ANALYSIS OF WOUND IRRIGATION DEVICES

Amogh Pawar and Tony L. Schmitz Department of Mechanical Engineering and Engineering Science University of North Carolina at Charlotte, Charlotte, NC

INTRODUCTION

Wound irrigation is defined as the steady flow of a fluid across an open wound for removal of bacteria, necrotic tissue, and deeper debris [1]. In a wound irrigation process, the surface pressure obtained at the wound is critical. Correct pressure determination ensures that the pressure at the wound due to an irrigation device is enough for the removal of bacteria and foreign debris, but not so high that it causes further tissue damage.

Surface pressure measurements were performed for three irrigation devices, including a 500-ml bottle with four holes in the pouring cap, a 60 ml Monoject[™] COVIDIEN[™] syringe, and an IRIG-8[™] Wound Irrigation System from CENTURION[™]. The irrigation trials were performed by a total of 20 participants consisting of doctors and nurses using the three devices (60 trials) at the Carolina Medical Center Emergency Department, Charlotte, NC. The current literature does not contain a standard pressure measurement method for wound irrigation. It is anticipated that this study will help to standardize irrigation pressure measurement within the medical community.



Figure 1. Target and dynamometer setup.

METHODOLOGY

A setup was designed to perform the measurements and subsequent data analysis. This setup included a 3D printed target (a post that represented the wound area), containers (to catch the fluid after impact), a force Kistler MiniDyn force dynamometer, and a digital single-lens reflex (DSLR) camera to photograph the stream image during fluid application. See Figs. 1 and 2.



Figure 2. Photograph of the experimental setup.

Surface wound pressure was calculated from measurements of: 1) the fluid stream force at the point of impact; and 2) the cross-sectional area of the fluid at the same location. The impact force was measured by the dynamometer, while the impact area was determined from the camera images and subsequent image processing in MATLAB® R2017a.



Figure 3. Time domain force data (F_z) for participant 13. (Top) measured, (bottom) filtered.

Time domain force data for all 60 trials was also analyzed in MATLAB. Measured *z* direction force data for a single trial using the 60 ml syringe is shown in Fig. 3 (top panel). Electrical noise was present in the measured data as well as drift and a DC offset. A 3^{rd} order low pass Butterworth filter with a cut off frequency of 1 Hz was used to attenuate high frequency noise. Drift compensation was completed by finding the slope of the line passing through the fluid impact start time and end time and then subtracting that line from the force data set. Noise filtering, slope removal, and DC offset removal was completed for the measured force in all three directions separately (F_x , F_y , and F_z). The components were then combined vectorially to obtain the resultant force (F). The same process was followed for all 60 trials.

The cross-sectional impact area of the fluid stream was estimated by locating the edges of the stream close to the point of impact from its digital image captured during fluid application. The distance between the edges provided the diameter of the impact area which, in turn, was converted into the cross-sectional area of the fluid. The Canny edge detection algorithm was applied in this study. An edge detection example using the 60 ml syringe is shown in Fig. 4.



Figure 4. Edge detection for participant 13 using the 60 ml syringe. (Top) image, (bottom) result.

The time-dependent fluid stream pressure was calculated by dividing the time-dependent force by the total stream impact area. This was done for each participant using all three irrigation devices. Also, an uncertainty analysis was completed to evaluate the measured pressure uncertainty for each trial.

UNCERTAINTY ANALYSIS

Every measurement result has an associated uncertainty. It is essential to evaluate this uncertainty to fully describe the measurement result. By the law of propagation of uncertainty, the combined standard uncertainty of the dependent variable, or measurand (fluid stream pressure in this case), can be determined by combining the uncertainties in the independent variables (force due to fluid impact and total stream impact area). Equations 1-3 show the pressure equations for the three irrigation devices.

$$P_{1} = \frac{F_{1}}{A_{1}} = \frac{F_{1}}{2\pi \left(\frac{Dp_{d1}}{2p_{D}}\right)^{2}} = \frac{2F_{1}p_{D}}{\pi D^{2}p_{d1}^{2}}$$
(1)

$$P_{2} = \frac{F_{2}}{A_{2}} = \frac{F_{2}}{\pi \left(\frac{Dpd_{2}}{2pD}\right)^{2}} = \frac{4F_{2}pD^{2}}{\pi D^{2}pd_{2}^{2}}$$
(2)

$$P_{3} = \frac{F_{3}}{A_{3}} = \frac{F_{3}}{5\pi \left(\frac{Dp_{d3}}{2p_{D}}\right)^{2}} = \frac{4F_{3}p_{D}}{5\pi D^{2}p_{d3}}^{2}$$
(3)

where,

 $P_{1,2,3}$ = time-dependent fluid stream pressure

 $A_{1,2,3}$ = total impact area of fluid streams

 $F_{1,2,3}$ = time-dependent force

- *pD*1, 2, 3= average pixel count of the post top between edges
- $p_{d1, 2, 3}$ = average pixel count of the impact stream
- D =diameter of the post top/target area

