MVA2015 IAPR International Conference on Machine Vision Applications, May 18-22, 2015, Tokyo, JAPAN

Automated visual inspection of pharmaceutical tablets in heavily cluttered dynamic environments

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Abstract

We present a framework for automated visual inspection of pharmaceutical tablets in heavily cluttered dynamic environments. A two light camera system is proposed, which acquires two images with different lighting directions. With two images, pose of each tablet in the scene is first estimated. Second, regions that are shadowed or overlapped by neighboring tablets are detected. The final analysis is then performed on the remaining areas of the tablets. The proposed framework was evaluated on a set of real pharmaceutical tablets, imaged with the proposed system inside a rotating drum. The rotating drum simulated the movement of the tablets inside the tablet coating machine. Acquired images were analyzed with the proposed framework and the analysis results were compared with a gold standard, which was prepared manually. With the proposed framework we detected 81% of defective tablets while 5% of good tablets were erroneously classified. The results indicate that the proposed framework is a viable approach for the on-line and in-line analysis of partly diffuse objects.

1 Introduction

In 2004, U.S. Food and Drug Administration (FDA) released a guidance for industry document (PAT - A Framework for innovative Pharmaceutical Development, Manufacturing and Quality Assurance), in which they recommend the use of a quality-by-design paradigm (QbD) in the pharmaceutical industry. The document encourages the pharmaceutical industry to employ new techniques in order to measure critical process parameters on– and in-line, to obtain a better control over the manufacturing processes; consequently, decreasing the risk of faulty products [1].

Visual appearance of the pharmaceutical tablets is one of the important quality parameters, which is nowadays controlled by automated visual inspection machines after the manufacturing process [2, 3]. With the PAT initiative in mind, a part of the automated visual inspection could be integrated to the production lines, enabling a detection of faulty products early enough to be able to take an appropriate action. For example, most of the tablets produced undergo the tablet film coating process. During this process, a thin layer of coating is applied to the batch of mixing tablets by tablet coating machines. The quality of the tablet's coating is a critical process parameter as it can influence the operation of the active pharmaceutical ingredient inside the tablets. Because coating defects are often visible, it should be possible to integrate a visual inspection device into the existing coating machines, analyze the visual appearance of the tablets during the process and provide a feedback about the process. For example, missing parts of the coating on the tablets can indicate that the spray rate of the coating process is too high [4]. In addition, the statistics about the overall quality of the batch could also be obtained that way.

Automated visual inspection of the tablets in heavily cluttered dynamic environments is a challenging problem. It cannot be solved using a traditional, state of the art approaches that require that the tablets are precisely positioned and imaged in controlled conditions [2, 3]. An innovative solution is required, which can estimate unknown tablets' poses and can deal with the presence of the shadows and the mutual overlapping of the tablets.

Given only one image of the scene, it is hard to determine tablets' poses in a cluttered environment. Additionally, it is not feasible to determine, whether the imaged appearance of the tablets is a result of their real appearance, or it is distorted by shadows and occluded by the neighboring tablets. Applying algorithms like the ones proposed in [2, 3] without taking shadows or occlusions into account would result in a very high number of false positive classifications.

We present a framework for an automated visual inspection of the pharmaceutical tablets in heavily cluttered dynamic environments. In this framework, we propose a system composed of a high-speed camera and two lights placed at different directions. The system is able to acquire two images of the same scene with different lighting direction in a very short period, so that the movement of the tablets between the two consecutive frames is negligible. Given the two images we are able to estimate tablets' poses, detect areas on the tablets that are shadowed or overlapped and finally perform the analysis of the surface of the tablet with shadowed and overlapped areas removed.

2 Method

Automated analysis of the tablets in the imaged scenes is performed for each pair of the acquired images in four successive steps:

(1) calculation of the projections of the tablet's surface normals

(2) detection and pose estimation of the tablets

(3) detection of the shadowed and overlapped regions

(4) surface analysis

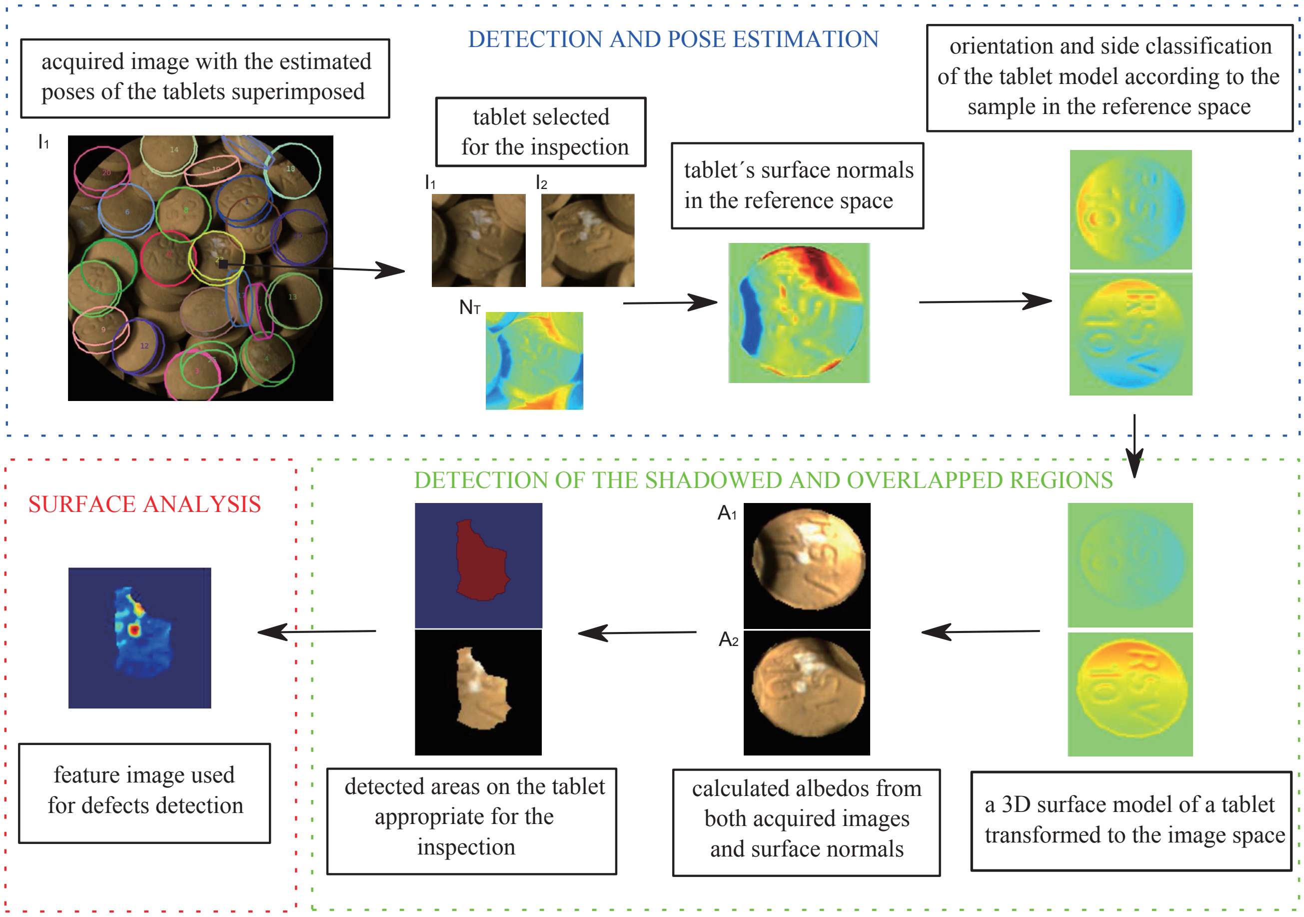


Figure 1: The proposed framework for the analysis of pharmaceutical tablets in heavily cluttered dynamic environments. A two light camera system is used to acquire two images of a scene with different lighting directions. Locations and out-of-plane rotations of the tablets are estimated given the two images. In order to compensate for out-of-plane rotation, each tablet is transformed to the normalized space, where rotation around the z-axis of the tablet is determined and side of the tablet is classified. Shadowed or overlapped regions on each tablet are detected by transforming a detailed 3D model of a tablet by an estimated pose to the image space and by comparing two albedo images, which can be calculated given the model of the tablet and the two acquired images. Finally, the analysis of the tablet's appearance is performed on the remaining regions.

2.1 Calculation of the projections of the tablet's surface normals

Given an assumption of a Lambertian scene, we can calculate surface normal projections with a modified photometric stereo technique [5]. Here, we calculate only the projections of surface normals N_T to the plane T, because we use only two images I_1 and I_2 of the same scene illuminated from two different directions $\vec{L_1}$ and $\vec{L_2}$. For each image pixel $I1(x, y)$ and $I2(x, y)$, we can calculate the corresponding surface normal projection N_T to the plane T by solving the following equation:

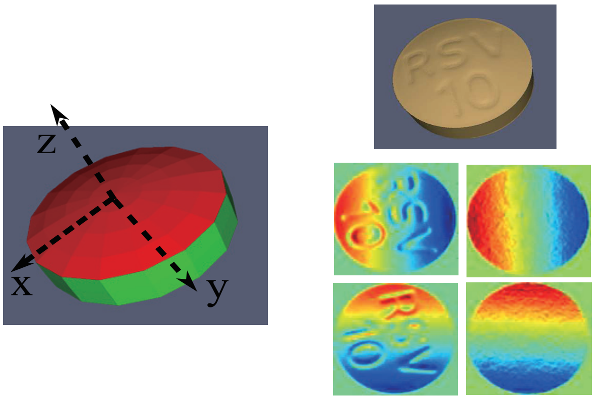
$$[I_1(x,y) \quad I_2(x,y)] = A_s(x,y)\, \vec{N_T}^T(x,y)\, \left[\vec{L_1} \quad \vec{L_2}\right], \quad (1)$$

where A_s is a combination of an albedo image affected by the shading (due to the geometry of the scene). The calculated projections of surface normals and the shadowed albedo provide additional information about the imaged scene; consequently, improving both the pose estimation accuracy and the accuracy of the surface analysis.

2.2 Detection and pose estimation of the tablets

We use an algorithm proposed in [6] to detect locations and estimate out-of-plane rotations of the tablets in the scene. This algorithm requires an approximate a priori knowledge of the tablet's shape in a form of a 3D CAD model (figure 2a). In industrial environments, the model is often already available. Otherwise, it can be easily created with any modern CAD software.

The pharmaceutical tablets often include an embossing that can be different on both sides of the tablet [7, 8]. Therefore, to recover the full pose of the tablet, it is also necessary to classify which side of the tablet is visible and estimate the rotation around the z-axis. In order to compensate for the out-of-plane rotation, each tablet is transformed to a normalized space, where the rotation around the z-axis of the tablet is determined and side of the tablet is classified. The transformation is performed with the approximate 3D model (figure 2a) and the estimated out-of-plane rotation of the tablet.



(a) (b)

Figure 2: A simple 3D model used for the detection and out-of-plain rotation estimation of the tablets on the acquired images (a). A detailed 3D model of tablet's surface including the information about the embossing (b). The detailed model is used for the estimation of the rotation of the tablet around its z-axis and for tablet side classification.

In the normalized space, we estimate the rotation around the z-axis of the tablet using an algorithm described in [8]. Transformed normals are compared to reference models of both faces (figure 2b) of the tablet at different model orientations. The angle that produces the best match defines the estimated rotation and the side of the tablet. Pose estimations that produce fits with bad scores are excluded, because low score usually indicates an inaccurate pose estimation. Note that the reference model used for classification and rotation estimation around z-axis differs from the model used for tablets detection and out-of-plane rotation estimation. The model used here is a detailed representation of imaged tablets. It contains both a depth map and the corresponding surface normals and holds the detailed information about the shape of the imaged tablets, including the embossing, separately for both sides of the tablets. It has to be obtained from the designer of the tablets or produced manually.

2.3 Detection of the shadowed and overlapped regions

Once the full pose of the tablet is determined, we detect the potentially shadowed or occluded regions on the tablet. First, we transform the detailed reference surface model of the tablet using a 3D transformation, describing the full pose of the tablet; the transformed model contains the reference surface normal directions for the region of the currently inspected tablet. Second we use the equation 2, that describes a relation between the image intensities I_1 and I_2, the image surface normals $\vec{N}$ and the image albedo. We calculate the albedo of the tablet's area from the estimated normals and acquired images. With two images of the same scene, we can calculate two different albedos A_1 and A_2:

$$\begin{aligned} I_1 &= A_1\, \vec{N}\, \vec{L_1}, \\ I_2 &= A_2\, \vec{N}\, \vec{L_2}. \end{aligned} \tag{2}$$

In an ideal case, when the imaged tablet would not be shadowed or occluded on any of the captured images, both calculated albedos would be the same. By contrast, when albedos A_1 and A_2 differ, shadows, occlusions, or both are present. Therefore, we can detect and mask shadowed or occluded areas by detecting the areas where both albedos differ by more than a certain threshold.

2.4 Surface analysis

It is much easier to inspect the tablets once the areas with shadows and overlapped parts of the tablets are removed. These areas can be masked and the analysis of the tablet's surface can be performed only on the remaining areas that contain no shadowed of occluded areas.

Theoretically, the most appropriate way to analyze the object's appearance would be to inspect calculated albedo images A_1 and A_2, because these images contain only the information about the color of the tablet. Any deviation in the albedo images A_1 and A_2 then indicates the visual defect. The projections of surface normals in one direction that are obtained by photometric stereo, could also be used and compared to the final estimated normals in both the horizontal and the vertical direction. Different features can be calculated from these two images. For example, the ones proposed in [2]. We do not limit our framework to any of them, as the selection of the most appropriate feature is by our opinion a problem specific task.

