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Value from Innovation

COMFORT COMP– Prioritizing patient comfort during mammography

Fujifilm's third generation digital mammography system, ASPIRE Cristalle (known as AMULET Innovality outside the United States), combines state-of-the-art imaging capabilities, a unique hexagonal close pattern detector design, and advanced image processing to maximize image quality and diagnostic accuracy for early detection of breast cancer. This paper describes the advantages of **Comfort Comp,** a feature designed to augment patient comfort through decreased compression without compromising image quality or workflow.

Although overall mortality rates for breast cancer have decreased in recent years, it remains the most common and the second deadliest cancer among women worldwide.[1] In the US alone, an estimated 284,000 new breast cancer cases and over 44,000 related deaths occurred in 2021,[2] highlighting the urgency of effective preventive strategies.

Early detection can save lives: the 5-year survival rate for breast cancer patients who are diagnosed in the early, localized stage is 99% compared to 26% if diagnosis occurs after spread to the lymph nodes.[3] Regular screening via routine mammograms is our first line of defense and most powerful tool in the fight against breast cancer.[4,5] However, despite being relatively inexpensive and widely available, approximately 35% of women over age 40 haven't had a mammogram in more than two years in the US.[6] Screening rates vary greatly around the world (Fig. 1), but the fact remains–compliance with periodic screenings continues to be a major challenge to a potentially life-saving strategy.

Inadequate patient education about the importance of early detection and fear of receiving a cancer diagnosis are two of the major factors affecting screening compliance.[7] Pain also ranks high on this list[8]– breast compression during mammography is associated with discomfort and pain,[9] and many patients are reluctant to undergo screening due to the expectation that it will hurt. Improving the patient experience therefore represents our best opportunity to encourage participation in routine screening.

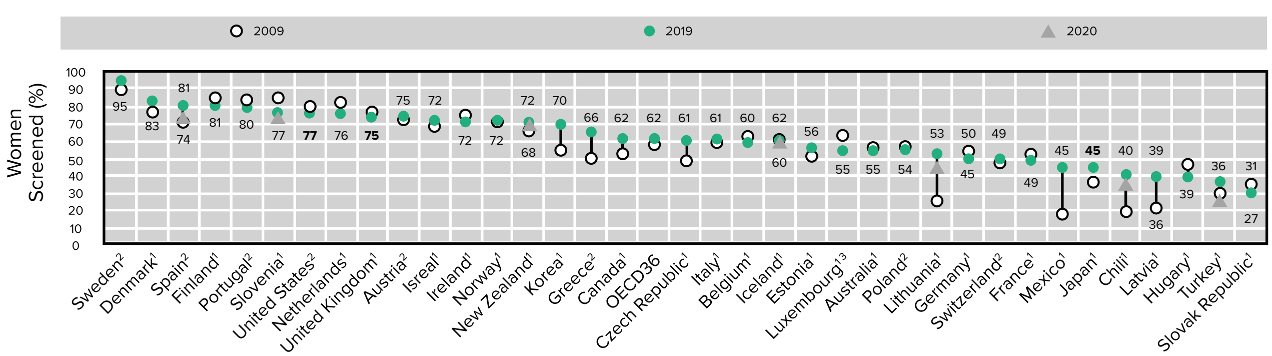

Figure 1. Mammography screening in women aged 50-69 within the past 2 years, 2009, 2019 (or nearest years) and 2020. 1, Program data; 2, Survey data. Source: OECD Health Statistics 2021.[7]

Fujifilm's ASPIRE Cristalle System– Advances in breast imaging that transcend image quality and processing improvements

Drawing on more than 35 years of digital mammography detector and image processing expertise, Fujifilm's ASPIRE Cristalle mammography system combines technological advances with patient-focused ergonomics designed for faster, more confident diagnosis and exceptional patient comfort.

First approved by the FDA in 2014, ASPIRE Cristalle incorporates a number of unique features that optimize image quality at low patient dose, including innovative detector engineering, analytical and adaptive image processing, and Digital Breast Tomosynthesis (DBT) capabilities.

Patient experience enhancements also cater to augmented physical and emotional comfort. The device's Comfort Paddle's soft edges, flexible composition, and four-way pivot contours to varied breast shapes to more comfortably apply compression for optimal tissue separation. The system also features patient grip handles and padding for added stability and comfort, soft backlighting and graphic decals to help ease patient anxiety, and improved access for wheelchair exams, among others.

