Does an Incision and Drainage Need to be Performed Following Emergency Root Canal Treatment?

A Thesis

Presented in Partial Fulfillment of the Requirements for

the Degree of Master of Science in the

Graduate School of The Ohio State University

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2016

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Abstract

The purpose of this randomized, prospective, single-blind investigation was to compare the efficacy of incision and drainage vs. mock incision and drainage following emergency endodontic debridement of a tooth with a pulpal diagnosis of necrosis accompanied by an acute apical abscess or cellulitis.

Eighty-one adult patients had emergency root canal therapy and were randomly divided into two treatment groups: incision and drainage or mock incision and drainage. During the I&D or Mock I&D procedure pain of incision, drainage, and dissection were recorded on 170-mm visual analog scales. A four day postoperative survey was supplied to patients where daily pain was rated on a 170-mm VAS and pain medication use was recorded.

A significant difference was noted in the male patient population between procedures for the I&D and Mock I&D group where the Mock I&D had significantly lower pain ratings. From the four day postoperative survey a significant difference was seen between gender, day, and group. The male gender had significantly more days that were recorded as a success (as defined by no-to-mild pain and no narcotic use) during the four days postoperatively. A significant difference of successful recordings was noted between the initial days compared to the final days. The Mock I&D group had significantly more successful recordings compared with the I&D group.
In conclusion, the Mock I&D procedure resulted in significantly decreased pain ratings and less narcotic use, when compared to the I&D group in symptomatic patients experiencing an acute apical abscess or cellulitis.
This celebration of my knowledge required great sacrifice, which was probably experienced more by my family than myself. I owe eternal gratitude to my supportive team at home.

Daniel, your unselfish love (and ability to listen to hours of endodontic literature) was never unnoticed.

Lyla, you have brought a perspective to my life that I never knew existed. It is, and always will be, a joy to be your Mother.

Dad, thank you for never losing faith in me and teaching me to take on a little more than I can handle, I love you.

Mom, your soul exudes pure charity, love, and optimism. Thank you for being my personal cheerleader for all these years; it’s my turn to be yours. I love you.
Acknowledgements

Dr. Fowler – Grammar girl, you’ve got the gift. This would not have been possible without you, seriously. Thanks for keeping me focused on the long term perspective, and giving me an encouraging message (with emojis) when needed. I owe you millions of boxes of Trader Joe’s maple leaf cookies for the help you’ve lovingly shared. I’m so glad you’re ‘my person’ because you’ve been my calm in this thesis storm.

Dr. Drum – You have high standards that you exceed, so it’s always been a constant goal of mine to match those efforts. Thank you for recognizing the real priorities in life and truly practicing what you’re preaching. Your genuine care for the residents is so apparent and appreciated. I’ll never forget when you motioned that you ‘cut the cord’ and set me loose. Thank you for guiding us on this endodontic journey!

Dr. Reader – Mr. Ray of Sunshine, it has been such a blessing to have been graced with your infinite wisdom. I love how you can’t contain your wealth of knowledge, and so passionately impart endodontic literature at any opportunity. Thank you for the laughs, and the healthy banter. I’m already getting nostalgic of the residency and our seminars shared with you. You’ve created an incredible endo family that I’m honored to be a part of.

Dr. Nusstein – The amazing amount of knowledge that you store up in your brain astounds me. You’re humble about your talents, one of which is balancing your duties as the chair, which hasn’t gone unnoticed. You’ve taught me to be realistic as I approach these upcoming life changes and I’ll forever remember your skepticism as I cautiously continue my studies of endodontic literature.

Dr. Beck – Your ability to take numbers and give them meaning is incredible. Thank you for presenting such a difficult topic in a way that I can comprehend. You manage so many of us, and do it with ease! Thank you for sharing your light-hearted attitude with me during such a stressful time.

Chase, Tommy, and Daniel – Well boys, we made it! Thank you for being so flexible through it all, I couldn’t have asked for better comrades through the residency.
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Chapter 1: Introduction

Patients without a dentist or access to immediate dental care may present to hospital emergency rooms with dental pain and swelling. They are often prescribed pain medication and antibiotics and referred to a dentist for evaluation and treatment (91). Physicians are not prepared to perform intraoral incision and drainage, it is not known what happens to these patients once they leave the hospital setting.

How do we best serve these patients when they present to our offices for treatment? While reviewing the literature and considering the different techniques to best treat the patients, questions may arise. What caused this swelling to occur? What swellings need incision and drainage? Where and when in the orofacial region is an incision and drainage indicated? How do we perform the incision and drainage procedure? The currently available information on managing these non-serious, localized, intraoral swellings may be unfounded or outdated. A review of the disease process, current literature and text-based treatment options, pain management, and possible alternatives will be discussed in the hopes of improving our approach to providing the highest quality of care for these swollen patients.

To fully understand how the patient contracted the swelling, the progression of the disease must be discussed. Swellings of odontogenic origin may arise from a periodontal, carious, or traumatic event. Most commonly, odontogenic swellings are
related to a carious tooth with a diagnosis of pulpal necrosis. The carious lesion is initiated by oral bacteria coursing through enamel, dentin, and eventually arriving within the small confines of the pulp. Kakehashi & Stanley (1) proved the requirement of bacteria to lead to infection and necrosis of the pulpal tissue. It is now known that not all the causative bacteria can be cultivated, and thus the complexity of organisms involved may be more numerous than we are aware of (2). This presence of bacteria within the canal system, when left untreated, may enter the periapical tissues. Once the bacteria have spread they continue activating surrounding fibroblasts, osteoblasts, and cementoblasts to attract immune cells (neutrophils, polymorphonuclear leukocytes, monocytes, macrophages), and release cytokines via activation of Toll-like receptors initiating the immune response (3). The upregulation of host-derived proinflammatory cytokines, such as IL-1α, IL-1β, TNF-α & TNF-β (the osteoclast-activating factor or OAF) begins the process of killing offending bacteria, and also leads to bone destruction and inflammatory byproduct accumulation. Thus, the periapical abscess formation commences (3).

