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Title: THE VALUE OF 3D IMAGES IN THE AESTHETIC EVALUATION OF BREAST CANCER CONSERVATIVE TREATMENT. RESULTS FROM A PROSPECTIVE MULTICENTRIC CLINICAL TRIAL.

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Corresponding Author: Dr. Maria João Cardoso, MD, PhD

Corresponding Author's Institution: Champalimaud Cancer Centre

First Author: Maria João Cardoso, MD, PhD

Order of Authors: Maria João Cardoso, MD, PhD; Conny Vrieling, MD,PhD; Jaime S Cardoso, PhD; Helder P Oliveira, PhD; Norman R Williams, PhD; JM Dixon, MD, PhD; Pedro Gouveia, MD; Mohammed Keshtgar, MD, PhD; Ash Mosahebi, MD, PhD; David Bishop; Rene Lacher, MSc; Gerrit J Liefers, MD; Barbara Molenkamp, MD; Cornelius Van de Velde, MD, PhD; Isabel Azevedo, MD; Rebecca Canny, Bsc; David Christie, MD; Andy Evans, MD, PhD; Florian Fitzal, MD, PhD; Peter Graham, MD, PhD; Moustapha Hamdi, MD, PhD; Jorgen Johansen, MD, PhD; Siobban Laws, MD; Belen Merck, MD, PhD; Gregory Reece, MD; Virgilio Sacchini, MD; Marie-Jeanne Vrancken, MD, PhD; Louise Wilkinson, MD; Gustavo Zucca-Mattes, MD, PhD

Abstract: Purpose: BCCT.core (Breast Cancer Conservative Treatment. cosmetic results) is a software created for the objective evaluation of aesthetic result of breast cancer conservative treatment using a single patient frontal photography. The lack of volume information has been one criticism, as the use of 3D information might improve accuracy in aesthetic evaluation. In this study, we have evaluated the added value of 3D information to two methods of aesthetic evaluation: a panel of experts; and an augmented version of the computational model - BCCT.core3d.
Material and Methods: Within the scope of EU Seventh Framework Programme Project PICTURE, 2D and 3D images from 106 patients from three clinical centres were evaluated by a panel of 17 experts and the BCCT.core. Agreement between all methods was calculated using the kappa (K) and weighted kappa (wK) statistics.
Results: Subjective agreement between 2D and 3D individual evaluation was fair to moderate. The agreement between the expert classification and the BCCT.core software with both 2D and 3D features was also fair to moderate.
Conclusions: The inclusion of 3D images did not add significant information to the aesthetic evaluation either by the panel or the software. Evaluation of aesthetic outcome can be performed using of the BCCT.core software, with a single frontal image

Lisbon, May 24th 2018

Dear Editor-in-Chief of The Breast
Dr. Fatima Cardoso

We would like to submit our manuscript entitled "THE VALUE OF 3D IMAGES IN THE AESTHETIC EVALUATION OF BREAST CANCER CONSERVATIVE TREATMENT. RESULTS FROM A PROSPECTIVE MULTICENTRIC CLINICAL TRIAL." to The Breast.

Currently. there is no standard for the aesthetic evaluation of Breast Cancer Conservative Treatment (BCCT). The last recommendation of the EORTC was in 2005. The methods for evaluation currently used are not only time consuming and costly but additionally lack the reproducibility needed to make useful comparisons between treatments. As a consequence the vast majority of women who undergo this form of treatment are not aesthetically evaluated. We know from previous publications, retrospective mainly, that 30% of results are estimated to be fair or poor. However, this lack of standard evaluation makes it very difficult to compare results and to propose solutions.

The BCCT.core software was created to try to solve the lack of reproducibility and cost attributed to subjective evaluation. The BCCT.core evaluates objectively aesthetic results of BCCT using a single patient frontal photography. One of the criticisms, however, has been the lack of 3D information that could help to improve the accuracy of aesthetic evaluation.

The current work was a part of a FP7 grant – PICTURE and in this cross-sectional cohort we assessed the performance of several methods for the aesthetic evaluation of BCCT trying to understand the added value of 3D information.