Improving the patient experience– the case for reducing compression

Pain associated with mammography screenings results from compression of the breast, which is required to obtain high-quality mammograms at low radiation doses. Breast compression reduces motion blur, breast thickness, and radiation scatter for improved contrast, resolution, and overall image quality that enables better diagnostic distinction between tumors and artifacts.[10,11,12]

The lack of guidelines on the compression force required to acquire an adequate mammogram has led to significant variation among technologists, screening centers, and countries.[4,13] Current measures of compression are subjective and variable, and the compression force used in mammography typically ranges between 100-200 N.[14] While it is generally accepted that increased compression leads to better image quality, studies also report that too much compression can lead to dissolving of suspicious densities,[15] further underscoring the need for elucidating the relationship between breast compression and cancer detectability, and establishment of adequate quantitative guidelines.

In an effort to improve screening compliance, focus is now shifting towards alleviating compression-associated pain via patient- or technologist-assisted compression control strategies.[16,17] In response to these challenges, Fujifilm developed an automatic compression reduction solution that is not dependent on patient control, requiring less patient education time, and eliminating the possibility of human error.

Comfort Comp- Automatic compression reduction control

Comfort Comp extends the patient experience enhancement features currently available on the ASPIRE Cristalle mammography system. Based on the hysteresis phenomenon by which soft biological tissues such as breast[18] and adipose tissue maintain the position generated by past force for a period of time before returning to their neutral position, Comfort Comp triggers a reduction in the amount of compression force after normal breast compression is completed and prior to exposure.

Mammography using Comfort Comp requires that normal breast compression be applied initially to ensure proper breast positioning and to take full advantage of the hysteresis principle (Fig. 2). Once completed, automatic decompression is activated, shortening the time that the breast is under maximum pressure with minimal changes to breast thickness[19] or image quality.[20]

Auto-release via Comfort Comp is operated by pressing 2 buttons on the gantry so decompression can be confirmed while monitoring the condition of the breast (Fig. 2).

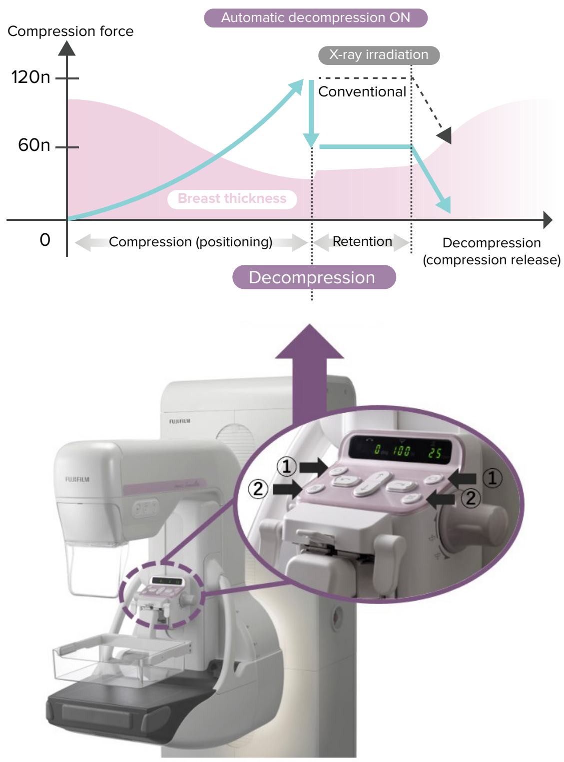

Figure 2. Comfort Comp Workflow. Once breast is fixed using conventional compression and positioning, compression reduction is automatically activated at the push of a button. Due to hysteresis of breast tissue, Comfort Comp activation results in minimal impacts to breast thickness, and can be performed within the same workflow, without delaying exposure time.

It can be performed in the same flow as conventional positioning and therefore does not prolong the time until exposure. In addition, while the decompression value can be set arbitrarily, the system will automatically stop decompression even if the target force value is not reached to ensure that breast thickness does not increase by more than 3 mm.

Study Findings- Comfort Comp reduces discomfort without compromising image quality

Fujifilm conducted a single-blind prospective randomized study to compare the effects of conventional and Comfort Comp compression modes on breast thickness, patient dose, overall image quality, and patient comfort.