Bacteria, even though valiantly attacked by the host defense mechanisms, may continue to persist within the periapical tissue of the offending tooth. In some cases this infection is exacerbated with continued bone destruction and growth of the swelling to surrounding tissue spaces. The infection spreads by the path of least resistance through cancellous bone and, in some instances, penetrates the periosteum, and erodes through the cortical plate, entering soft tissue. Once outside the bone, the swelling is then confined by surrounding tissue, bone, and muscle attachments. Depending on the location of the muscle attachment, the swelling may be vestibular or fascial. The
vestibular swelling is the most commonly seen swelling in odontogenic infections and occasionally enters fascial spaces (4). Fascial spaces are potential spaces that may be dissected by fluid exudate during infections. Fascial space swellings are denoted as primary or secondary space swellings. Primary maxillary spaces include: canine, buccal, and infratemporal. Primary mandibular spaces include: submental, buccal, submandibular, and sublingual (4, 5). Secondary spaces are involved when the infection spreads beyond the primary spaces and include: masseteric, pterygomandibular, superficial and deep temporal, lateral pharyngeal, retropharyngeal and prevertebral. We will be directing our focus in this study to those swellings that are localized to a primary space and do not encroach on vital functions.

An acute apical abscess, as defined by the American Association of Endodontists (AAE), is an inflammatory response to necrotic pulp tissue resulting in spontaneous pain, sensitivity to pressure, pus accumulation, and swelling of the surrounding tissues (6). It is important to note that not every swelling can be immediately categorized as an abscess. Odontogenic swellings have a wide variety of presentations. The type of swelling depends on its developmental state.

Swellings are also classified as a cellulitis or a fluctuant swelling. A cellulitis is defined by the AAE as an inflammatory reaction to infection by invasive microorganisms resulting in diffuse edema of tissue spaces and subsequent breakdown of connective tissue (6). The first response of the body's inflammatory system is sending inflammatory cells to combat the offending bacteria. In doing so, the vasculature within the infected area becomes "leaky" due to widening of endothelial cell junctions in capillaries via histamine attachment to H₁ receptors. This widened gap
allows for passage of inflammatory cells as well as fluid out of the vessel (7). The increased blood flow to the offending area results in the cardinal signs of inflammation: calor (heat), rubor (redness), tumor (swelling), dolor (pain), and functio laesa (loss of function), resulting in the initial cellulitis experienced by the patient (6). As the influx of inflammatory cells continues the fight, the dead cells release byproducts that contribute to the amplified inflammatory response. The collection of dead leukocytes (predominantly neutrophils) and byproducts coalesce, forming the more contained fluctuant swelling. An abscess is characterized by accumulation of pus and pyogenic membrane formation, resulting in better infection containment within the host. (6). The bacteria to induce this type of abscess formation must be very resistant to the host’s response, continuing the attraction of neutrophils to the area.

Bahl and co-authors (8) found in their retrospective study of 60 patients, that these swellings are mainly comprised of mixed growth (aerobic and anaerobic) bacteria, with the most common facultative aerobic bacteria *Streptococcus viridans*, while *Bacteroides* and *Prevotella* predominate in the anaerobic category (8). Many authors have also concluded that a polymicrobial infection is present, but stated it is predominantly comprised of strict anaerobes (9-13). The anaerobic bacteria produce volatile sulfur compounds which result in the fetor of a necrotic pulp and contribute to the abscess formation by their release of proteolytic compounds (11). Van Winkelhoff’s study from 1985 (14), in which the cultivation of black pigmented bacteroides (specifically *Bacteroides intermedius* and *Bacteroides endodontalis*) within odontogenic abscesses was established, has also been supported by subsequent authors’ findings (15, 16). The black pigmented bacteria, namely *B. melaninogenicus*, have been linked to the painful
symptoms associated with acute apical abscesses (17). An association with *Tannerella forsythia* and pain in primary endodontic infections was discovered by Sassone (18). These examples suggest that particular bacterial species, specifically strict anaerobes, are correlated to the presence of pain in endodontic infection.

Van Winkelhoff (14) found gram negative motile bacteria, (spirochetes) within his initial study, although they were not as abundant as the bacteroides species. Santos et al (19) found spirochetes 2.6% of the time in acute apical abscesses, as well. The Santos et al study focused on the differing types of bacterium in acute and chronic apical abscesses. Overall, 13 phyla were represented in endodontic infections. In acute infections, *Firmicutes* (52%), *Fusobacteria* (17%), and *Bacteroidetes* (13%) were the most abundant phyla, and the most common genera were *Fusobacterium* (19%), *Parvimonas* (11%) and *Peptostreptococcus* (10%). The most prevalent phyla in chronic cases were *Firmicutes* (59%), *Bacteroidetes* (14%), and *Actinobacteria* (10%). Overall, *Fusobacterium* and *Parvimonas* dominated acute infections. Santos and Siqueira also noted acute infections to be more diverse than chronic infections (19).

It is now known that bacteria alone don’t reside in these swellings, but viral involvement has also been identified. Herpesvirus types, including: herpes simplex virus (HSV-1/2), varicella zoster virus (VZV), Epstein-Barr virus (EBV), human cytomegalovirus (HCMV), human herpesvirus-6 (HHV-6), human herpesvirus-7 (HHV-7), and human herpesvirus-8 (HHV-8), as well as human papillomavirus (HPV) have been identified at some point in the acute apical abscess (20–23). During early identification of viruses within the periapical pathosis the question of viral presence began to be understood as a necessity in abscess formation, with a predominance of
EBV and HCMV (24, 25). More recently, authors have stated that the role of viruses in abscess formation isn’t definitive and their existence within the abscess needs more clarification (23). The various bacteria and viruses within these swellings have been cultivated over the years, and as advances in sampling, culturing, and identification continue to be made, it is likely that more viruses remain to be discovered (10).

The treatment of these bacterial infections is commonly combated with antibiotics. The use of broad spectrum antibiotics is not advocated. The narrow spectrum, beta-lactam antibiotics are the current drug of choice to treat these odontogenic swellings (4, 26, 27). Emergency medical physicians are directed to prescribe Penicillin V or erythromycin (26). In a systematic review conducted by Flynn (28) and published in Oral Maxillofacial Surgery Clinics, applicable articles focusing on antibiotic of choice and duration of use were considered. Flynn concluded that there was no significant difference in the number of patients cured between a shorter and longer course of treatment when appropriate surgical management was administered. As for the type of antibiotic recommended, the most affordable antibiotics, penicillin V and amoxicillin, are still advised. The less expensive antibiotic is assumed to be the reason for better patient compliance. Clindamycin remained the replacement for patients with penicillin allergies (28).