Our results confirm, by means of a correctly conducted trial, that 3D images did not add significant information to the aesthetic evaluation.

We hope that you consider our manuscript a valuable contribution to this important problem.

I sign this letter on behalf of all authors, Sincerely,

Maria João Cardoso, MD, PhD
Breast Unit, Champalimaud Foundation
Av Brasilia, 1400-038 Lisbon, Portugal
Email: maria.joao.cardoso@fundacaochampalimaud.pt

*Title Page

THE VALUE OF 3D IMAGES IN THE AESTHETIC EVALUATION OF BREAST CANCER CONSERVATIVE TREATMENT. RESULTS FROM A PROSPECTIVE MULTICENTRIC CLINICAL TRIAL.

Maria João Cardoso[1], Conny Vrieling[2], Jaime S. Cardoso[3], Helder P. Oliveira[3], Norman R. Williams[4], JM Dixon[5], the PICTURE Project Clinical Trial Team [6] and the PICTURE Project Delphi Panel [7]

[1] Breast Unit, Champalimaud Foundation and Nova Medical School, Lisbon, Portugal
[2] Clinique des Grangettes, Geneva, Switzerland
[3] INESC TEC and University of Porto, Portugal
[4] Royal Free Hospital and University College London, UK
[5] Breast Cancer Now Research Unit, Edinburgh, UK

[6] Pedro Gouveia, Breast Unit, Champalimaud Foundation, Lisbon, Portugal
Mohammed Keshtgar, Royal Free Hospital and University College London, UK , † Deceased November 15 2017
Ash Mosahebi, Royal Free Hospital and University College London, UK
David Bishop, Medical Illustration Services, University College, London, UK
René Lacher, Surgical Robot Vision Group, Centre for Medical Image Computing (CMIC), University College London, UK
Gerrit Jan Liefers, Leiden University Medical Centre, Leiden, The Netherlands
Barbara Molenkamp, Leiden University Medical Centre, Leiden, The Netherlands
Cornelius Van de Velde, Leiden University Medical Centre, Leiden, The Netherlands

[7]Isabel Azevedo, Instituto Português de Oncologia, Porto, Portugal
Rebecca Canny, Royal Free Hospital, London, UK
David Christie, Genesis CancerCare, Tugun, Australia
Andy Evans, University of Dundee, School of Medicine, Dundee, UK
Florian Fitzal, Medical University Vienna, Breast Health Center, Vienna, Austria
Peter Graham, St George Hospital, Sydney, Australia
Moustapha Hamdi, Brussels University Hospital, Brussels, Belgium
Jorgen Joahensen, Odense University Hospital, Odense, Denmark
Siobban Laws, Hampshire Hospital, Winchester, UK
Belén Merck, Universidad CEU Cardenal Herrera, Valencia, Spain

Gregory Reece, MD Anderson Cancer Center, Houston, Texas, USA
Virgilio Sacchini, Memorial Sloan Kettering Cancer Center, New York, USA
Marie-Jeanne Vrancken, Netherlands Cancer Institute, Amsterdam, Netherlands
Louise Wilkinson, St Georges University Hospital, London, UK
Gustavo Zucca Matthes, Hospital de Cancer, Barretos, Brasil

Corresponding author/address for reprints:

Maria João Cardoso, MD, PhD

Champalimaud Foundation, Breast Unit

Av, Brasilia 1400-038 Lisboa

T: +351210480004

F:+3151210480298

www.fchampalimaud.org

maria.joao.cardoso@fundacaochampalimaud.pt

Keywords: Aesthetic Results, Breast Cancer Conservative Treatment, Expert Observers, 2D, 3D, Objective Evaluation, Software, Delphi

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Keywords: Aesthetic Results, Breast Cancer Conservative Treatment, Expert Observers, 2D, 3D, Objective Evaluation, Software, Delphi.

