 (1.5%)
2021	4,055	79 (1.9%)	45 (1.1%)	30 (0.7%)	91 (2.2%)
2022	3,722	48 (1.2%)	39 (1.0%)	29 (0.7%)	41 (1.1%)

Data are presented as number or n (%). The incidence was calculated by truncation.

high cost. During SBI insertion, the TE is removed after capsule incision, and the edge of the capsule is incised and undermined over the entire circumference without capsulectomy. A grillwork incision of the capsule is made, as required. The inframammary fold (IMF) is typically made using the method of Nava *et al.* or the drawstring suture technique (10,11). Finally, the SBI is inserted under the capsule and appropriately set in the sitting position. Skin closure is performed after the insertion of a suction drain.

The standard procedure for immediate, one-stage IBR in Japan remains unclear. The usual method may be as follows: the SBI is inserted under the pectoralis major muscle and serratus anterior fascia or split-thickness muscle, and an IMF is performed using anchoring sutures, as required.

Major surgeries combined with immediate IBR in Japan include flap transfer (local flap and latissimus musculocutaneous or muscle flap), fat grafting, and revision surgery in the contralateral breast. However, as the annual JOBSS report on TEs and SBIs used in each hospital does not include their combination with other surgeries, the number of other surgeries is unknown. Flap transfer is covered by insurance. In contrast, fat grafting and revision surgery for the contralateral breast are not covered by insurance but are actually provided free of charge. Flap transfer is performed in patients with a large contralateral breast or long and thick tissue defects on the cranial side of the affected breast. Latissimus musculocutaneous or muscle flaps are often used (12,13). Fat grafting is performed in patients for whom an SBI appropriate for the contralateral breast contour is not available and for those with long and thin tissue defects on the cranial side of the affected breast (14,15). Fat grafting by injection is widely performed according to the guidelines published by the JOBSS (14). The procedure involves local injection via the tumescent technique, liposuction via an injector, centrifugal separation, and fat injection via Coleman's technique (16). Fat grafting combined with stem cell transplantation or cultured adipose cells is performed only in large hospitals, such as university hospitals. Revision surgery for the contralateral breast is performed in patients with a large or moderate-to-severely ptotic contralateral breast. As for revision surgery in Japan for the contralateral breast, vertical reduction mammaplasty is the most preferred to avoid long scars along the IMF, particularly in patients with large and moderately ptotic breasts (17,18). In addition, classical reduction mammaplasty based on McKissock's method is performed in patients with severely large and ptotic breasts (19), and periareolar mastopexy is performed in patients with mildly large and ptotic breasts (20). Patients in Japan may more commonly decline surgery on the contralateral breast, even if it is ptotic and large, than those in Western countries. Achieving symmetrical breasts in such patients is often challenging.

Trend in postoperative complications after immediate IBR in Japan

Table 1 shows postoperative complications after immediate IBR in Japan in the past 3 years (5). Incidence rates of infection, wound dehiscence, capsule contracture, and malpositioning in Japan are lower than those in other countries, and incidence rates of hematoma and seroma in Japan are similar to those in other countries, although differences between countries, especially smoking habits and BMI, should be considered (21). Japanese breast reconstructive surgeons undertake preventive measures to lessen these incidence rates according to guidelines and experts' opinions (22). For prevention of infection, they routinely wear double layers of surgical gloves, perform sufficient irrigation of pockets with saline and change their surgical gloves before opening the package containing the SBI just before insertion, and perform intravenous administration of antibiotics during the insertion of a suction drain. Surgical salvage treatments for infection

Table 2 Comparison of the incidence of postoperative complications in the last 3 years between immediate one-stage and two-stage implant-based breast reconstructions

Year	Stage	Infection	Hematoma/bleeding/seroma	Skin necrosis/wound dehiscence	Capsule contracture/malposition	Total complications
2020	One-stage	2.7	2.4	4.6	1.8	9.2
	Two-stage	0.6	1.6	0.3	1.4	3.6
2021	One-stage	3.4	1.8	3.6	2.8	9.3
	Two-stage	1.8	1.0	0.4	2.2	4.7
2022	One-stage	3.6	2.0	6.2	3.6	11.8
	Two-stage	1.0	0.9	0.1	0.8	2.7

The incidence was calculated by truncation.