The question arises of when to administer the antibiotic. It has been argued to only prescribe the antibiotic when signs of cellulitis and/or systemic spread occur (10, 26, 27). The Summer 2006 Endodontics: Colleagues for Excellence specifies when antibiotic administration should be considered. The table lists: fever > 100 °F, malaise, trismus, increased swelling, lymphadenopathy, osteomyelitis, persistent infection, and
cellulitis (29). This specific identifying of a cellulitis to justify administration of antibiotics, while to some practitioners may seem obvious, has proven unfruitful. Classically, the erythema, pain, warmth, size, duration, and history of symptoms are used by physicians to diagnosis a cellulitis (4, 30). Relying solely on these signs can be misleading, because the exact time of maturation from cellulitis to abscess is difficult to determine. Flynn et al (31) assessed the accuracy of practitioners’ ability to define the presence or absence of drainable purulence, with participants scoring correctly 63% of the time. Shanti (32) found practitioners to have 55% accuracy in fluctuant identification in his cohort. This low percentage has led to adjunct methods in diagnosing swellings. In medicine, ultrasonography is frequently employed to recognize fluid within the cavity of soft tissue swellings. The ultrasound aids in identifying progression of the infection, even within fascial space swellings (33). In a study by Tayal et al. the fluid filled cavity wasn’t always the classic abscess containing pus. Some of the drainage procedures of fluid filled areas only produced blood, possibly representing a bloody serous exudate or hematoma (34). Ultrasound may help identify fluid, but it does not identify the type. Therefore its accuracy in diagnosing an abscess (pus containing cavity) cannot be called definitive. Poweski et al (35) studied the effectiveness of ultrasonography in odontogenic acute apical abscess diagnosis, with similar results to those listed above: 68% with clinical examination and 70% with clinical assessment plus ultrasonography. There was not a significant difference between the groups, thus the addition of ultrasonography wouldn’t prove effective with recognizing a fluctuant swelling vs. cellulitis when diagnosing a swelling of odontogenic origin (35).
In addition to antibiotic use and determination of swelling type, the appropriate surgical management can be debated as well. Gronholm and co-authors (36) stress the risk window of local abscess development when inadequate or incomplete primary endodontic therapy was initiated. They recommend “thorough canal debridement during the first session as essential to minimise the risk of spread in addition to incision and drainage of the abscess” (36). Decisions on how to treat these swellings are predicated on learned adages such as “Never let the sun go down on undrained pus.” (32). One article describes selecting one of the following: root canal therapy, extraction, or incision and drainage, as a satisfactory treatment option (31). Another study supports performing the extraction or root canal therapy at the same appointment as the incision and drainage, resulting in a shorter hospital stay (37). Generally, “There is no consensus over gold standard treatment as evidenced by the wide variety in endodontic and surgical protocols and antibiotic prescribing” (10, 38). No study has been done in the commonly seen non-serious swellings to determine the need for incision and drainage. Upon reviewing Endodontic Surgery: Online Study Guide provided by the Journal of Endodontics, only four references are listed in the incision and drainage section, with the most recent literature on the topic from 1991. (39). Flynn et al’s prospective study proved the length of hospital stay for patients that underwent incision and drainage, whether it was for a cellulitis or fluctuant swelling, did not statistically differ (40). Shanti and Aziz concluded, “Today, there is no universal agreement on issues, such as optimal timing for surgical drainage and the duration of antibiotic therapy for the management of deep neck infections.” (32). Currently, practitioners clinical decisions on whether to drain are not based on sound scientific
The lack of consensus regarding whether to drain or not to drain extends to the decision of how to perform an incision and drainage, pain management during the procedure, and type of drain placement. Cutaneous abscesses, addressed within the hospital emergency department, are routinely treated with incision and drainage (4). The additional intervention of pain control, type of incision, irrigation use, and wound culturing and packing were studied by Schmitz and co-authors (41). The results of their survey concluded that treatment strategies differ among providers. Most physicians used narcotic analgesics (76%). The majority (71%) used local anesthetic over the roof of the abscess, with 60% administering local anesthetic block for pain management. Eighty-five percent performed a linear incision to relieve the swelling and 91% packed the wound cavity. Wound cultures, irrigation, and oral antibiotic prescriptions were not routinely completed (41). The use of irrigation as a predictor of treatment success was argued in an article by Chinnock (42). Chinnock et al. had 209 patients enrolled in their study with a 187 completion rate. They found that no difference in pain or need for further intervention whether the incision and drainage was completed with or without irrigation (42). We did not study the use of irrigation within our study.

Intraoral incision and drainage is described in various texts as performing a vertical incision in the most fluctuant area of the swelling, (which, as discussed above, can be deceptive) when possible. Once drainage is witnessed, a blunt dissection using curved hemostats is conducted to assist in exploration of fascial space and location of purulence (4, 5, 27). Most dental literature advises the placement of an indwelling drain
to promote tissue drainage, preventing the closure of the mucosal incision and reformation of the abscess cavity (4, 27, 29). Drains are available in various designs including fingers of surgical gloves, rubber dam wicks, penrose tubing, and iodoform drains. No drain has been shown to provide a better outcome than another (4, 5, 26). In the medical literature, the use of a surgical drain has been debated, and it has been postulated that a drain may hinder more than it helps in healing (43, 44). A prospective five-year study of 23,649 surgical wounds found that the placement of a drain in senior patients was more of a detriment to healing and was associated with infection following the incision and drainage procedure (44). Recently, negative-pressure therapy has been used following surgical incision in wounds that may continue to have fluid accumulation and release. Negative pressure therapy is described as applying sub-atmospheric pressure with a sealed dressing that is attached to a vacuum pump. Continued negative-pressure draws the fluids from the incision and maintains the tissue approximation post-operatively. This practice has been studied in the surgical setting of non-infected wounds. Semsarzadeh et al conducted a meta-analysis with findings that this new therapy had overall decreased rates of surgical site infections in closed incisions (45). This procedure has not yet been studied following an incision and drainage but may be a better alternative to current drain placement.

Although wound packing was the most commonly completed adjunctive procedure with an incision and drainage in Schmitz’s article (41), Kessler et al (46) found no statistical significance in failure rates of 57 patients followed for 15 months after packing or not packing the wound. Pain scores among the packed and unpacked wounds did not appear to differ significantly either (46). Another study completed by
O’Malley found the pain induced during and immediately after the wound packing procedure proves wound packing to be unnecessary (47). O’Malley conducted a study with subjects randomly assigned to 2 groups, one with packing following incision and drainage of the cutaneous abscess, and the other without packing following the incision and drainage. Patients assigned to the packing group reported significantly higher pain scores immediately after the procedure and 48 hours postoperatively, as well as using more ibuprofen and oxycodone/acetaminophen to manage their pain. We did not pack the wound following incision and drainage in our study.