ABSTRACT

Purpose: BCCT.core (**B**reast **C**ancer **C**onservative **T**reatment. **co**smetic **re**sults) is a software created for the objective evaluation of aesthetic result of breast cancer conservative treatment using a single patient frontal photography. The lack of volume information has been one criticism, as the use of 3D information might improve accuracy in aesthetic evaluation. In this study, we have evaluated the added value of 3D information to two methods of aesthetic evaluation: a panel of experts; and an augmented version of the computational model - BCCT.core3d.

Material and Methods: Within the scope of EU Seventh Framework Programme Project PICTURE, 2D and 3D images from 106 patients from three clinical centres were evaluated by a panel of 17 experts and the BCCT.core. Agreement between all methods was calculated using the kappa (K) and weighted kappa (wK) statistics.

Results: Subjective agreement between 2D and 3D individual evaluation was fair to moderate. The agreement between the expert classification and the BCCT.core software with both 2D and 3D features was also fair to moderate.

Conclusions: The inclusion of 3D images did not add significant information to the aesthetic evaluation either by the panel or the software. Evaluation of aesthetic outcome can be performed using of the BCCT.core software, with a single frontal image.

INTRODUCTION

Breast cancer conservative treatment (BCCT), including breast conserving surgery and breast radiotherapy, is the gold standard treatment for early breast cancer. It is expected to gain even more popularity as recent publications of large retrospective database series show that BCCT has not only identical results in terms of disease free and overall survival (OS), but may possibly result in a better outcome compared to mastectomy (1,2). The indications for BCCT have also expanded, associated with an increase in the types of surgical and radiotherapy techniques available, although many have not been rigorously evaluated. There is, however, also a challenge to this success story. Although BCCT is very easily evaluated in oncological terms (re-excision rate, number of recurrences, disease-free survival and OS), the aesthetic outcome, one of the main reasons for its existence, is very difficult to evaluate and a standard evaluation method is still missing (3). The absence of a widely accepted standardized tool for the aesthetic evaluation of BCCT limits the applicability of any comparative analysis of cosmetic outcome, resulting in a gap in the quality control of this important parameter. Methods for evaluating the cosmetic result are traditionally considered to be either subjective or objective. Results of subjective evaluation show only a modest inter-observer agreement (4). Objective methods increase the reproducibility of the assessment, but it has been argued that they do not take into account the global appearance of aesthetic results, as they include only a limited number of measures (5).

The BCCT.core software was developed to provide an objective and automatic evaluation of aesthetic results based on parameters extracted from 2D photographs, such as breast asymmetry, skin colour and scar (6). The aim was to develop a simple to use, reproducible and widely available methodology, enabling an effective comparison of outcomes between centres and allowing a cost-effective method for quality control of this fundamental outcome of BCCT. The BCCT.core software has gained popularity due to its user-friendly interface and its use has increased steadily in the last five years (7).

One of the often-mentioned limitations of BCCT.core is related to the lack of volume information (3D) as the current version of the BCCT.core software uses a frontal-only photographic view of the patient. No evaluation is done on the side or oblique views (8). Such images were deliberately not included due to the difficulty in standardizing these additional positions during image acquisition.

Since the launch of BCCT.core, there have been dramatic improvements in the capabilities of RGB-D (red-green-blue plus depth) cameras, which provide both RGB and depth information in each image pixel (as in Microsoft Kinect) (9). Combining depth and colour information is challenging, but opens new possibilities in different fields, including medical applications (10). Several research groups have made considerable progress in dealing with 3D depth scans and camera images; the technology has advanced to a point where advantage can be taken of these improvements (11).

In the current work, we investigated if by adding 3D information, the aesthetic outcome was evaluated more accurately subjectively by human experts and objectively by computational models.

MATERIAL AND METHODS

This study was performed within the scope of the EU-Seventh Framework Programme FP7-ICT-2011-9-600948 Acronym PICTURE Project (http://vph-picture.eu/). Written informed consent was obtained from 106 women who had undergone BCCT (classic conserving surgery and radiotherapy) for early breast cancer with a follow-up of more than one year from three clinical centres (Royal Free Hospital, UK; Champalimaud Cancer Center, Portugal; Leiden University Medical Center, The Netherlands) – ClinicalTrials.gov – NCT02310984 – Picture Breast XS. Each woman was assigned a study-specific unique identifier to maintain confidentiality.

