



WHITE PAPER

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# Improved Surgical Outcomes and Breast Implant Selection

Application of Automated Volumetric  
Breast Measurements  
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# White Paper: Improved Surgical Outcomes and Breast Implant Selection

## Application of Automated Volumetric Breast Measurements

Positive breast surgery outcomes are important to the physical and psychological well-being of patients. Surgeons can now achieve these outcomes more easily by using automated software to assess breast tissue volumes preoperatively.

This white paper describes how the Volpara® TruDensity™ clinical function provides automated, objective volumetric measurement of breast tissue from mammograms to:

- Support cosmetic surgical outcome prediction in breast conservation treatment
- Guide implant selection for breast-reconstructive surgeries and nipple-sparing mastectomy
- Provide guidance for contralateral breast augmentation
- Aid in predicting recurrence and survival

### Breast-Conserving Surgery

Preoperative volumetric breast measurements are necessary to determine if breast-conserving surgery (BCS) is appropriate. The use of accurate, reproducible measurements, coupled with new volume-preserving oncoplastic surgery techniques, allows larger tumors to be considered for BCS. Studies suggest that tumors 2 to 5 cm in size are considered for BCS with radiotherapy because survival rates are equivalent to those of mastectomy.<sup>1, 2, 3</sup>

In a study of 151 Japanese women who received oncoplastic breast-conserving treatment, the volumetric breast density (measured by Volpara TruDensity) and percent breast volume excised (PBVE) were identified as independent predictors of cosmetic outcomes.<sup>4</sup> Specifically, women with lower breast density (i.e., <15%) had worse cosmetic outcomes compared to women with higher breast density (i.e., ≥15%). In a longer-term study with a different cohort of 99 women, higher PBVE was correlated with worse cosmetic outcomes in the early stage after BCT, and low volumetric breast density (VBD) was correlated with worse cosmetic outcomes

and increased fibrosis in the later stage.

Large excision volumes (10 to 20% of the total breast volume) have also been associated with poorer cosmetic outcomes.<sup>5, 6</sup> Furthermore, there is evidence that the ratio of preoperative tumor volume (TV) to breast volume (BV) can predict cosmetic results following BCS.<sup>7</sup> The TURACOS Trial, a randomized controlled trial nearing completion, is investigating whether the TV/BV ratio, in conjunction with tumor location, is a good predictor of cosmetic results.<sup>8</sup>

While the body of literature is currently quite small, it is logical that accurate volumetric measures should help surgeons preserve the shape and symmetry of the breasts and be key considerations in predicting cosmetic outcomes after BCS.

### Implant Selection Guidance

#### For Breast-Reconstructive Surgery

For women who opt for mastectomy with breast reconstruction, presurgical estimation of the breast volume is important for optimal implant selection to improve aesthetic results. Breast shape, along with mastectomy weight and volume, is often used to help guide implant selection. In a small study of 31 women, researchers found that Volpara TruDensity's estimate of breast volume was consistently higher than the skin-sparing mastectomy volumes, but there was a strong correlation between the two.<sup>9</sup>

#### For Nipple-Sparing Mastectomy

Estimating implant volume during direct-to-implant reconstruction following nipple-sparing mastectomy is difficult for surgeons with less experience. Using automated software to estimate breast volumes aids physicians pre- and intraoperatively in estimation of implant sizes. In addition, improved estimation of implant size is important to the patient as it directly impacts the appearance of the breast after reconstruction.

A study of 118 Taiwanese patients found that breast volume from the craniocaudal view of the contralateral breast, as estimated by Volpara TruDensity, highly correlated with the implant size.<sup>10</sup> Though the final implant volume must be determined by the surgeon, automated implant size estimation is an important starting point that can be used for most patients.

## Contralateral Breast Augmentation

Contralateral breast surgery is often performed to improve breast symmetry and patient satisfaction. When breast reconstruction is performed in a single procedure, estimates of breast volume and breast density become more important.