Study Design and Participants

2,400 consenting female patients who underwent screening or diagnostic 2D mammography with ASPIRE Cristalle (known as AMULET Innovality outside the United States) at 24 different sites between March 2019 and March 2020 were enrolled in this study. Each participant had one breast ("breast of interest") imaged with both conventional and Comfort Comp compression modes, while the other breast was imaged with conventional mode only, per standard of care. Conventional compression and image acquisition were performed first, followed by Comfort Comp compression imaging on the same breast.

Normal compression force used for conventional and initial settings was set to 110-120 N to match the preliminary study conditions. The recommended setting for compression reduction was 80 N; however, application of the Comfort Comp function was judged at the site before each examination since it can affect positioning for some patients.

Image Acquisition and Data Collection

Mammography procedures were performed by qualified personnel, and standard CC and MLO views were obtained for each compression mode. Additional parameters recorded included compression force, breast thickness, and entrance skin air kerma (ESAK; used to calculate average glandular dose).

Patient Survey

Following mammography examinations, each patient completed a 4-item, 5-point scale anonymous survey to explore how several factors were ranked during and after the exam. Additional patient feedback and impressions were also recorded.

Image Analysis

24,000 images were acquired and independently evaluated by a qualified reader who was blinded to patient histories and the compression mode used in image acquisition. All image sets were displayed per a randomization scheme and evaluated for contrast, sharpness, and granularity.

Results

Automatic compression reduction control via Comfort Comp leads to negligible changes in breast thickness and average dose and produces images of similar quality compared to those obtained under conventional compression (Fig. 3).

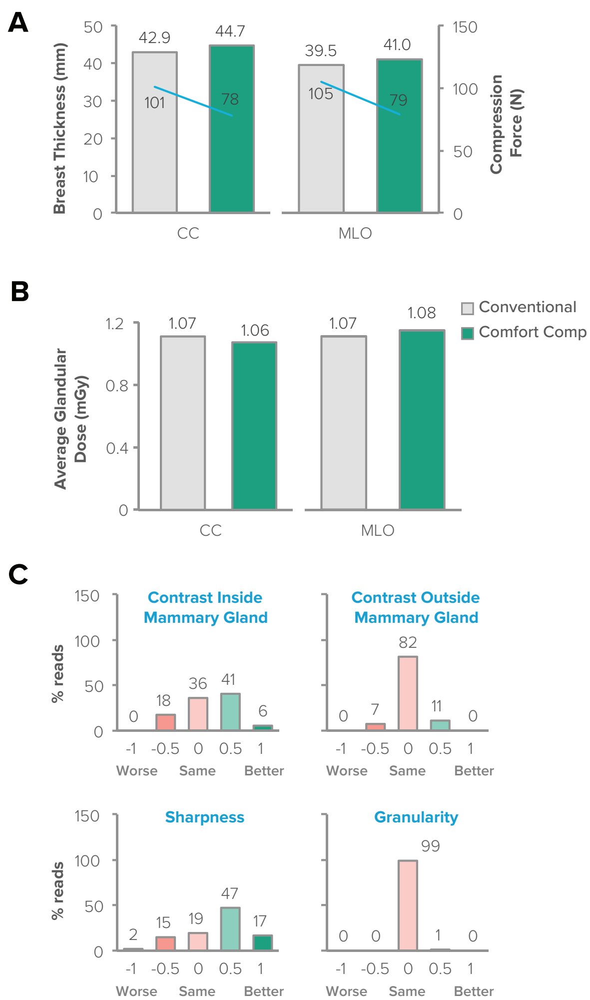

Figure 3. Comfort Comp compression reduction does not affect breast thickness, average glandular dose, or image quality. A, Compression force effects on breast thickness. B, Compression mode impact on average glandular dose. C, Image contrast, sharpness, and granularity obtained with conventional and Comfort Comp modes were evaluated by a qualified reader using a 5-point scale.

In contrast, the patient experience is markedly improved (Fig. 4): 56% of participants indicated they had a negative general impression of mammography prior to exposure to Comfort-Comp, while 79% answered they felt more relaxed and/or experienced pain reduction once Comfort Comp was explained to them, and 78% of patients stated they would use it again. In addition, explaining Comfort Comp had a significant effect in enhancing the patient experience, regardless of whether the breast in which Comfort Comp was used was specified, underscoring the importance of patient education.