A digital camera (Canon EOS 1100D, red-green-blue components) was used for the acquisition of 2D images (Figure 1). All anonymised 2D images were sent for evaluation to the PICTURE panel of expert evaluators selected based on their previous experience in this type of evaluation (12) (Table 1). Individual panel experts were not told the names of other experts in the panel until the conclusion of the study. The evaluators classified each image according to the Harris Scale into excellent, good, fair and poor (13). Results were combined centrally and it was determined that a consensus had been reached for each case when at least 9 experts (over 50%) gave identical scores.

Microsoft Kinect (red-green-blue components, plus depth sensor data) images were acquired continuously (and simultaneously unless interference was encountered) while the patient made a full 180° rotation between lateral views, performed as smoothly as the patient was capable of performing (Figure 2). Subsequently, a 3D model was generated and the models of all patients were evaluated by the PICTURE expert panel without reference to the previously evaluated 2D images (Figure 3).

A new aesthetic evaluation model (BCCT.core3d) was developed, integrating volumetric information extracted from depth data with the information already used in the BCCT.core. The BCCT.core and the BCCT.core3d score were determined for all patients, followed by a comparison between the 2 scores.

A paired t-test was performed to determine if the agreement strength was statistically different between the 2D and 3D evaluation (14). The observations have been paired and the mean differences compared. To determine agreement between the classification systems, we calculated the kappa (K) and weighted kappa (wK) statistics, the latter allowing some deviation from perfect agreement (0 – no agreement; 0.01 – 0.20 slight agreement, 0.21 – 0.40 fair agreement, 0.41 – 0.60 moderate agreement, 0.61 – 0.80 substantial agreement, 0.81 – 0.99 almost perfect agreement; 1 – perfect agreement) (15).

RESULTS

Panel 2D versus 3D evaluation

In evaluating the 2D images, the panel reached a consensus in 99 patients. The result was scored as excellent in 40 patients, good in 40 patients, fair in 13 and poor in 6 patients. With the 3D image evaluation, consensus was not reached in 14 patients. Of the 92 consensus patients, the result was considered excellent in 33 patients, good in 36, fair in 17 and poor in 6 patients.

To evaluate whether the agreement was facilitated or improved by 3D images compared to 2D images, the agreement strength was computed for each patient (percentage of experts voting in the consensus score). The agreement strength was not significantly different from zero ($p = 0.73$), therefore, there was no evidence to favour either of the methods of evaluation.

As expected, a moderate to substantial agreement was obtained when comparing the individual subjective evaluation with the consensus, for both 2D and 3D data, as the consensus was built over individual expert classification (K = 0.57 and 0.55, respectively and wK = 0.69 and 0.67, respectively; Figure 4 a and b). However, the agreement for the subjective evaluation by each observer between 2D and 3D was only fair to moderate (K = 0.30 and wK = 0.43; Figure 4 a and b). The level of agreement of the 2D consensus to the 3D consensus was comparable to that of the individual observers (K = 0.39 and wK = 0.54; Figure 4 a and b).

BCCT.core versus BCCT.core3d evaluation

The BCCT.core scored the cosmetic result as excellent in 26 patients, good in 58 patients, fair in 20 and poor in 2 patients. The BCCT.core3d scored the cosmetic result as excellent in 40 patients, good in 54 patients, fair in 10 and poor in 2 patients. The agreement between the two objective scores was almost perfect (K = 0.85 and wK = 0.89; Figure 4 a and b).

Panel evaluation versus objective evaluation

The agreement between the 2D consensus classification and the BCCT.core was fair to moderate (K = 0.37, wK = 0.51), and comparable to the agreement between the 2D consensus classification and the BCCT.core3D (K = 0.35, wK = 0.49) (Figure 4 a and b).