The significance of an odontogenic swelling isn’t limited to encroachment on vital body functions, but can have a social influence as well (48). The inconvenience of an acute apical abscess can diminish quality of life and patients may miss days of work while they are coping and recovering from the condition (49). The pain and symptoms of an acute apical abscess can lead to emergency room attendance and even hospital admittance (50). Siqueira et al. (16) writes, “Almost 60% of all nontraumatic dental emergencies are associated with acute apical abscesses and toothaches.” These emergencies can lead to dire complications as severe as death. Most deaths related to odontogenic infections are due to airway obstruction brought on by an acute apical abscess (16).

Adequate anesthesia to comfortably accomplish the incision and drainage procedure is a challenge for practitioners (5, 64, 67). Singer and co-authors (51) found that incision and drainage of abscesses in a medical emergency department was the second most painful procedure performed after nasogastric intubation. Local anesthetics were administered overall in only 13% of the patients. They recommended
that local anesthetic be administered prior to incision and drainage. However, in
dentistry, adequate pain control during the procedure is difficult even when local
anesthetics are administered (64, 67). This difficulty anesthetizing the area may be due
to multiple factors such as inflammatory tissue damage, propagating inflammatory
mediators, neural sensitization, and increased activation of nociceptors.

Nociception is conducted by neurons within our central and peripheral nervous
system. An action potential, mediated by an influx of sodium ions through receptors
located along the neuronal membrane, depolarizes the nerve membrane and propagates
the signal from the site of noxious stimuli to our cerebral cortex.

Unmyelinated C and lightly myelinated A-delta fibers, unlike the heavily
myelinated A-beta fibers that mediate touch and proprioception, mediate pain
perception. These pain neurons are actually less susceptible to lidocaine than the
myelinated nerve fibers (52).

There are many factors that can contribute to altering this pain signal; notably
during infection, inflammation, and following surgical procedures (trauma). Strichartz
(53) lists 3 factors affecting postoperative pain: "(I) impulses generated from injured
nerve fibres innervating the site of the incision/retraction/sutures; (II) inflammatory
mediators, such as cytokines, prostaglandin, endothelin-1, and nerve growth factor,
which are elevated at the surgical site (54) and which sensitize uninjured and injured
nerve fibres; and (III) a sensitization of the pain-transmitting circuits in the spinal cord
that increases their response to noxious stimuli and can introduce their responsiveness
to non-painful stimuli such as light touch or gentle pressure."

Strichartz discussed inflammatory and nervous system responses affecting
postoperative pain. The initial wound damages and activates nerve fibers, eliciting a perception of pain. The resultant tissue damage and hemorrhage leads to a release of chemoattractants fostering local inflammation.

The vasodilation from tissue injury has been expressed as a concern with obtaining anesthesia, as it may increase the systemic absorption of the local anesthetic. Most anesthetics have been combined with a vasoconstrictor to prevent dissolution (53).

Chemokines/cytokines, TNF-alpha, IL-6, prostaglandin E2 and prostacyclin, are produced, released, and amplify the response to painful stimuli. Some inflammatory factors, such as bradykinin, actually activate the nociceptors via a cell surface receptor (BK1 or BK2). If not directly activating, they may alternatively enhance the excitability of nociceptors via receptor channels: Tetrodoxin resistant Nav1.8, Nav1.9, and TRPV-1 (55).

Voltage-gated TTX receptors are found in neurons, skeletal muscle, and cardiac muscle. Between 2 types TTX-S (sensitive) and TTX-R (resistant); TTX-R (Nav1.8 and Nav1.9) are less sensitive to lidocaine and although found normally on neurons, the concentration doubles after exposure to prostaglandin E2 (a product of inflammation after tissue injury) (56). This may help explain the difficulty in obtaining adequate anesthesia during inflammation (57).

The voltage-gated Nav1.9 channel is found within the human dental pulp and trigeminal ganglion. Nav1.9 channels are known to increase neuronal excitability and have low sensitivity to blockade by local anesthetics. Wells et al. compared the concentration of Nav1.9 to be higher in symptomatic (painful) dental pulps vs. asymptomatic pulps. They also found the expression of them increased in the trigeminal
ganglion. The group concluded that this increased expression might be contributing to hypersensitivity of inflamed pulps in local anesthetic failure (58). Warren et al. found Nav1.8 to have a six-fold increase in the relative density in inflamed pulp compared with control pulp (59). The Nav1.7 channel additionally has been linked to nociception (60). Luo et al. found the number of Nav1.7 channels increased in painful human dental pulp. The increase in these channels may add to the easily activated pain response (61).

Hyperalgesia is possible because the neuron’s threshold for activation has been lowered and requires less sodium ions to pass the membrane to send an action potential, leading to more signals being sent. The now amplified response more easily and continuously sends the message of a painful encounter. This leads to allodynia; non-noxious stimuli now activating the pain pathway. The resultant barrage of nociceptive signals to the spinal cord second order neurons results in central sensitization. The convergence of 1st-order neurons to second order neurons in the nucleus caudalis results in referred pain, where surrounding tissues not involved in the injury now send a nociceptive impulse. In addition, the TRPV-1 also assists in the development of hyperalgesia following injury and inflammation. Lidocaine has been seen to directly activate the receptor, propagating a pain signal to the central nervous system (62).

The actual measuring of pain experienced by the patient has been assessed with various types of scales. The Heft-Parker 170 mm Visual Analog Scale, has descriptors that more accurately provide the patient opportunity to correctly express their pain (63).

Our body tissue average pH is 7.4. The pH value of inflamed or infected tissues is between 5-6, and the pH of the pus within a swelling averages 6-7 (64). Local anesthetics are normally at a lower pH for shelf-life (and for preserving the
vasoconstrictor). Although they have varying pKa’s that assist with buffering of the anesthetic when administered; example mepivacaine is less resistant to ion trapping than lidocaine. The local anesthetic, when administered, is given in its acidic form (charged), but must release the H+ ion, becoming the basic form to pass through the membrane. Once it passes through, it must regain the H+ ion to return to the charged form and block the sodium channels, preventing the action potential that would send the perception of pain. Thus, the theory is that the anesthetic molecules are 'ion trapped' in their basic form and unable to pass the membrane barrier and block the transduction of pain.

Studies have discounted this theory, stating that the buffering action within the tissues combats the acidity of the local anesthetic. In inflamed tissue the pH may be lower than normal and is usually confined to the area within the liquefaction necrosis (pus). Some studies have shown that the surrounding inflamed tissue may have an even better buffering capacity (65).

