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DEVELOPMENT OF A MOBILE MEDICAL APPLICATION FOR IMAGING AND ANALYSIS OF ARTHRITIS OF THE HAND

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ABSTRACT

This project introduces a new smartphone and tablet deployable mobile medical application that utilizes device sensors, internet connectivity and cloud-based image processing to document and analyze physiological characteristics of hand arthritis. The application facilitates image capture and performs image processing that identifies hand fiduciary features and feature metrics to report and quantify the progress of arthritic disease. In addition to describing this process, we discuss the technical issues and regulatory challenges related to development and deployment of mobile medical applications with reference to the 2013 FDA Final Guidance on Mobile Medical applications, HIPA requirements, and compliance with the ISO/IEEE 11073-10201 Domain Information Model (DIM) standard for integration with personal or institutional health records.

INTRODUCTION

Arthritis is one of the most common health problems affecting people throughout the world. It is a goal of this work to provide individuals who may be developing or have developed arthritis, digital tools to assess and monitor the progress of their disease using their smartphone or tablet as a mobile medical device.

Hand arthritis primarily affects the articulating joints of the hand and can cause pain, deformity and moderate to severe disability. Hand arthritis is actually many diseases but is grouped into two main types; osteoarthritis (OA) and inflammatory arthritis (IA), (including rheumatoid arthritis). While radiographic features of OA are found in 67% of women and 55% of men 55 years and older, symptomatic OA is less prevalent 0. Recent studies have shown that erosive OA of the interphalangeal (IP) joints is an important subset of OA because it causes significant functional impairment and pain. While not as severe in terms of pain and disability as IA, painful erosive OA has a greater impact in the general population [2]. One of the common features of symptomatic erosive OA is inflammatory episodes in the early course of the disease that result in swelling and tenderness and this condition is sometimes referred to as inflammatory OA. This swelling and tenderness manifests in the nerves, blood vessels and supporting matrix that supplies the synovial membrane that encapsulates the joint and produces the synovial fluid that lubricates the joint. It can be assessed by visual observation and palpation, and by quantitative measurements of grip strength. Many research reports have attempted to quantify and correlate radiographic measurements, functional measurements and patient questionnaires [3]-[6]. Treatment remains primarily palliative with very few surgical interventions such as IP joint replacement or fusion. Symptomatic rather than radiological presence of OA remains the primary indicator of the need for intervention, in most cases by pain control medication.

There have been a number of research initiatives to use optical methods to analyze IP joint disease including optical coherence tomography, diffuse optical tomography, laser trans-illumination imaging, photo-acoustic tomography and digital imaging of both hands and radiographs [7]-[12]. In many areas of disease the understanding of the interaction of light and tissue and its application in diagnosis has expanded rapidly. These techniques have historically required specialized equipment for measurement and interpretation. With the advent of wireless mobile computing devices such as smartphones and tablets this constraint is rapidly changing. Mobile devices are becoming part of the health care ecosystem and applications for smartphones and tablets are proliferating rapidly. The use of imaging and other sensors in smartphone applications is now common for the majority of the population in the developed world and many in the developing world.

Coincident with universal deployment of smartphones, is the development and ongoing standardization of the electronic health record as well as the evolution of legislative guarantees of personal access to health records and privacy requirements for agencies transmitting and using electronic health records. [13]-[16] These provide ways in which an individual can now have greater autonomy in how they engage with their health providers or payers and have access to their health records. This has also resulted in the evolution of the personal health record services now offered by major telecom and software companies, including Microsoft [17].

Active patient participation in the management of their disease has been shown to reduce the perceived pain and disability and provide a greater sense of well-being [18].

We have developed a smartphone application that allows an individual concerned about or experiencing the symptoms of arthritis to use their smartphone to collect information and to make measurements of their hands which can be analyzed to identify changes in the anatomy of the hand that are inconsistent with normal expectations and to track these changes over time. This application is intended to collect sensor data from the smartphone and to analyze and correlate this with biographical information, experiential measures of pain and movement, medication use, weather and regional demographics. It is intended to integrate with existing health record systems compliant with the ISO/IEEE 11073 standards, meet HIPA/HIPAA and other privacy standards and connect to personal health records, like Microsoft HealthVault.