The agreement between the 3D consensus classification and the BCCT.core3D was fair (K = 0.26, wK = 0.40) and comparable to the agreement between the 3D consensus classification and the BCCT.core (K = 0.27, wK = 0.41), (Figure 4 a and b).

DISCUSSION

Aesthetic evaluation of BCCT remains without a standard. Traditionally used methods are patient self-evaluation, subjective evaluation by experts of patient's photographs, and more recently, objective methods such as the BCCT.core software (3). The BCCT.core software is capable of objectively evaluating aesthetic results of BCCT by comparing symmetry, differences in colour, scar and appearance of the treated breast compared with the untreated breast. Although possibly not as complete as the eye of a trained expert, it attains a level of acceptable agreement and is very cost-effective in large series of patients.

The absence of volume information is one of the most frequent criticisms for both subjective and objective methods (16). In the current work we included volume information by reconstructing 3D images captured through the Kinect device (9).

We performed a subjective panel evaluation of 2D and 3D images and an objective evaluation with the BCCT.core and BCCT.core3D software in order to analyse how all these evaluations correlate. We observed that the inclusion of the 3D images did not improve the agreement in the panel consensus score. This result is consistent with our previous work (8) where the inclusion of lateral views did not improve agreement between observers. The intra-observer variability between the 2D and 3D evaluation was only fair to moderate (K = 0.30). This result is not surprising in light of an earlier study, that showed that the intra-observer variability for the subjective evaluation (same image, evaluated twice at different times) was only moderate, with a Kappa-value of 0.42 (17). In the different comparisons made between the 2D and 3D evaluations, both in terms of the subjective panel as well as the objective evaluation, we did not find any added value of the 3D evaluation. Therefore, the requirement to capture 3D images would add unnecessary complexity to the process.

The use of the BCCT.core software has been increasing, mainly due to its practicality compared to subjective forms of evaluation (7, 18-21). The software is also more and more used in the evaluation of the cosmetic result after oncoplastic surgery (22-25). The study of Preuss et al. suggests that the BCCT.core can also be used in the evaluation of the aesthetic outcome after mastectomy and immediate reconstruction (26).

In the current study, no patient evaluation was used. Many studies evaluating the cosmetic result after BCCT include patient evaluations, usually focusing on the global cosmetic outcome using the Harris scale. Patient self-assessment is generally reported to be more favourable regarding overall cosmetic outcome than a panel or objective evaluation (27,28). More recently, patient-reported outcome measures (PROMs) have been used as well. Lagendijk et al. (29) showed a significant association between the BCCT.core result and the BREAST-Q (30), whereas the BCCT.core was not significantly associated with the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ-C30/BR23) (31) and the Euro-Quality of Life 5D-5L (32). The BREAST-Q is a validated PROM quantifying the impact of breast surgery on health-related quality of life (including physical, psychosocial, and sexual well-being) and patient satisfaction (including satisfaction with cosmetic outcome) (30). Dahlbäck et al. confirmed the statistically significant association between BCCT.core at 1 year and the quality of life results of the BREAST-Q at longer follow-up (33).

The BCCT.core software is also used in studies aiming to predict whether the postoperative cosmetic result will be acceptable. Pukancsik et al. described the maximum percentage of breast volume resectable per breast quadrant without resulting in an unacceptable cosmetic result, varying from 8% for the upper-inner quadrant to 18% for the upper-outer quadrant (34). Larger excisions would require oncoplastic techniques or even mastectomy with immediate reconstruction. A prediction model for cosmetic outcome based on the tumour to breast volume ratio and tumour location in the breast has been developed and is currently being tested in a randomized trial (18).

CONCLUSION: The addition of 3D information to subjective and objective evaluation methods did not make an appreciable difference in the quality of aesthetic evaluation. It is therefore unnecessary to add the complexity of capturing 3D images to the process of cosmetic evaluation.

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Conflict of interest

The authors declare that they have no conflict of interest.