A study of 40 Japanese women found that both adjuvant therapy and the patient's breast density influenced contralateral breast volume following mastectomy with breast reconstruction.<sup>11</sup> The greatest changes in contralateral breast volumes were seen in women with dense breasts. These findings should be considered in preoperative planning to resolve asymmetry, especially in women that receive adjuvant therapy and have dense breasts.

## Recurrence and Survival

Understanding a woman's risk of loco-regional recurrence can aid in surgical and treatment planning. Several studies have shown that breast cancer recurrence after BCS or mastectomy is associated with increased breast density.<sup>12, 13, 14, 15</sup> There appears to be an interaction between breast density and radiation therapy, as increased breast density was associated with reduced mortality in women who received radiation therapy, whereas increased breast density was associated with increased mortality and higher rates of recurrence in women who did not receive radiation therapy.<sup>16</sup> Thus, there is evidence that a reliable measure of breast density can inform pre- and postoperative treatment planning.

## Application of Volpara TruDensity in Breast Surgery

The only known clinical studies that associate automated volumetric breast measurements with surgical outcomes were performed with Volpara TruDensity.

As Volpara TruDensity operates on presurgical mammograms, surgeons now have a repeatable, objective measure of the in vivo breast tissue before procedure planning or surgery begins. This provides a new form of guidance that can optimize implant selection, both for ipsilateral mastectomy reconstruction and contralateral implant selection.

### In Summary

The automatic, objective, and reliable nature of Volpara TruDensity can improve surgical outcomes and streamline selection of appropriate breast implants for reconstructive surgery.

## About Volpara TruDensity

The Volpara TruDensity clinical function automatically assesses the physical composition of the breast by estimating the fibroglandular tissue volume (FGV) and the overall breast volume (BV); the volumetric breast density (VBD) is the ratio of the two.

Volpara TruDensity's VBD measure has been shown to correlate with BI-RADS Atlas 5th Edition breast composition<sup>17</sup> (Figure 1) as well as with the risks of developing breast cancer<sup>18, 19, 20, 21, 22</sup> and cancers being diagnosed in the interval between two screens.<sup>18, 22, 23, 24, 25</sup>

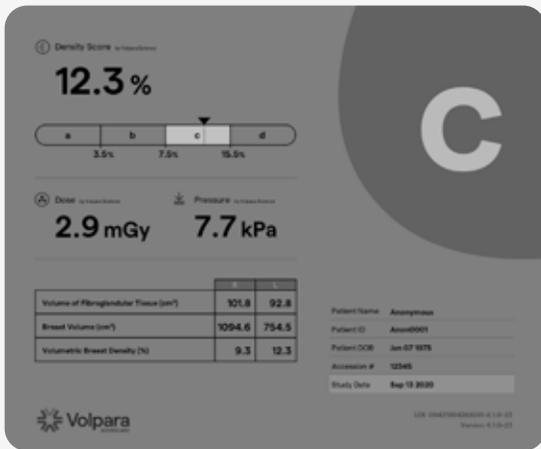


Figure 1. Volpara TruDensity's VBD values lie on a continuous scale; thresholds correlate VBD values to BI-RADS categories.

The various Volpara TruDensity volumetric measurements are readily available on a scorecard that becomes part of the permanent patient record on PACS (Figure 2).

	Right	Left
Volume of Fibroglandular Tissue (cm <sup>3</sup> )	101.8	92.8
Volume of Breast (cm <sup>3</sup> )	1094.6	754.5

Figure 2. Volpara TruDensity's measurement of breast tissue volumes per breast.

## Correlation to Ground Truth

Because the breast is a three-dimensional organ, breast MRI is viewed as the appropriate gold standard for ground truth. Volpara TruDensity has been shown to have strong correlation to breast MRI in several studies.<sup>26, 27, 28, 29</sup>

## Validation summary

Volpara TruDensity has been validated in more than 300 peer-reviewed papers and research abstracts. It is well established as the leading automated breast density assessment software used in clinical research and for routine patient clinical triage in personalized breast screening programs.

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