The first phase of this development is the creation of a prototype app on a smartphone that collects basic biographical information, captures and calibrates images of the hand, performs anatomical analysis of the calibrated hand image to identify key fiduciary features and reports and tracks these measurements over time. The analysis will identify key features of hand arthritis such as the presence and location of Heberden or Bouchard nodes, angular deviation of the phalanges at the IP and phalange-metacarpal joints and other characteristic features of OA or IA. Individuals may provide their personal physician, or other health providers, access to this information via their personal health record.

The second phase of this development will incorporate biographical and environmental data to provide graphical reports of correlations between individual pain, hand appearance, weather, location, age, and gender, and comparison to typical expectations of those who are without symptoms comparable symptoms, etc.

MATERIALS AND METHODS

Our system consists of two distinct parts: a mobile application that acts as an interface for the user, facilitates image capture, creates patient profiles and displays analytical results, and a Cloud server that stores patient profiles, provides image and data management and performs image processing as shown in Figure 1.

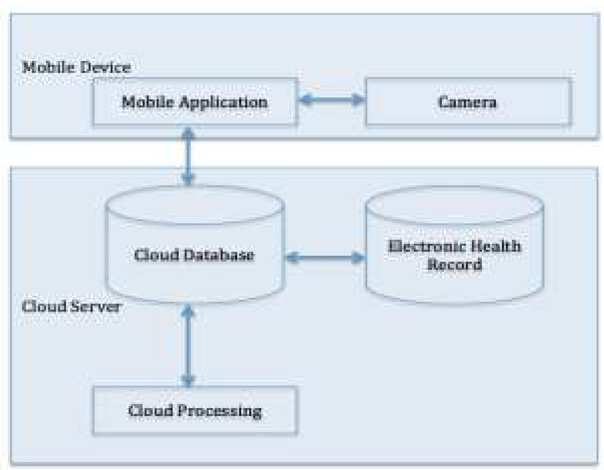

Figure 1: Mobile application processing flowchart

The mobile application uploads image and sensor data and receives analysis reports from the Cloud server. New users create profiles that comply with electronic health record standards to facilitate communication with common electronic health record service providers such as the Microsoft HealthVault. This functionality enables integration with other platforms that may provide or accept complementary data such as ongoing medication, weight, pain, blood pressure, etc. for correlation and review of changes over time.

Host device app design

The core implementation of the Android, iOS and Windows apps have been subcontracted to development teams that specialize in this type of deployment. The concept development for the user interface was developed using wireframe methods. Wireframes are mockups of screens with operating system standard controls that can be tested using html to get feedback on user interaction and flow.

Our team used the *justinmind Prototyper* software to design and simulate the user mobile application experience. Running simulations for multiple interface designs and data representations helped us optimize the flow of information to the end user.

Image Capture

The system uses the default onboard camera device of a smart phone to capture images of a subject's hand for processing. People will always take pictures differently and under various lighting conditions. Our image processing methods attempt to minimize dependencies on image capture conditions; however we do require some constraints on the parameters of the image to be analyzed. These include capture against a white background, preferably a standard letter or A4 sized sheet of printer paper. The hand needs to be oriented correctly, relative to the paper. It must be within the bounds of the paper and the wrist should cross one of the short sides of the paper at approximately the middle (see Figure 2).

Guidance in the form of correct and incorrect example frames is given before the application proceeds to the image capture function to ensure that image data conforms to the layout requirements of the processing algorithm.

Cloud Database

Image and user data is stored on a Cloud database server that interfaces with a Cloud image processing server. The image processing server is responsible for analysis of patient images and transmittal of analysis data to the Cloud database server. Housing both the database and image processing software on Cloud servers minimizes latency, automates scalability and provides a secure environment. These servers also provide large-scale infrastructure for data management, maintenance, security and backups.