The BCCT.core software use licence is free of any charge

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Table 1 – Picture panel of expert evaluators

Speciality	Name	Institution	City, Country
Radiation Oncologist	Azevedo, Isabel	Instituto Português de Oncologia	Porto, Portugal
Breast Nurse	Canny, Rebecca	Royal Free Hospital	London, UK
Radiation Oncologist	Christie, David	Genesis CancerCare	Tugun, Australia
Breast Surgeon	Dixon, Mike	Breast Cancer Now Research Unit	Edinburgh, UK
Breast Imaging	Evans, Andy	University of Dundee, School of Medicine	Dundee, Scotland
Surgical Oncologist	Fitzal, Florian	Medical University Vienna, Breast Health Center	Vienna, Austria
Radiation Oncologist	Graham, Peter	St Georges Hospital	Sydney, Australia
Plastic Surgeon	Hamdi, Moustapha	Brussels University Hospital	Brussels, Belgium
Clinical Oncologist	Johansen, Jorgen	Odense University Hospital	Odense, Denmark
Breast Surgeon	Laws, Siobhan	Hampshire Hospital	Winchester, UK
Breast Surgeon	Merck, Belen	Universidad CEU Cardenal Herrera	Valencia, Spain
Plastic Surgeon	Reece, Gregory	MD Anderson	Houston, Texas, UK
Breast Surgeon	Sacchini, Virgilio	Memorial Sloan Kettering Cancer Center	New York, USA
Surgical Oncologist	Vrancken, Marie-Jeanne	NKI	Amsterdam, Netherlands
Radiation Oncologist	Vrieling, Conny	Clinique des Grangettes	Geneva, Switzerland
Breast Imaging	Wilkinson, Louise	St Georges University Hospital	London, UK
Breast Surgeon	Zucca-Matthes, Gustavo	Hospital de Cancer	Barretos, Brasil