Some researchers have suggested other ideas as to why local anesthetic solutions are less effective in swollen patients with a cellulitis or abscess. Due to the inflammatory response increasing blood flow to the area of inflammation, Hargreaves et al (57) have suggested this as a dilution or “washing away” of local anesthetic in the area of injury, thus reducing its efficacy. Although this is countered by Fouad’s (66) explanation that the areas within an acute apical abscess are composed of inaccessible necrotic tissue; thus local anesthetic is prevented from reaching the intended site within the swelling.

Balasco et al. found that moderate to severe pain was reported from 56% to 88%...
of the time for an incision and drainage procedure in dental patients (67). Harreld et al (64) also found incision and drainage in a dental setting to be a painful procedure (34% to 54% moderate to severe pain) but found a 4% anesthetic to be useful for numbing the incision site prior to incision and drainage.

Even in serious deep neck infections there is some question as to whether immediate surgical drainage is indicated. According to Shanti, “No current standard of care has been established for the treatment of deep neck infections” (32). We do not know whether incision and drainage in localized intraoral swellings affects the course of healing. We do know that incision and drainage is a painful procedure. In these mildly swollen cases, would patients improve at the same rate over time without incision and drainage? If so, a painful procedure could be avoided. The purpose of this investigation is to compare incision and drainage to mock incision and drainage in healthy patients with mild to moderate, localized intraoral swellings, following emergency endodontic treatment.
Chapter 2: Materials and Methods

Eighty-one adult emergency patients of the College of Dentistry volunteered to participate in this study. The patients completed a written health history form and were verbally questioned to confirm ASA I or II health status, distinguishing eligibility to partake in the study. Exclusion criteria were as follows: younger than 18; allergies to local anesthetics or sulfites; pregnancy; history of significant medical conditions; pain medication within the last six to eight hours; and inability to give informed consent. Any female patients who were unaware of their pregnancy status were offered a urine pregnancy test (Osom®, Genzyme Diagnostics Corp, San Diego, CA).

The Ohio State University Human Subjects Review Committee approved the study, and written informed consent was obtained from each subject. After completion of the medical history and consent form, the subjects completed the Corah’s Dental Anxiety Scale questionnaire (68-70). Patients also completed a HIPPA authorization form.

Patients included in the study had a clinical diagnosis of a symptomatic tooth with a pulpal diagnosis of necrosis, periapical radiolucency, and clinical swelling of an acute abscess or cellulitis at the time of treatment. Each tooth tested negative (80/80 reading) to an electric pulp tester (Analytic Technology Corp., Redmond, WA)
and to 1,1,1,2-tetrafluoroethane refrigerant spray (Endo-Ice™, Hygenic Corp., Akron, OH). A periapical image of the tooth in question was obtained using a paralleling device (Rinn Corp., Elgin, IL) and digital radiography (Schick Technologies, Long Island, NY). A periapical radiolucency was confirmed by the investigator from the initial radiograph. No patients exhibited a draining sinus tract.

Each patient rated his or her initial pain on a Heft-Parker visual analogue scale (VAS) (Appendix H) (63). The VAS was divided into 4 categories. No pain corresponded to 0 mm. Mild pain was defined as greater than 0 mm and less than or equal to 54 mm. Mild pain included the descriptors of “faint”, “weak”, and “mild” pain. Moderate pain was defined as greater than 54 mm and less than 114 mm and had the descriptor “moderate”. Severe pain was defined as equal to or greater than 114 mm. Severe pain included the descriptors of “strong”, “intense”, and “maximum possible”.

The maximum diameter of the swelling was measured using a clear flexible ruler (No. 36, C-Thru Ruler Co., Bloomfield, CT). A preoperative photograph was taken of patients (approving image capture) with an Apple iPhone 5 (Apple Inc., Cupertino, CA). The patient’s body temperature was taken orally using a SureTemp® digital thermometer (Welch Allyn Ltd., Navan, CO). The patient was interviewed regarding the swelling and their answers were recorded on a questionnaire form (Appendix G). The questions included the time the swelling began and if they had been taking a prior antibiotic regimen and/or pain medication. The type of swelling (cellulitis or fluctuant) was assessed and recorded by the investigator via palpation prior to starting the procedures. A cellulitis was characterized by a firm, warm
swelling with no observable fluid movement and induration. A fluctuant swelling was characterized by the sensation of fluid movement under the tissue upon palpation, indicating that pus (purulence) was present. Ethnicity, gender, age, location of swelling within the mouth and tooth type was also recorded in the preliminary data to assess potential variables affecting treatment outcomes.

One cartridge of 2% lidocaine with 1:100,000 epinephrine (Xylocaine, AstraZeneca LP, York, PA) were administered as either a maxillary infiltration or a mandibular inferior alveolar nerve block depending on the tooth requiring treatment. Before both the mandibular and maxillary injections, topical anesthetic (20% benzocaine; Patterson Brand Dental Supply, Inc., St. Paul, MN) was placed on a cotton swab and placed passively at the injection sites for 60 seconds. The patient was informed prior to the injection that the investigator would be saying the words “insertion”, “placement”, and “deposition” to identify 3 different segments of the administration of anesthesia. They were told to remember their associated pain level experienced with each word and record the pain level on three 170 mm VAS’s immediately following the initial injection.

Once local anesthesia was achieved, a rubber dam was placed over the tooth to be treated and the access opening prepared. The patient was advised to raise his/her hand if any discomfort was felt at any time during endodontic treatment. A VAS, as described earlier, was used to record any pain felt during initial access into dentin, upon opening the pulp chamber, or while instrumenting canals during the entire debridement procedure. If the patient rated the pain as moderate to severe, additional anesthetic would have been administered before continuing treatment. However, no patient required additional
anesthetic during the debridement procedure.

Magnification was utilized with an OPMI Pro Ergo Dental Microscope (Zeiss, Dublin, CA) to locate canals and identify pulp chamber anatomy. Once canals were located, files were placed and a digital radiograph was taken to establish working length 1 mm from the radiographic apex. An apex locator locator (Root ZX II, J. Morita USA, Irvine, CA) was also utilized to confirm working length.

After working length was established, each canal was cleaned and shaped to a #20 K-type hand file, creating a glide path. Then Vortex® rotary instrumentation (Vortex, Dentsply International, Inc., Johnson City, TN) was employed using a crown-down technique; shaping the coronal portion, then the mid-root, then the apical portion of each canal. The minimum canal preparation was a size 30 with a .04 taper. The final cleaning and shaping size and taper was determined by the initial size of the canal, while also considering curvatures.