Major Cloud service providers permit the deployment of applications that meet industry-specific certification requirements, which includes HIPAA-compliant healthcare applications. The ability to conform to HIPAA enables interfacing with secure health information systems such as the Microsoft Healthvault and updating secure patient data.

Cloud Processing

We chose to execute processing on a Cloud server due to the challenges that arose when attempting implementation of image processing function using mobile device native processors. Some of these problems were due to the lack of compatible functions provided by the software development toolkits for Android, Apple and Windows mobile device operating systems compared to desktop computer environments. An example of this would be OpenCV functions (for Java and C++) in desktops that do not port into the smart phone environment. Cross-platform implementation of core algorithms natively also requires ongoing update for new devices and operating systems. Hosting the core algorithms on a Cloud server and programming more simple front-end applications for the mobile device enables us to circumvent this issue. In addition, working with one standard program ensures that the development team

Figure 2: Mobile GUI for image capture.

would be able to offer a consistent system across all mobile platforms. Furthermore, limited memory and compatibility difficulties associated with older devices would bottleneck onboard device processing. Therefore, our team determined that a Cloud server would be a feasible avenue for implementation.

Algorithm Development

Our team chose to develop the image processing algorithms in MATLAB due to the robust toolboxes and comprehensive documentation provided by the environment.

The image processing software deployed on the Cloud server is an executable based on the MATLAB code but optimized for server deployment. We have tested the cloud functionality by installing the compiled processing software as an executable running on a virtual server on the Windows Azure cloud platform.

The algorithm performs the following core functions: Resizes the image to a standard size; Spatially calibrates the image; white balances the image; converts the image to a color space suitable for segmentation; extracts hand border coordinates for analysis; analyzes the border data to provide image coordinates of anatomical fiduciary points. These include coordinates of finger-tips, finger vertices, finger centerline coordinates. The algorithm determines finger width along the centerline, finger joint coordinates, and from the anatomical fiduciary points measures other features. These include finger spacing, size of the hand, width of the fingers, location and size of joints, length of fingers, angulation of fingers, angular deviation at joints, identification of Heberden nodes, and identification of Bouchard nodes

Once these anatomical features are located they can then be correlated to user biographical and demographical information information, including, age, sex, family history, location, pain, mobility, medication, hormonal status, any co-existing arthritis in other joints, blood pressure, local weather, weight, height, BMI and other environmental or statistical risk factors.

RESULTS AND DISCUSSION

The initial phase of processing performed color correction by white balancing using the white paper background as a reference. The image was then transformed to a color space appropriate for segmentation, and the hand was segmented from the background using K-means clustering. The image was then segmented the hand from the background. Boundary details were extracted for analysis and an outline was drawn for clarity as shown in Figure 3a.

By detecting the finger tips and vertices on the hand (Figure 3b), we were able to isolate and label each finger, obtain centerline (Figure 3c) and joint coordinates (Figure 3d), and finger width along the centerline. A graph of boundary coordinates was generated that mapped out the change in width of fingers to identify location and size of joints. Image coordinates of anatomical fiduciary points were then located, differentiated and illustrated (Figure 3e).

The 4 sets of hands used for processing encompassed both genders, an age group ranging from 24 to 50+, and individuals with and without arthritic symptoms to enable testing of regular and irregular features. Based on the analytical results it is evident that the algorithm is capable of isolating the hand from the background and extracting an appropriate boundary. Although a basic step, it is crucial that the boundary information is correctly gathered for accurate results from the following processes. Optimizing the initial image processing led us to develop some basic user guidance for image capture that could reduce complications in processing. We decided to guide the user to pick a standard background (A4 or letter size white paper) and to indicate which size they would use in their profile. The use of a known size rectangular background gave our team four reference edges to correct lens caused distortion by warping the image and for image spatial calibration.