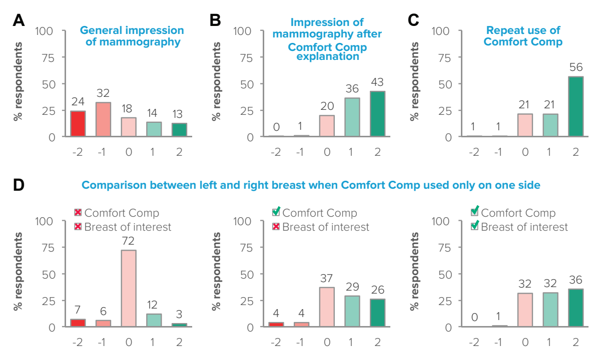

Figure 4. Comfort Comp is effective in reducing stress, anxiety, and pain associated with mammography. Following mammography examinations, patients answered the following questions: A, What is your general impression of mammography? B, How did your perception of mammography change once Comfort Comp was explained to you? and C, Would you use Comfort Comp for your next mammography? Panel D summarizes patients' experiences on the right vs left breast when Comfort Comp was used only on one side and: Left- the function was not explained nor the breast of interest indicated, Center- Comfort Comp was explained but the breast of interest was not specified, or Right- both Comfort Comp and breast of interest information were provided. *5-point scale: -2: Very poor/bad, -1: Inferior/bad, 0: Unchanged, 1: Good, 2: Very good.

Conclusions

Based on hysteresis of breast tissue, the Comfort Comp compression control feature in ASPIRE Cristalle systems allows for automatic decompression that does not affect breast thickness. To determine how differences in compression force impact average dose and overall image quality, image sets from 2,400 distinct patients obtained using ASPIRE Cristalle's conventional and Comfort Comp modes were analyzed and compared. The study results confirm that Comfort Comp-mediated compression reduction does not alter breast thickness or patient dose, while producing images of similar quality to those acquired with conventional compression modes. Furthermore, patient feedback indicates that Comfort Comp effectively reduces anxiety and pain associated with mammography, improving the likelihood of patients adhering to periodic screenings and making it a viable strategy for increasing early cancer detection.

Prioritizing the patient experience can bring about additional benefits beyond increased screening compliance, with studies showing that increased patient relaxation during mammography can translate to better positioning and improved image quality.[22] Our results seem to agree with these findings, with improved image quality observed when Comfort Comp was used compared to images acquired with conventional compression.

In general, patient feedback suggests Comfort Comp is effective in reducing pain and anxiety associated with mammography, and highlights the importance of patient education (Fig. 5).

"I did not feel much pain. Hearing the explanation in advance helped me feel relaxed and less scared."

"Discomfort was reduced enormously"

"I felt relieved to hear that compression force would be reduced."

"This time felt easier compared to past mammograms."

"I felt relieved just hearing the introduction. I hope to take a mammogram with Comfort Comp next time too."

"I felt relaxed because I had to bear it only one moment."

"I would recommend it to others."

Figure 5. Patient feedback suggests Comfort Comp can reduce anxiety and pain associated with mammography, and highlights the importance of thorough patient education.

References

[1]Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, Bray F. 2021. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin 71(3):209-249, PMID: 33538338, https://doi.org/10.3322/-caac.21660.

[2]American Cancer Society. 2021. Cancer Facts and Figures 2021. [Website]. Atlanta, GA, USA: American Cancer Society. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf. [accessed 25 Jul 2022].

[3]National Cancer Institute (NCI). 2022. Surveillance, Epidemiology, and End Results Program|Cancer Stat Facts: Female Breast Cancer. [Website]. Bethesda, MA, USA: National Institutes of Health (NIH). https://seer.cancer.gov/statfacts/html/breast.html. [accessed 8 Aug 2022].

[4]Smith RA, Duffy SW, Gabe R, Tabar L, Yen AM, Chen TH. 2004. The randomized trials of breast cancer screening: what have we learned? Radiol Clin North Am 42:793–806, PMID: 15337416, https://doi.org/10.1016/j.rcl.2004.06.014.

[5]Tabár L, Yen AM, Wu WY, Chen SL, Chiu SY, et al. 2015. Insights from the breast cancer screening trials: how screening affects the natural history of breast cancer and implications for evaluating service screening programs. Breast J 21:13–20, PMID: 25413699, https://doi.org/10.1111/tbj.12354.

[6]Centers for Disease Control and Prevention (CDC). 2022. National Center for Health Statistics | Health, United States 2020-2021| Mammography. [Website]. Atlanta, GA, USA: Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/hus/topics/mammography.htm. [accessed 22 Jul 2022].