The tooth was irrigated with 3% NaOCl (Clorox, Clorox Company, Oakland, CA) upon access, during the debridement, and after the final file. The canals were then dried with sterile paper points. Calcium hydroxide (Ca(OH)_2) (Multi-Cal, Pulpdent Corp, Watertown, MA) was then deposited in each canal with the 1.2 mL manufacturer’s syringe by placing a capillary tip (0.014” Diameter Capillary Tip, Ultradent Products Inc., South Jordan, UT) to length and backfilling. The Ca(OH)_2 was then worked into the canals with K-type hand files. A cotton pellet was placed and the tooth was temporized with Gray Cavit G (3M ESPE, Seefeld, Germany) and the rubber dam removed.

An infiltration of one half cartridge (0.9 ml) of 4% articaine with 1:100,000 epinephrine was then administered mesial to the swelling. The other half of the
cartridge (0.9 ml) was then administered distal to the swelling. Prior to the injection, topical anesthetic gel (20% benzocaine, Patterson Dental Supply, Inc., St. Paul, MN) was passively placed simultaneously at each infiltration site for 60 seconds using cotton tip applicators. Following initial needle penetration (insertion), the needle was advanced toward the target site over a time period of 5 seconds (needle placement). After reaching the target site, aspiration was performed and the anesthetic solution was deposited over a 1-minute time period (deposition). A VAS, as described earlier, was used to record any pain felt during needle insertion, needle placement, and solution deposition.

Before the experiment, the two protocols were randomly assigned five-digit numbers from a random number table (random.org). Each patient was randomly assigned to one of the two protocols. Only the random numbers were recorded on the data collection sheets to help blind the experiment.

The investigator was blind to which group the patient was assigned until appropriate emergency endodontic debridement had been completed. Before the incision and drainage or mock incision and drainage were initiated, the investigator was notified of the random number which determined the group assignment. The blinded subjects then randomly received either an incision and drainage with placement of a drain or mock incision and drainage with placement of a drain in the alveolar mucosa next to the swelling.

Following the administration of local anesthesia, the incision and drainage or mock incision and drainage procedure was performed depending on the random number assignment. Patients were informed they would hear the words “incision”,

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“drainage”, and “dissection” vocalized by the investigator during the correlating phase of the procedure. The patients were informed that they were to remember the level of pain associated with each word to be logged on the appropriate VAS after completion of the procedure. An incision was made through the most dependent site of the swelling using a scalpel, equipped with a #15 blade (Benco Dental, Wilkes-Barre, PA). Cellulitis or fluctuant drainage was established by palpation of the swelling to express any fluid (drainage). A blunt dissection using a curved hemostat was performed to the depth of the swelling (dissection). Each subject rated the pain for all three phases using the VAS as previously outlined.

During the mock incision and drainage, the same words “incision”, “drainage”, and “dissection” were used correlating with the mock incision, drainage and dissection. For the mock incision, the scalpel had the blade removed and was placed against the attached gingiva (an area without swelling) imitating the motions of an incision. A trained assistant would simulate suctioning drainage with suction of saliva in the area. Then a hemostat was moved mesially-distally on the surface of the attached gingiva mimicking blunt dissection. The time for the Mock I&D mimicked the time for the real I&D. The patients also marked the VAS for all of the mock phases.

A rubber dam T-drain (13x9 mm, with 4x5 rectangles cut from the bottom right and left corners, forming a T shape), that was previously prepared and sterilized by the investigator, was sutured (4-0 Perma-Hand Silk Black Braided, Ethicon Johnson & Johnson Co., San Lorenzo, PR) into position within the incision (active incision and drainage). For the Mock I&D, a small 5x5 mm square of rubber dam material (Non-
Latex Dental Dam Coltene/Whaledent Inc., Cuyahoga Falls, OH) was sutured in alveolar mucosa next to the involved swelling. A 5x5 mm square was utilized in the mock drainage group, to accurately simulate how a T-drain would have been submerged within the incisional area and only the 5x5 mm remaining material would be visible.

Each patient received postoperative instructions and a prescription for an appropriate antibiotic (500 mg penicillin; if allergic – 300 mg clindamycin) to be taken every six hours until gone. The patient was also given a five day supply of 600 mg ibuprofen with instructions to take 1 tablet every six hours as needed for pain. In addition, each patient also received a five day supply of 500 mg acetaminophen with instructions to take two tablets every six hours as needed for pain. Patients were informed both non-narcotic pain medication could be taken at the same time. If the ibuprofen/acetaminophen given to the patient was not managing their pain, the patients were given a prescription for Norco (hydrocodone/acetaminophen) 5/325mg, 20 tablets, with instructions to take 1 to 2 tablets every 6 hours. The patient was instructed to stop taking the acetaminophen once starting the escape medication to avoid taking multiple doses of acetaminophen and was informed not to exceed the maximum recommended dosage of 3000 mg per day (McMeal Consumer HealthCare Johnson & Johnson Co. 2011) (100). The patient was notified they could be seen in the clinic on an emergency basis at any time if the need arose. Patients in each group were given the same local anesthesia and pain medications.

Patients received a postoperative survey for the evening (Day 0) of the appointment and three days postoperatively to record any pain they had and the pain
(study or escape) medication they took. They recorded the number of pain medications taken within each 24-hour period. The time of day was recorded and any pain was recorded on visual analog scales as described earlier for pain. Questions on the survey included the patient’s perception of their feeling of symptoms improving, worsening, or remaining the same, as well as their perception of the swelling increasing, decreasing, or remaining the same. Patients were allowed to take and submit to the investigator any pictures of the extraoral swelling or drain area. Patients returned on day 4 (3rd day postoperatively) to evaluate healing, drain removal and further treatment, if necessary. A postoperative photograph was taken of those patients who earlier agreed to a preoperative image, using the same Apple iPhone 5. The patients received $50 at the end of the endodontic emergency treatment/incision and drainage appointment. Upon the completion and return of the survey and presentation for drain removal, including further treatment if necessary, subjects received an additional $50. Patients could schedule for continued treatment at a time point later than day 4 if that was more convenient to the patient.