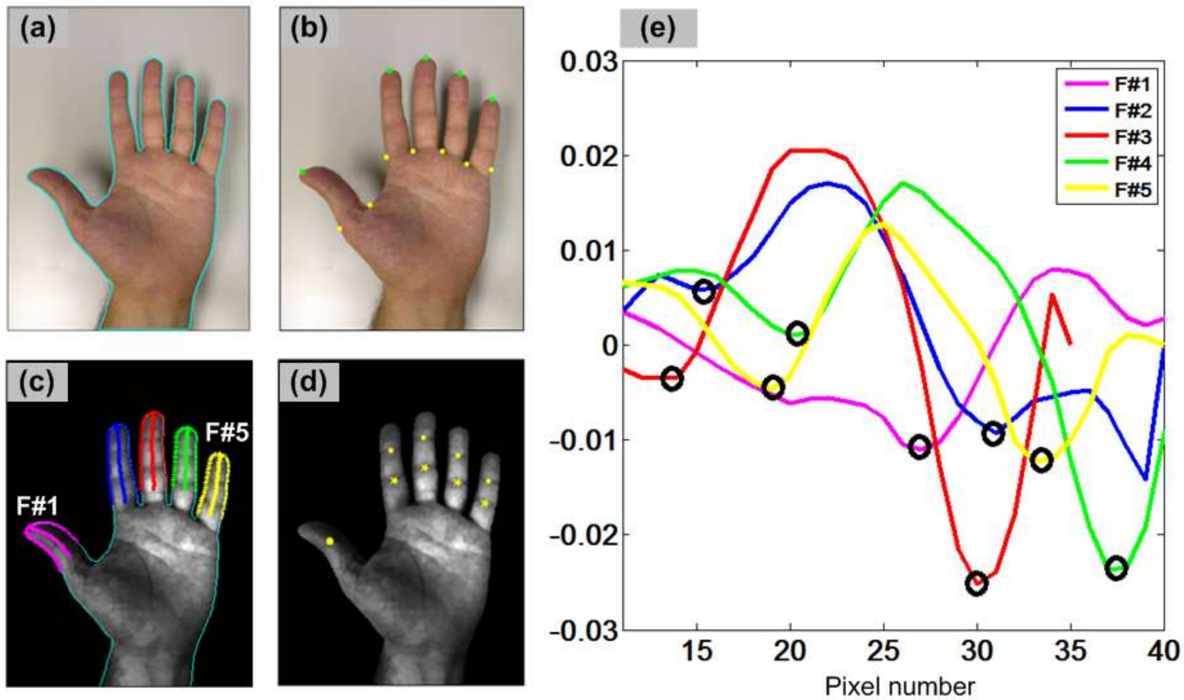

Figure 3: (a) RGB color image of hand with detected boundary overlay; (b) finger tips and vertices extracted from boundary information; (c) finger centerlines and boundary coordinates; (d) finger joints coordinates; (e) relative grayscale intensity map at finger centerlines to obtain finger joint locations (black circles)

The corrected image of the hand was separated form the background using color space conversion and a clustering algorithm to create a binary image of the hand [19].

A boundary tracing algorithm was applied to generate a linear array of sequential boundary pixels [20][21]. The boundary pixel data was analyzed to identify the fiduciary points. The vertices enabled us to label and isolate each finger for independent processing whereas the fingertips were used as a reference point to extrapolate the centerline

By quantifying the distance between the centerline and the finger boundary, we were able to quantify relative finger thickness. Using the other fiduciary points as references a number of anatomical features can be identified and measured including pathologies like IP joint angulation, Heberden and Bouchard nodes and other abnormal changes in width that could be indicative of inflammation. It is also possible to identify other features not limited to just the image silhouette. It is possible to computationally identify features by using the fiduciary points as reference locations and then analyzing the intensity data in color or gray scale images to determine features such as joint locations along the finger center line axis. This can be extended to identify other characteristics in the image such as specific hand creases and other geometric relationships.

CONCLUSION

This prototype image analysis system for hand arthritis demonstrates that while current mobile device processors are limited in the ability to execute some complex matrix based image analysis algorithms, cloud deployment of these algorithms can provide useful measures of anatomical features for applications that can be deployed on mobile devices such as smartphones and tablets.

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