include debridement and curettage of the capsule and, in certain cases, continuous irrigation with intermittent aspiration (23). For prevention of bleeding and hematoma, they routinely perform elaborate hemostasis via coagulation when the patient's blood pressure is 30–40 mmHg higher after administration of vasopressor drug than that when the patient entered the operating room. For prevention of hematoma and seroma, they routinely perform compressive dressing for several days postoperatively and remove the suction drain after the volume of drained fluid is less than 30 mL per day. For prevention of wound dehiscence, they routinely resect all of the thin skin with poor circulation and perform appropriate dermal buried suturing, covering the SBI below the incision line via a muscular pocket. Occurrence of hematoma, seroma, and infection is a risk factor for capsule contracture, which is why these preventive methods are carefully performed. Massage to prevent capsule contracture is not usually performed considering the risk for SBI malpositioning.

The incidence of postoperative complications of immediate, one-stage and immediate, two-stage IBR is shown in *Table 2* (5). As for immediate, one-stage IBR, incidence rates of infection, hematoma, seroma, wound dehiscence, and capsule contracture in Japan are generally lower than those in other countries (24). Regarding immediate, one-stage IBR in Japan, the ratio of cases with prepectoral SBI to cases with subpectoral SBI is unknown. According to the JOBSS guidelines, many breast reconstructive surgeons may insert the SBI under the pectoralis major muscle (1). Nevertheless, in Japan, the incidence of postoperative complications after immediate, one-stage IBR is higher than that after immediate, two-stage IBR. This would be because SBIs may be inserted above the pectoralis major muscle in most cases with postoperative complications of immediate, one-stage IBR. In Japan, many candidates for immediate, one-stage IBR have a low BMI; therefore, their mastectomy flaps tend to be thin. Furthermore, ADM is unavailable in Japan. These factors may increase postoperative complications of immediate, pre-pectoral IBR.

Occurrence and countermeasure of BIA-ALCL in Japan

BIA-ALCL was first reported in 1997 and identified as a disease by the World Health Organization in 2016. One study showed that textured SBIs contribute to the occurrence of BIA-ALCL, and the incidence of BIA-ALCL in patients with macrotextured SBIs was significantly higher than that in patients with microtextured SBIs (25). Since 2018, the use of macrotextured SBIs has been regulated in various countries. In July 2019, the Food and Drug Administration made a statement requesting the voluntary recall of Biocell worldwide. Biocell was a macrotextured SBI, manufactured by Allergan, and the only SBI covered by insurance in Japan at the time. It was never made available after the recall. Since 2020, smooth and microtextured SBIs have been covered by insurance. As of April 2022, the total number of patients with BIA-ALCL worldwide was 1,130, of whom 59 died (26). BIA-ALCL is known to have a difference in incidence depending on the region, and it is most common in North America, Europe, Australia, and New Zealand (27). In Japan, five patients with BIA-ALCL due to the use of Biocell were reported in 2019, 2021, and 2022, none of whom died due to BIA-ALCL (28).