The data from this study were collected and statistically analyzed. Comparisons between the I&D and Mock I&D for age, initial pain, temperature, swelling diameter, procedural pain, postoperative patient perception of pain and swelling, patient satisfaction, and overall treatment pain were analyzed using the Randomization test. Comparisons between groups for gender, affected jaw, affected side of the mouth, tooth type, use of antibiotics, use of analgesics, and success of clinical findings, were made using the Chi-Square test. Comparisons between groups for ethnicity were analyzed via the Fisher Exact Test. Corah dental anxiety comparisons were made using the Mann-
Whitney-Wilcoxon Test. For VAS pain scores, assuming a standard deviation of 50 a difference of ±30 mm could be detected with a power of 0.80 with 39 in each group.
Chapter 3: Results

There were 81 total subjects in the study, with 39 subjects in the Incision and Drainage (I&D) group and 42 in the Mock Incision and Drainage (Mock I&D) group (Table 1). The preliminary data for the Incision and Drainage group included 19 females and 20 males with the average age of 37.5 (±12.8) years. The initial pain was recorded using a 170 mm Heft-Parker Visual Analog Scale, with a mean of 136.6 (±29.1) mm for the I&D group, and an average Corah Dental Anxiety scale reading of ten (moderate anxiety). The I&D group included 16 maxillary teeth and 23 mandibular teeth (eight anteriors, nine premolars, and 22 molars). Twenty-one I&D subjects were taking pain medication (including ibuprofen, acetaminophen, and/or Norco 5/325 mg), and 15 were currently taking antibiotics (penicillin, amoxicillin, or clindamycin). The average recorded body temperature was 98.5°F (±0.5) and the mean soft tissue lesion diameter was 5.1 cm (±2.4) in the I&D group (Table 1).

Of the 42 Mock I&D subjects, 23 were females, and 19 were males with the average age of 37.3 (±14.7) years. The mean initial pain was 133.4 (±28.9) mm for the Mock I&D group, with the average Corah Dental Anxiety scale reading of ten. The Mock I&D group included 19 maxillary teeth and 23 mandibular teeth (seven anteriors, 19 premolars, and 20 molars). Twenty-eight Mock I&D subjects were taking pain medication (including ibuprofen, acetaminophen, and/or Norco 5/325 mg), and 23 were
currently taking antibiotics (penicillin, amoxicillin, or clindamycin). The average recorded body temperature was 98.3°F (±0.4) and the mean lesion diameter was 4.4 cm (±2.4) in the Mock I&D group (Table 1).

There were no significant differences between the groups with regard to gender, age, ethnicity, initial pain, dental anxiety, jaw, side of mouth, tooth type, prior pain medication or antibiotic usage, and lesion diameter. There was a significant difference between groups for body temperature (p = 0.0220). Subjects in the I&D group had a 0.2°F higher recorded temperature than the Mock I&D group (Table 1), which will be discussed at length in the discussion.

Pain during anesthetic administration and access preparation were recorded using a Heft-Parker 170 mm Visual Analog Scale (Table 2). There were no significant differences in pain recordings in any of the injection or access categories.

The Incision and Drainage or Mock Incision and Drainage procedural pain was recorded (Heft-Parker 170 mm VAS) and the results are reflected in Table 3 and Figure 1. No significant difference was noted for females in I&D vs. Mock I&D groups for the incision, drainage, or dissection steps. A significant difference was noted during each procedural step (incision, drainage, dissection) between the I&D vs. Mock I&D groups for males. Males averaged higher pain recordings in the I&D group and lower pain recordings in the Mock I&D group.

Tables 4, 5, 6, and 7 are the female and male postoperative pain and swelling survey responses recorded over a period of four days. The patients answered questions regarding pain and swelling status, (“better”, “worse”, or “the same”) at the end of each day (Appendix M).
Figures 2 and 3 are line graph representations of the recorded patient perception of improvement by group and gender. All groups increase in average response signifying decreased pain and decreased swelling perception (2 = better). No significant difference was seen between the Incision and Drainage and the Mock Incision and Drainage groups.

Female and Male overall pain recorded on the Heft-Parker 170 mm VAS by day are seen in Tables 8, 9 and Figure 2. The recordings in both male and female show an average decrease with no significant difference between the Incision and Drainage and the Mock Incision and Drainage groups.

The summary of success by group is listed in Table 10 and Figure 4. Success was defined as no or mild pain (≤54 mm on Heft-Parker VAS) and no narcotic use. The count represents the success or failure on each day over the four postoperative days total. Fifty-one recordings of success (33.1%) were seen for the Incision and Drainage group and 74 recordings of success (44.8%) for the Mock Incision and Drainage group. A significant difference (p = 0.0037) was noted between the groups using the Chi-Square test.

Table 11 summarizes the Success by Day for both groups (I&D and Mock I&D). Progressively from Day 0 to Day 3 the success count of “yes” (no or mild pain (≤54 mm on Heft-Parker VAS) and no narcotic use) increased from Day 0 from 13 (16%) successful recordings to 50 (66%) successful recordings on Day 3. Overall, patients improved in terms of less pain and less narcotic usage over the four postoperative days. The Odds Ratio Estimates of Success are seen in Table 13 with the corresponding confidence intervals. A significant difference was noted by day, gender, and group, which can be seen in Table 14 with the adjusted odds ratios. Table 15 exhibits the specific comparison of days where significance is noted (Day 0 vs. Day 2, Day 0 vs. Day 3, Day 1
vs. Day 2, Day 1 vs. Day 3). Overall, subjects significantly improved from Day 0 to Day 3.

The main variables with significance in success were group (Incision and Drainage vs. Mock Incision and Drainage), day, and gender (Table 14). The Success by Gender was found to be significant (Table 12). Males recorded less narcotic usage and improved perception of pain, thus having a higher success rate than females. The odds ratio and confidence intervals are noted in Table 13, confirming the statistically significant difference of Day zero compared to Day one, and Day two compared to Day three. The Mock I&D group and male gender reported higher success; and significant improvement was recorded over four days, postoperatively. These recordings are summarized in Table 13, 14, and 15. Table 14 represents odds ratios for success using type III tests fixed effects.

Table 16 shows that the majority of patients in both treatment groups were satisfied with their treatment. Descriptors of the 100-mm VAS for Satisfaction: “A score of 0 mm indicated the subject was not satisfied. Greater than 0 mm and less than or equal to 33 mm indicated the subject was somewhat satisfied. Greater than 33 mm and less than or equal to 67 mm indicated the subject was moderately satisfied. Greater than 67 mm up to and including 100 mm indicated that the subject was completely satisfied” (105). The mean was 94.5 mm for the I&D group, and 97.0 mm for the Mock I&D group, no statistically significant difference was noted.