As per GUM [2-3], the combined standard uncertainty of a measurand (which is influenced by input variable uncertainties) is described as the square root of the sum of the products of squares of the input uncertainties and the squares of the sensitivity coefficients (i.e., partial derivative of the measurand with respect to the selected input); see Eq. 4, where the correlation between input variables has been taken to be zero. Therefore, to find the combined standard uncertainty the sensitivity coefficients and the standard uncertainties needed to be determined.

$$u_c = \sqrt{\sum_i c_i^2 u_i^2} \tag{4}$$

where,

 u_c = combined standard uncertainty

 c_i = sensitivity coefficient

 u_i = input standard uncertainty

The sensitivity coefficients were evaluated at the mean pressure for each measurement. The method for calculating the mean values of the input quantities (*F*, *D*, p_D , p_d) is described in the following paragraphs.

For *F*, the following steps were used. First, the time interval for the applied pressure was determined. For the pressurized device there is single interval per trial. For the bottle and syringe, however, there were multiple intervals. In all cases, the interval was identified by two points based on the start and end points (Fig. 5 shows an example for the bottle with four holes). The force data for the interval was truncated to contain only force data between these start and end points. The mean force value of the trial was then calculated by taking the mean value of the truncated force data. Equation 5 shows the mean force calculation.



Figure 5. Force for bottle with four holes in pouring cap.

$$F_{m1,2,3} = \overline{x} \left(\overline{x}(F_{t1}), \overline{x}(F_{t2}) \dots \overline{x}(F_{tm}) \right)$$
 (5)

where,

 $F_{m1, 2, 3}$ = mean force value from all intervals $F_{t1}, F_{t2}...F_{tm}$ = truncated force data from *n* intervals

The diameter of the post top (*D*) was measured using a digital Vernier caliper (Mitutoyo CD-6 ASX). This was taken as the mean value. From the post diameter image, the number of pixels between the edges of the post top diameter, p_D , was taken as the mean value.

The mean value of p_d was found by counting the number of pixels between the edges of the fluid stream or by calculating the average number of pixels in the case of multiple fluid streams.

Sensitivity coefficients (c_i) were determined by taking the partial derivatives of the measurand (P in this case) with respect to the input quantities (F, D, p_D , p_d). For the bottle with four holes in the pouring cap, the sensitivity coefficients were calculated using Eqs. 6-9.

$$\frac{\partial P_1}{\partial F_1} = \frac{2 p D^2}{\pi D^2 p d 1^2} \tag{6}$$

$$\frac{\partial P_1}{\partial D} = -\frac{4F_1 p_D^2}{\pi D^3 p_{d1}^2}$$
(7)

$$\frac{\partial P_1}{\partial p_D} = -\frac{4F_1 p_D}{\pi D^2 p_{d1}^2} \tag{8}$$

$$\frac{\partial P_1}{\partial p_{d1}} = -\frac{4F_1 p_D^2}{\pi D^2 p_{d1}^3} \tag{9}$$

Similarly, the sensitivity coefficients were calculated for the syringe device and the pressurized irrigation device by taking the partial derivatives of P with respect to the corresponding input quantities (*F*, *D*, p_D , p_d).

The standard uncertainties (u_i) were set equal to the standard deviations of the corresponding inputs: F, D, p_D , and p_d . The uncertainty in F was calculated form the noise floor of the force data. The force data was truncated between the start of the sampling time and the start of the force interval. The standard deviation of these values was calculated and taken to be the uncertainty in F.

The uncertainty in D was obtained from the specifications for the digital Vernier caliper (Mitutoyo CD-6 ASX) since it was used for the measurement of the diameter of the post top (target area). The value represented as "accuracy" was taken to be the standard uncertainty in D.

The uncertainty in p_D was determined by first calculating the pixel count of 10 rows of values between post top edges at the impact point of the stream. The standard deviation of this range in pixel count values was taken as the standard uncertainty.

The uncertainty in p_d was determined by first calculating the pixel count of a range of values as close as possible to the impact point of the stream. The standard deviation of this range of pixel count values was taken as the standard uncertainty.