FIGURES

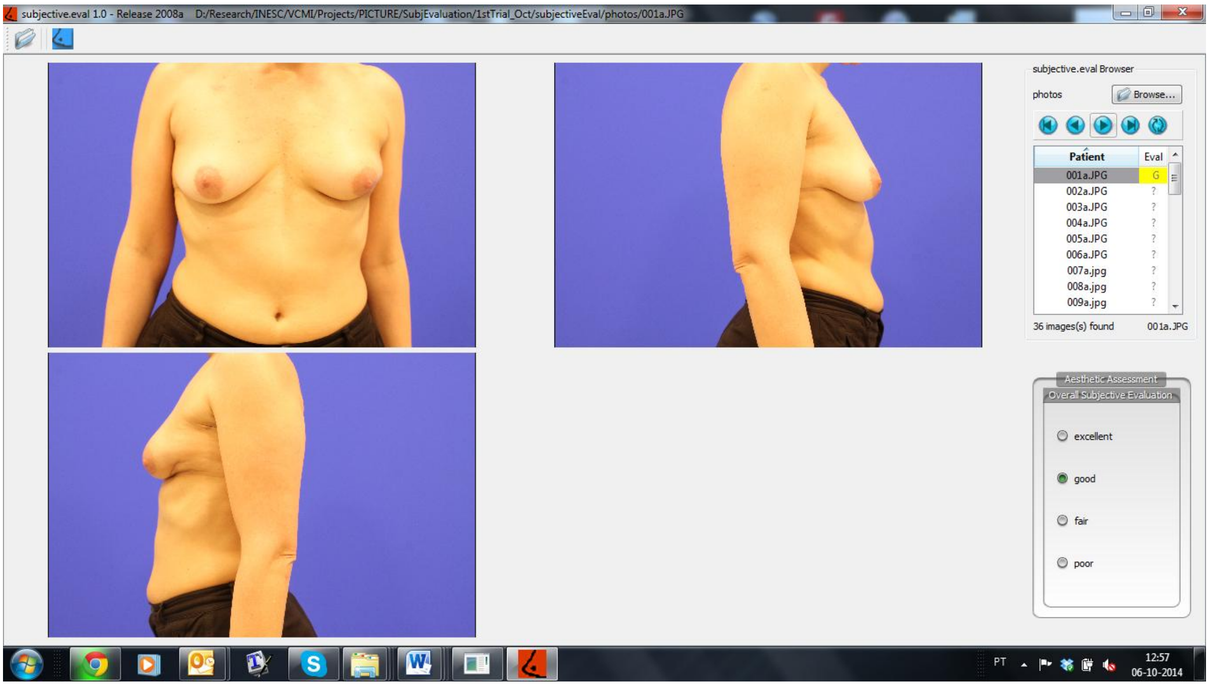

Figure 1 – 2D images (face and lateral views) for subjective evaluation – Software for experts with 2D case display of all views and classification online

Figure 2 – Microsoft Kinect captured images

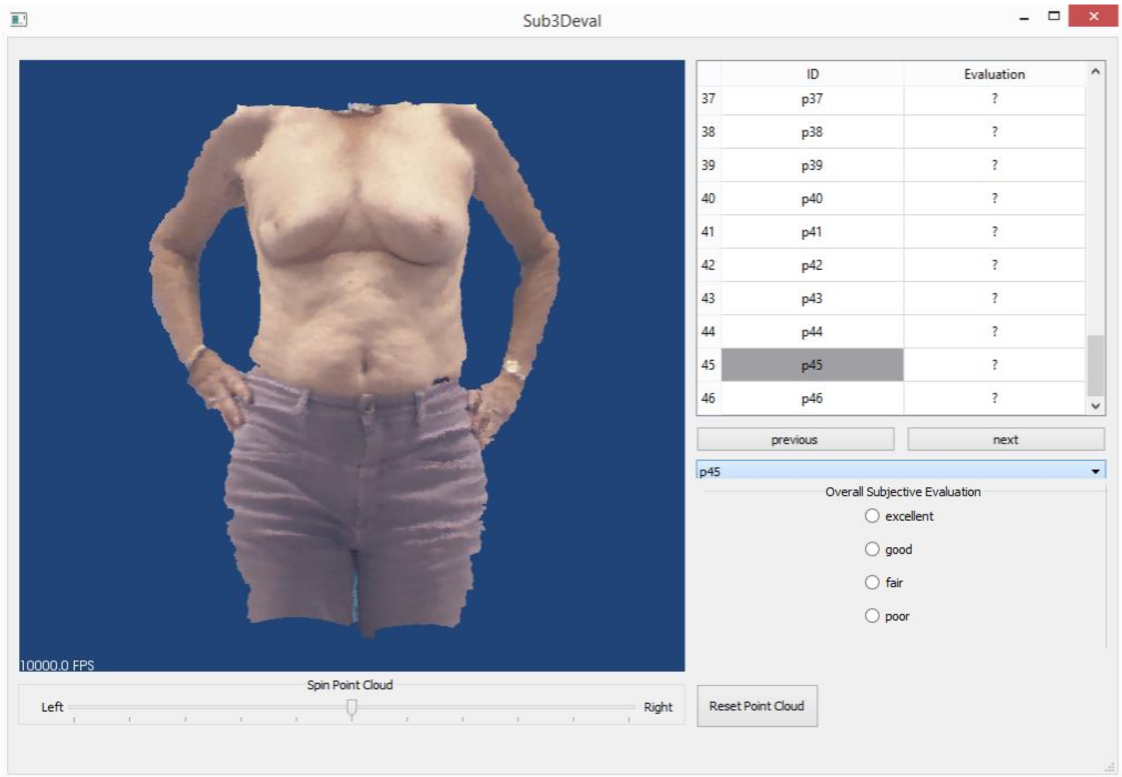

Figure 3 – 3D Model for subjective evaluation – Software for experts with 3D case display allowing subject rotation and classification online

