4.4.4 BP Monitoring during Dialysis at the University of Virginia Kidney Center

As part of a study at the University of Virginia Kidney Center 45 chronic kidney disease (CKD) dialysis patients were evaluated. The UVA main dialysis unit is comprised of 5 pods with each pod able to dialyze 6 patients simultaneously. After obtaining informed consent baseline blood pressure was obtained at the start of the dialysis treatment and then assessed every 15 minutes for the first hour, every half hour for the second and third hour and then every 15 minutes during the last hour of dialysis. All patients typically are dialyzed either sitting or reclining in a dialysis chair but begin dialysis in the sitting position.

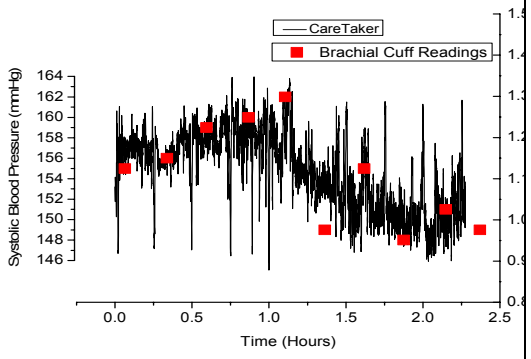

Figure 1: Trends in brachial cuff systolic pressure (red squares) and P2P1 over a 2.25 hr dialysis session (patient 17).

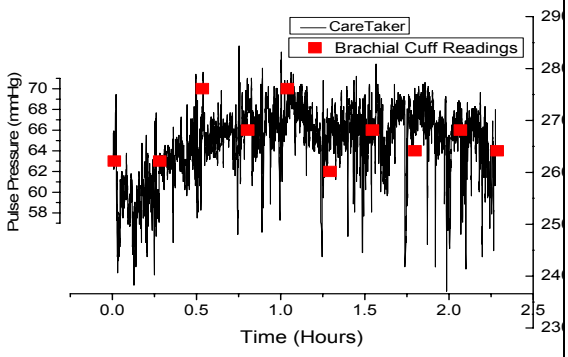

Figure 2: Trends in brachial cuff pulse pressure (red squares) and T13 over a 2.25 hr dialysis session (patient 17).

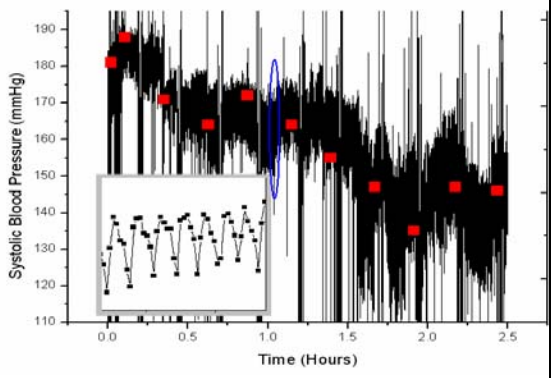

Figure 3: *Trends in brachial cuff systolic pressure (red sq.) and P2P1 over a 2.25 hr dialysis session (pt. 24). Detail inset displays inspiratory-based modulations.*

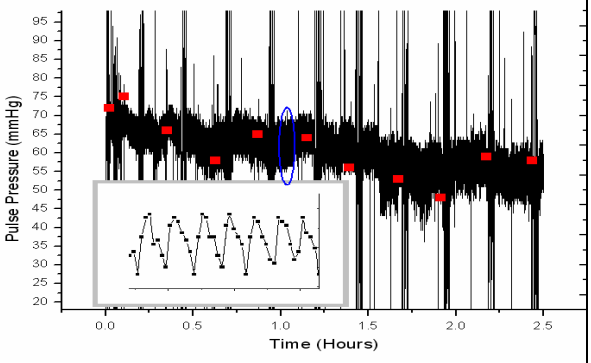

Figure 4: *Trends in brachial cuff pulse pressure (red sq.) and T13 over a 2.25 hr dialysis session (pt. 24). Detail inset displays inspiratory-based modulations.*

Changes in position were based upon patient preferences or the need for Trendelenberg for severe inter-dialytic hypotension. No changes were made in the routine management of the dialysis patients nor were any additional standard laboratory values taken during or after dialysis other than routine dialysis labs or emergent labs based on their clinical condition. Most patients had their dialysis through their non dominant arm and blood pressure was taken from the contralateral arm so as not to occlude their dialysis access. Blood flow, dose and duration of dialysis were according to standard practice and were

not altered for the study. Typical dialysis lasted 4 hours during which time the CareTaker recorded measurements. Each patient was monitored once. Besides blood pressure and pulse monitoring, demographic data including age, gender, race and ethnicity, cause and duration of ESRD, prior history of other vascular disease, weight, height and BMI, tobacco use, socioeconomic status was also collected.