Substituting the sensitivity coefficient expressions and the standard uncertainties, the combined standard uncertainty can be written as shown in Eq. 10. The expanded uncertainty (U) was obtained by multiplying the combined standard uncertainty (u_c) by a coverage factor (k). A coverage factor of 2 was selected here; see Eq. 11. Using Eq. 11, the expanded uncertainty values for the 20 participants using the three irrigation devices was calculated.

$$u_{c}(P) = \sqrt{\left(\frac{\partial P}{\partial F}\right)^{2} u^{2}(F) + \left(\frac{\partial P}{\partial D}\right)^{2} u^{2}(D)} + \left(\frac{\partial P}{\partial pD}\right)^{2} u^{2}(pD) + \left(\frac{\partial P}{\partial pd}\right)^{2} u^{2}(pd)}$$
(10)

where,

 $\frac{\partial P}{\partial F}, \frac{\partial P}{\partial D}, \frac{\partial P}{\partial p_D}, \frac{\partial P}{\partial p_d} = \text{sensitivity coefficient} \\ \text{associated with } F, D, p_D, p_d$

 $u(F, D, p_D, p_d) =$ standard uncertainty in

$$F, D, p_D, p_d$$

 $U(P) = ku_c(P)$

where,

U(P) = Expanded uncertainty of mean fluid pressure

k = coverage factor

 $u_c(P)$ = combined standard uncertainty of mean fluid pressure

RESULTS

Figure 6 shows the mean pressure obtained for all 20 participants using the three irrigation devices. The error bars represent the expanded uncertainty (k = 2) associated with each measurement. It is observed that the mean pressure obtained from all participants is the highest for the 60 ml syringe. The bottle with four holes in the pouring cap had the lowest mean pressure. However, the pressure uncertainty for the syringe was also the highest.



Figure 6. Mean pressure for all participants with expanded uncertainty (k = 2) error bars.

Figure 7 displays the mean of all the mean pressures obtained using each irrigation device. It was calculated by taking the mean of the mean pressure for each participant using the selected irrigation device. The error bars represent the mean of the expanded uncertainties.



Figure 7. Mean pressure of all participants with mean expanded uncertainty for the three irrigation devices.

From Figure 7, the mean pressure of all the participants using an irrigation device were:

- bottle with four holes in the pouring cap: 10.28 kPa
- syringe: 80.95 kPa
- pressurized device: 15.50 kPa.



Figure 8. Mean, maximum, and minimum pressures for all participants using the bottle with four holes in the pouring cap.

Figures 8-10 show the mean, maximum, and minimum pressures obtained by the participants using the three irrigation devices. The upper and lower endpoints of the error bars represent the maximum and minimum calculated pressure for the selected participant over all intervals in the trial. For the bottle and syringe, there were multiple intervals, so these maximum and minimum values were selected from all intervals in a single trial. For the pressurized device these values were obtained from the single interval in the trial.



Figure 9. Mean, maximum, and minimum pressures for all participants using the 60 ml syringe.



Figure 10. Mean, maximum, and minimum pressures for all participants using the pressurized device.



Figure 11. Mean force for all trials using the three irrigation devices.

Figure 11 displays the mean force obtained for all 20 participants using the three irrigation devices. For this result, the total stream area was not considered. Rather, the total impact force was considered only.

Figure 12 displays the duration of each trial for all 20 participants using the three irrigation devices. The trial started when the fluid impacted the target area and ended when the full 500 ml of irrigation fluid was dispensed. The mean duration of a single trial was the highest for the 60 ml syringe. The pressurized irrigation device required the least time and was most consistent.



Figure 12. Duration of each trial for all participants using the three irrigation devices.

The mean durations of the trials (i.e., the time taken for a participant to dispense 500 ml using an irrigation device) were:

- bottle with four holes in the pouring cap: 81 s
- syringe: 172 s
- pressurized device: 17 s.

CONCLUSIONS

The purpose of this study was to serve the medical community by studying the pressure imposed on wounds by three common irrigation devices, reporting the experimental techniques, and evaluating the measurement uncertainty. To collect data for the study, 20 doctors and nurses conducted wound irrigation trials using: 1) a bottle with four holes in the pouring cap; 2) a syringe; and 3) a pressurized irrigation device. The motivation for the study was based on a literature review. The current literature does not contain a standard pressure measurement method for wound irrigation. Further, there is no consensus on what pressure is required for proper irrigation. It is anticipated that this study will help to standardize irrigation pressure measurement within the community.

The study results are summarized here. From Fig. 6 it can be observed that the mean pressure obtained from all participants was highest for the 60 ml syringe. The bottle with four holes in the pouring cap had the lowest mean pressure. However, the pressure uncertainty for the syringe was also the highest. Further, the standard deviation of mean pressures

from all participants (as shown in Fig. 7) was the highest for the syringe. The pressurized irrigation device had the lowest standard deviation of mean pressures from all participants.

Observing Fig. 12, the mean duration of a single trial (500 ml dispensation of fluid) was the highest for the 60 ml syringe. The pressurized irrigation device required the lowest time. It was also observed that the standard deviation of trial durations is maximum for the 60 ml syringe and minimum for the pressurized irrigation device.

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