Countermeasures against BIA-ALCL in Japan have

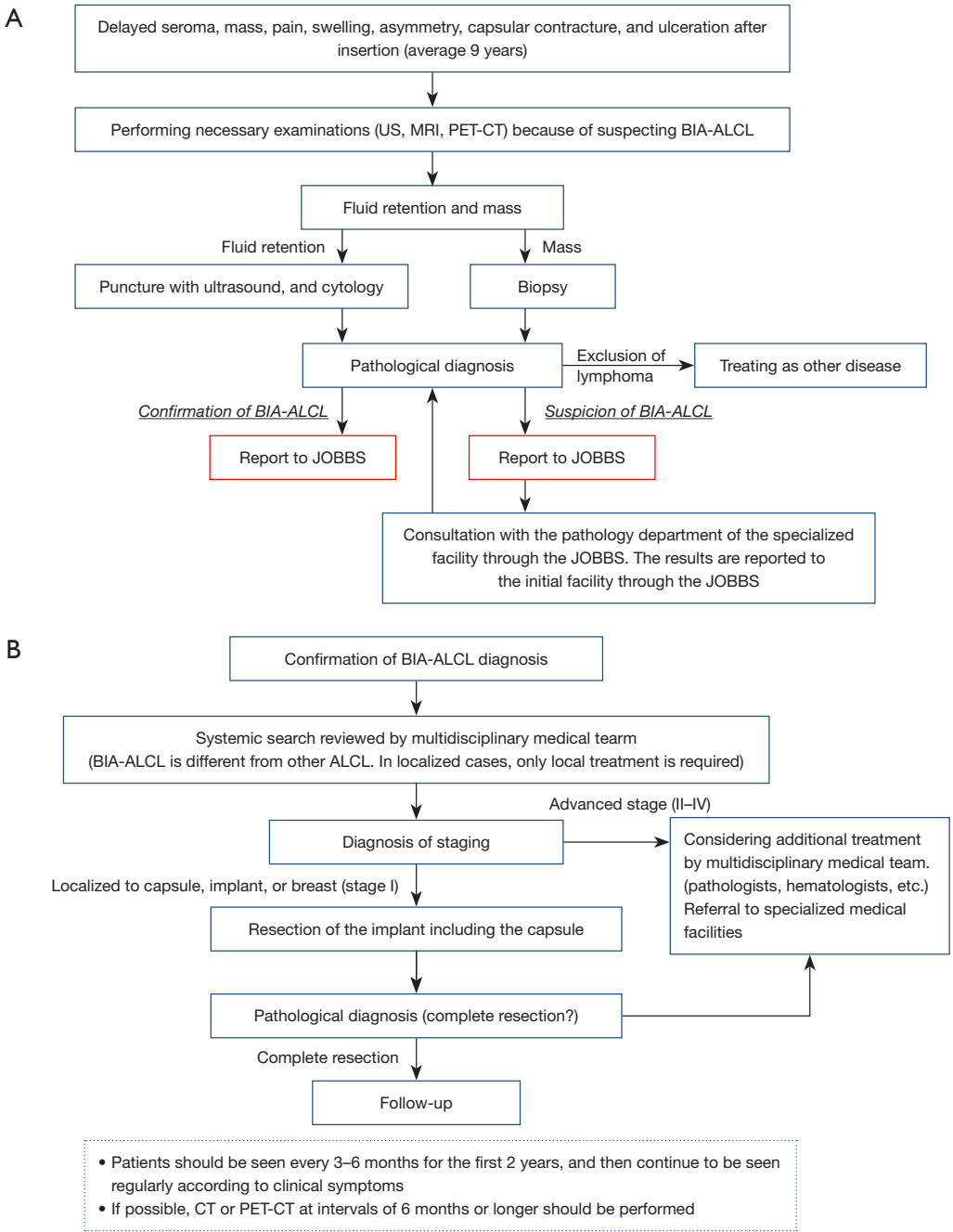

Figure 2 Flowchart of examination of and treatment for BIA-ALCL suspected cases. (A) Examination of suspected BIA-ALCL cases. (B) Treatment for suspected BIA-ALCL. US, ultrasonography; MRI, magnetic resonance imaging; PET-CT, positron emission tomography-computed tomography; BIA-ALCL, breast implant-associated anaplastic large cell lymphoma; JOBSS, Japan Oncoplastic Breast Surgery Society.

been implemented under the initiative of the JOBSS. Hospitals certified by the JOBSS must provide informed consent using explanatory notes made by the JOBSS for patients and their families and generally perform diagnosis and treatment for BIA-ALCL according to the JOBSS guidelines (*Figure 2*) (29). Furthermore, these hospitals must report to the JOBSS immediately if their patients have BIA-ALCL. According to the JOBSS guidelines, these

hospitals do not remove the inserted SBI for the prevention of BIA-ALCL and do not perform any additional screening examinations, except imaging examinations, to detect BIA-ALCL in patients with no symptoms of SBI.

Conclusions

A comprehensive review was conducted on the status of breast reconstruction with SBIs in Japan. This practice has gained momentum in the country, under the initiative of the JOBSS. The SBIs are generally placed under the pectoralis major muscle according to the JOBSS guidelines. Most immediate, IBRs are performed in two stages and the prevalence of immediate, one-stage, IBRs is approximately 10%. Fat grafting by injection is performed in many hospitals under the JOBSS initiative as a combination surgery with SBI insertion. Complications after SBI placement may be less common in Japan than in other countries. Procuring informed consent about BIA-ALCL and diagnosing and treating this disease is performed according to the JOBSS guidelines.

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Footnote

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