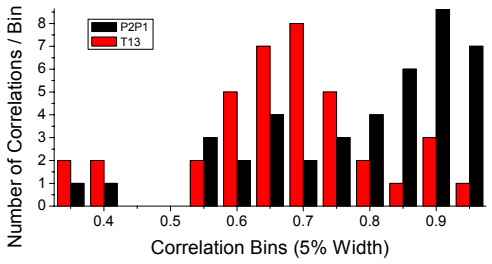

Figure 5: Distribution of correlation coefficients for P2P1 / cuff systolic pressure (black) and T13/cuff pulse pressure (red).

As an example, **Figures 28 & 29, 30, & 31** presents systolic and pulse pressure measurements, respectively, obtained from the brachial automatic cuff as well as the corresponding pulse parameters P2P1 and T13 obtained from the PDA algorithm during a 2.5 hour dialysis run of patient 17. Comparable temporal trends in systolic pressure can be seen in the evolution of P2P1 and the same appears to hold for pulse pressure and T13.

The original plan was to examine different groups of dialysis patients, separated according to their history and presence of diabetes and hypertension. In light of the comparison results of the automatic brachial cuffs with the aortic catheter as well as the LBNP experiments, which demonstrated the cuffs' large variability in readings, it was decided to instead analyze all patient results together since the primary aim of the study was to validate the PDA technology as a generally applicable continuous blood pressure monitoring technology. Data from one patient with Parkinson's disease could not be analyzed as the patient's tremors introduced too much noise. In two other patients sections of the data run were corrupted because inappropriately sized finger cuffs were used. Overall analyzable signals were obtained about 92% of the time.

For individual patient runs the systolic pressure determined by the automatic cuff and the PDA P2P1 ratio determinations based on the CareTaker data were linearly correlated. Similarly, correlations between cuff-based pulse pressure and the PDA T13 parameter were determined. These correlations ranged from 0.98 to 0.38 (mean: 0.78) in the case of P2P1 – systole correlations and 0.96 to 0.37 (mean: 0.67) in the case of T13 – pulse pressure correlations. **Figure 32** presents a histogram, with 5% bins, displaying the distribution of the correlation coefficients. Given the effectively summed uncertainties of determining systolic and diastolic blood pressures with an automatic cuff, the poorer correlations for pulse pressure are not surprising.

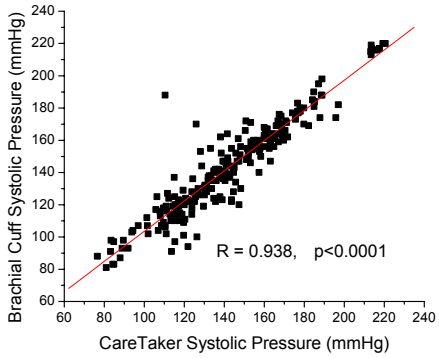

Figure 6: Overall correlation of systolic pressures from dialysis runs.

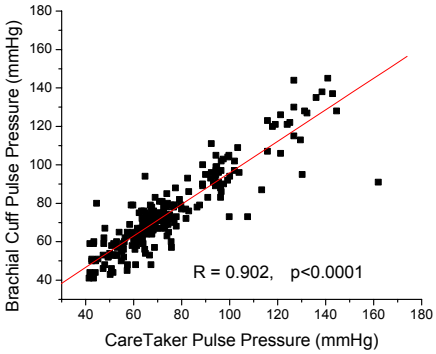

Figure 7: Overall correlation of pulse pressures from dialysis runs.

Figures 33 and **34** present the overall results of correlating the dialysis runs. Paired readings were obtained by using the correlations obtained above to convert P2P1 and T13 determinations into systolic and pulse pressures, respectively. This procedure anticipates how the PDA technology will be implemented in field settings, which will involve calibration and periodic re-calibration using a brachial cuff. Paired two-sample lower-tailed t-tests were used to establish statistical significance. The null hypothesis, which in both cases was that the difference in means exceeded 2 mmHg, could be rejected for both systolic and pulse pressure comparisons at a level of significance of 0.05 (paired systolic: $t = -4.08$, $p<0.00003$, confidence interval (95%): (-2.21, 0.53), power: 0.99), paired pulse pressure: $t = -3.09$, $p<0.0011$, confidence interval (95%): (-1.53, 1.22), power: 0.92).

4.4.4 Conclusions

The principal aims proposed under this project were accomplished.

Wirelessly operating prototypes were constructed and performed flawlessly throughout the various parts of the project. Further improvements to the hardware are currently being implemented.

The physical model of the arterial pulse reflections has been implemented in the PDA algorithm which operates in real time. Since all raw data streams are stored they can be re-analyzed as the PDA algorithm is continually updated.