3 Experiment and results

3.1 Setup

The performance of the proposed framework was evaluated with the setup shown in figure 3. A rotating drum was used to simulate the movement of the tablets similar to the real coating pans in the industry. The recording setup consisted of a color Basler industrial camera, a telecentric lens and two LED lights positioned at angle of 40° from the camera view. Two sequential images were captured inside a 600 μs time interval with an overlapping exposure mode. That way, the movement of the tablets between two sequential images was less than one pixel. Additionally, we removed specular reflections with cross-polarization filters (a polarizer on both the camera and the lights).

Figure 3: A rotating drum was used to simulate the movement of the tablets similar to the movement in real tablet coating machines.

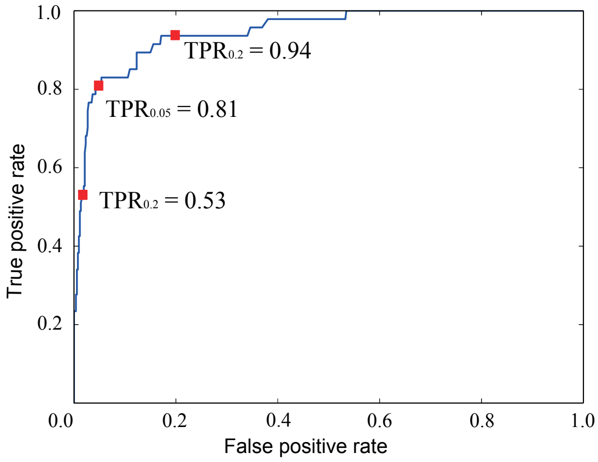


Figure 4: ROC curve, presenting the classification results. Manually prepared gold standard was used for the evaluation of the results that were obtained by automated analysis. Three TPRs for different values of FPRs are also plotted beside the ROC curve.

The illumination directions were obtained with a calibrating metal sphere.

With the described setup, we recorded and analyzed a real batch of pharmaceutical tablets. The batch included tablets with defects that occurred during a real tablet coating process.

3.2 Implementation details

Proposed procedure was implemented in a Python programming language. Images of the tablets in a rotating drum were acquired in advance and analyzed off-line. We used a manually set threshold to determine the shadowed or overlapped regions from the difference of both albedo images, calculated as shown in the Method section. We performed additional morphological dilation of these regions in order to make the analysis more robust. For the analysis, we used the shadowed albedo image A_s calculated using the equation 1. The feature image for defect detection was calculated as a blurred difference between shadowed albedo image and its median value. Maximum value of this feature image was used for the classification.

3.3 Evaluation

The proposed framework was evaluated on 500 images of the pharmaceutical tablets, of which approximately 450 were good and 50 were tablets with visible defects. Poses of these tablets were estimated by the pose estimation step and their surfaces were analyzed with the proposed automated approach. Same images were manually inspected and classified as good or bad. Manually obtained ground truth results were used to evaluate the automated ones.

3.4 Results

By comparing the automated classification results with the ground truth results, we obtained a Receiver Operating Characteristics (ROC) curve (figure 4). This curve shows the relation between the true positive detection rate (TPR) and the false positive detection rate (FPR). Additionally, an evaluation criterion TPR_{fpr} is marked on the ROC curve for three different $FPRs$.

4 Conclusion

In this paper, we present a framework for automated visual inspection of pharmaceutical tablets in heavily cluttered dynamic scenes. A two light camera system is used for image acquisition. This system can acquire two images illuminated from two different directions in a period that is short enough so that the tablets' movement is negligible between two consecutive frames. Two successive images enable extraction of additional information (projected surface normals) that improve the pose estimation accuracy and enable detection of shadowed and occluded tablet regions.

The proposed framework was tested on a real set of pharmaceutical tablets. Tablets were captured with the proposed recording system in a rotating drum, which simulated the movement of the tablets in the tablet coating machine. The results indicate that the proposed framework is viable for in- and on-line process analysis.

It is crucial for the performance of the system that the imaged area is illuminated as homogeneous as possible and that lights are as strong as possible because this enables shorter exposures times and thus less time needed for the acquisition of a two sequential frames. Angle of the lights used is another factor that affects the performance of the system, because it directly affects the accuracy of the surface normals estimation. The future work will be directed into improving the image acquisition system. Moreover, we will evaluate the proposed framework on a real production line in the pharmaceutical industry.

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