[7]Padoan M, Ferrante D, Pretti G, Magnani C. 2014. Study of socio-economic characteristics, diagnosis and outcome of women participating or not participating in mammogram screening. Ann Ig 26(6):518-26, PMID: 25524076, https://doi.org/10.7416/ai.2014.2010.

[8]Whelehan P, Evans A, Wells M, Macgillivray S. 2013. The effect of mammography pain on repeat participation in breast cancer screening: A systematic review. Breast 22(4):389-94, PMID: 23541681, https://doi.org/10.1016/j.breast.2013.03.003.

[9]Keemers-Gels ME, Groenendijk RP, van den Heuvel JH, Boetes C, Peer PG, Wobbes TH. 2000. Pain experienced by women attending breast cancer screening. Breast Cancer Res Treat 60(3):235-40, PMID: 10930111, https://doi.org/10.1023/a:1006457520996.

[10]Perry N, Broeders M, deWolf C, Tornberg S, Holland R, von Karsa L. 2008. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition--summary document. Ann Oncol 19:614–622, PMID: 18024988, https://doi.org/10.1093/annonc/mdm481.

[11]Helvie MA, Chan HP, Adler DD, Boyd PG. 1994. Breast thickness in routine mammograms: effect on image quality and radiation dose. AJR Am J Roentgenol 163(6):1371-4, PMID: 7992731, https://doi.org/10.2214/ajr.163.6.7992731.

[12]Heine JJ, Cao K, Thomas JA. 2010. Effective radiation attenuation calibration for breast density: compression thickness influences and correction. Biomed Eng Online 9:73, PMID: 21080916, https://doi.org/10.1186/1475-925X-9-73.

[13]Holland K, Sechopoulos I, Mann RM, den Heeten GJ, van Gils CH, Karssemeijer N. 2017. Influence of breast compression pressure on the performance of population-based mammography screening. Breast Cancer Res 19(1):126, PMID: 29183348, https://doi.org/10.1186/s13058-017-0917-3.

[14]Sullivan DC, Beam CA, Goodman SM, Watt DL. 1991. Measurement of force applied during mammography. Radiology 181(2):355-7, PMID: 1924771, https://doi.org/10.1148/radiology.181.2.1924771.

[15]Serwan E, Matthews D, Davies J, Chau M. 2020. Mammographic compression practices of force- and pressure-standardisation protocol: A scoping review. J Med Radiat Sci 67(3):233-242, PMID: 32420700, https://-doi.org/10.1002/jmrs.400.

[16]Ulus S, Kovan Ö, Arslan A, Elpen P, Arıbal E. 2019. A New Technical Mode in Mammography: Self-Compression Improves Satisfaction. Eur J Breast Health 15(4):207-212, PMID: 31620677, https://doi.org/10.5152/ejbh.2019.4480.

[17]Balleyguier C, Cousin M, Dunant A, Attard M, Delaloge S, Arfi-Rouche J. 2018. Patient-assisted compression helps for image quality reduction dose and improves patient experience in mammography. Eur J Cancer 103:137-142, PMID: 30223227, https://doi.org/10.1016/j.ejca.2018.08.009.

[18]Han L, Burcher M, Noble JA. 2002. Non-invasive Measurement of Biomechanical Properties of in vivo Soft Tissues. In: Dohi T, Kikinis R (eds). Medical Image Computing and Computer-Assisted Intervention — MICCAI 2002. MICCAI 2002. Lecture Notes in Computer Science Vol. 2488. Springer, Berlin, Heidelberg. https://doi.org/10.1007/3-540-45786-0_26.

[19]Poulos A, McLean D, Rickard M, Heard R. 2003. Breast compression in mammography: how much is enough? Australas Radiol 47(2):121-6, PMID: 12780439, https://doi.org/10.1046/j.0004-8461.2003.01139.x.

[20]Chida K, Komatsu Y, Sai M, Nakagami A, Yamada T, et al. 2009. Reduced compression mammography to reduce breast pain. Clin Imaging 33(1):7-10, PMID: 19135922, https://doi.org/10.1016/j.clinimag.2008.06.025.

[21]Chida K, Komatsu Y, Sai M, Nakagami A, Yamada T, et al. 2009. Reduced compression mammography to reduce breast pain. Clin Imaging 33(1):7-10, PMID: 19135922, https://doi.org/10.1016/j.clinimag.2008.06.025.