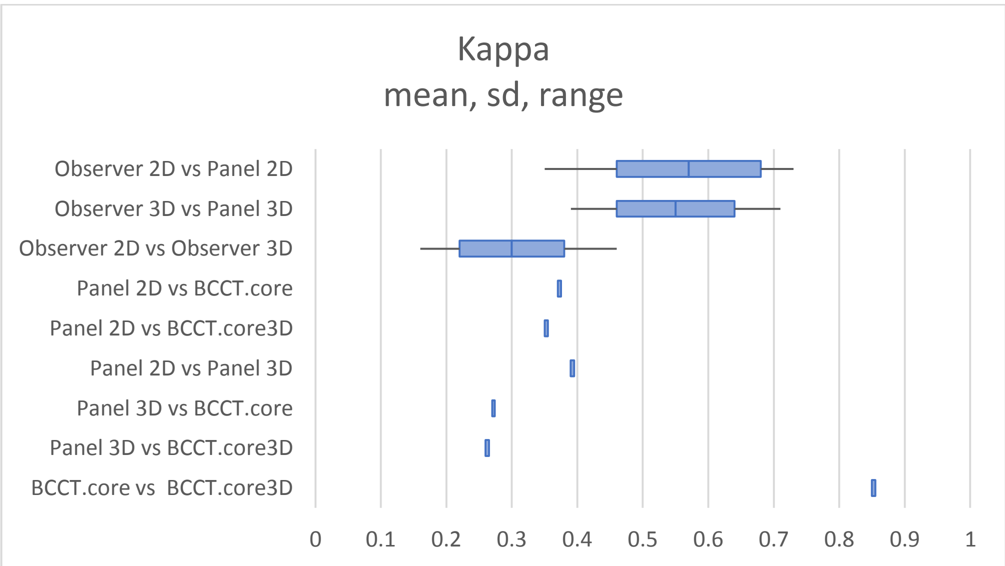

Figure 4 a – Kappa

Mean, Min, Max and Standard Deviation (SD) values - Comparison between panel evaluation with 2D and 3D images, individually and with the consensual classification.

Single value for comparison between consensus classification 2D and the BCCT.core and BCCT.core3D

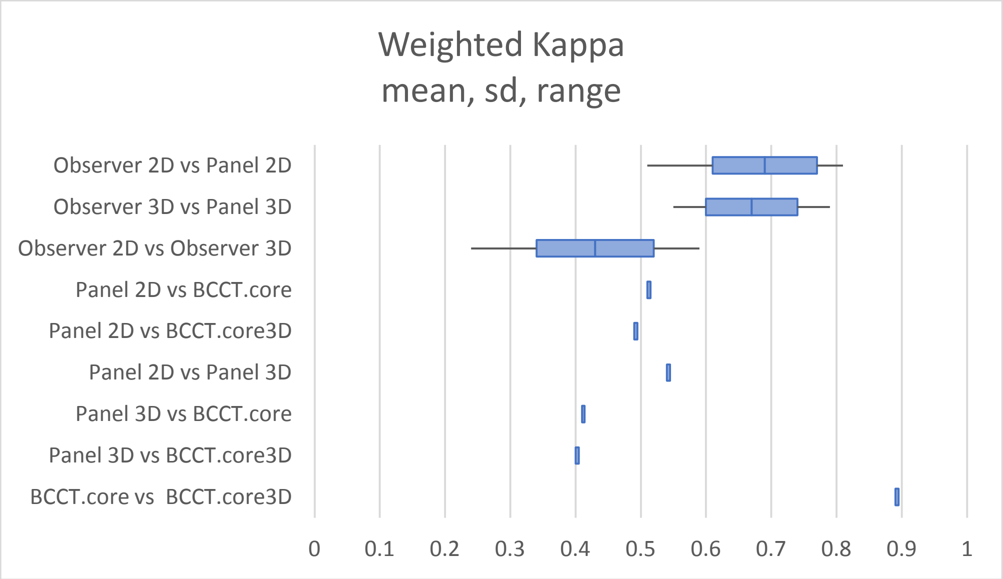

Figure 4 b – Weighted Kappa

Mean, Min, Max and Standard Deviation (SD) values - Comparison between panel evaluation with 2D and 3D images, individually and with the consensual classification.

Single value for comparison between consensus classification 2D and the BCCT.core and BCCT.core3D