For overall treatment pain, the Mock Incision and Drainage procedure was recorded as significantly less painful than the Incision and Drainage procedure, as recorded on a 170 mm VAS (Table 17).
The categorical data is listed in Tables 18, 19, 20, and 21. Table 18 reviews the pain upon access separated by group, gender and pain level (None = 0 mm, Mild = >0 mm and ≤54 mm, Moderate = >54 mm and <114 mm, Severe = ≥114 mm). The majority of patients recorded none to moderate pain with all access steps (dentin, pulp chamber, canal instrumentation) with no significant difference between group or gender (p = > 0.05, Table 2). Table 19 shows the pain recordings during anesthetic administration by group, gender, and pain level. Pain recordings varied between mild to moderate pain during insertion, placement and deposition with no significant difference between groups or gender (p = > 0.05, Table 2). Solution deposition was most commonly recorded as moderate but averaged the highest recording between all groups. The categorical summary of pain for the Incision and Drainage or Mock Incision and Drainage procedure is seen in Table 20, divided by gender and pain level. More frequent pain recordings of severe were seen in the I&D group than the Mock I&D group. Males recorded significantly different pain recordings between the I&D and Mock I&D group (p = < 0.05, Table 3) compared to females, with a lower average in the Mock I&D group. Finally, Table 21 exhibits the pain recordings four days post-operatively by gender and group. As time progressed, the recordings in both groups decreased in severity. A significant difference was seen between groups with more none to mild recordings in the Mock I&D group than the I&D group.
Chapter 4: Discussion

Preliminary Data

Of the 81 patients participating in this prospective, randomized clinical study, 42 were assigned to the Mock Incision and Drainage (Mock I&D) group and 39 were assigned to the Incision and Drainage (I&D) group. The average age of the 39 participants in the I&D group was 37.5 (±12.8) years and the average age of the 42 participants in the Mock I&D group was 37.3 (±14.7) years. The minimum age was 18 years old and the maximum age was 67 years old in both the Mock I&D group and the I&D group. There was no statistical significance found between the groups with relation to age.

There has been evidence suggesting a difference in pain perception depending on a patient’s age. Gibson and Farrell postulated that older individuals had a decreased tolerance of pain and slower resolution of post-injury hyperalgesia (71). More recently, Yezierski found that the increased pain perception, with patients of advanced age, is related to factors resulting “from age-related anatomical, physiological, and biochemical changes.” (72). Countering Gibson’s, Farrell’s and Yiezerski’s reports, Harkin’s and Chapman’s research documented that the older patient population reported lower pain levels when shock intensity of vital dental pulp tissue was increased in comparison with a younger patient population (73, 74). Within our study, the patient’s ages are represented
fairly equally with no statistical significance between group assignment (p = 0.9469), indicating that age most likely did not play a factor in pain perception assessments initially (p = 0.6139, Table 1) or during the performed procedures (anesthetic administration, access for endodontic therapy, incision and drainage). Children and elderly patients were not included in this study, thus the findings of this study are not meant to be applied to patients within those age groups.

Females and males were represented in both groups (Table 1). The I&D group was 45% females and 51% males. The Mock I&D group had a similar representation with 55% females and 45% males. There was no statistically significant difference for gender distributions between the groups. It has been suggested that female’s and male’s interpretation of pain may differ. Females have been found to have a lower pain tolerance and greater intensity of response to pain compared with males (75-77). Theories for this varied response have been attributed not to females actually feeling more or intense pain, but rather their social-emotional response with their surroundings during the experiment. Liddell and Locker found women sought medical attention sooner than men because of their increased fear of pain and tendency to be more greatly affected by pain (78). Other researchers found no difference in pain responses between males and females, regarding temporomandibular pain (79).

With regard to ethnicity, there were 25 Caucasians and 14 African-Americans in the I&D group. Thirty Caucasians, 11 African-Americans, and one Other ethnicity was recorded in the Mock I&D group. There was no statistically significant difference found between groups in regards to ethnicity, with no bearing on the outcome of success or failure in either group.
The location within the mouth was found to have no statistical significance between groups in any of the recorded categories. The jaw, side of mouth, and tooth type was recorded. The mandible was most commonly involved in both I&D (59%) and Mock I&D (55%) (p = 0.7022). Twenty-three participants in the I&D group (59%) had the left side of the mouth involved, with 20 individuals having the left side involved with the Mock I&D group (48%) (p = 0.3062). The tooth type was most commonly molars in both groups: 54% in the I&D group and 48% in the Mock I&D group (p = 0.6716). Past studies have shown the mandibular posterior teeth to be most commonly involved in odontogenic infections and the present study shows similar findings (35, 67, 80). Due to no statistical differences being noted with any of the location-related categories of the procedure, it is unlikely this variable can be used as a predictor of outcomes between groups.

An acute apical abscess, as described in the 2015 AAE Endodontic Glossary of Terms, is “an inflammatory reaction to pulpal infection and necrosis characterized by rapid onset, spontaneous pain, tenderness of the tooth to pressure, pus formation and swelling of the associated tissues” (6). The mean initial pain assessment for both groups, the I&D and Mock I&D, fell within the parameters for severe pain (Severe = ≥ 114 mm on a 170 mm Heft-Parker VAS). No statistically significant difference was noted between the groups for initial pain assessment (p = 0.6139, Table 1). This initial pain assessment confirms publications that state patients with a cellulitis or acute apical abscess of odontogenic origin commonly present in great pain with tissue redness, warmth, and swelling. (3, 6, 81).

Elevated body temperature has a known correlation with acute apical abscess or
swelling (4). Fever is defined as any rise in body temperature above the average body temperature of 98.6 °F (82). The definition provided by the medical community from the Mayo Clinic states that there is not usually great concern for a patient’s well-being, unless this temperature rises above 103 °F (83). In the American Association of Endodontists publication, Endodontics: Colleagues for Excellence (29), the authors state when body temperature rises higher than 100 °F, antibiotic administration is warranted. The average temperature recorded for the I&D group was 98.5 °F, with a minimum of 97.7 °F and maximum of 100.6 °F. The mean temperature recorded for the Mock I&D group was 98.3 °F with a minimum of 97.0 °F and 99.0 °F. This slightly increased average temperature of 0.02 °F in the Mock I&D group represents a statistically significant difference between the groups. One might propose that the patients might not have been aware of this small difference in temperature. The ability for a subject to identify changes in temperature over various regions of the body has been determined to be more accurate in the oral region but decreases with age (84). The bare skin at the base of the thumb has been found to perceive a difference of just 0.02-0.07 °C (.036 -.126 °F) (85), which is greater than the 0.02 °F difference observed within our study. Thus, the difference likely would not be realized by the patient and is not expected to have had an effect on the outcome of success.

Older adults (over 60 years of age) have a lower average body temperature and experience less variation when an infection occurs (86). This decrease in body temperature and variation has been proposed to deter the ability of the body’s defense mechanisms to combat the infection with a fever, killing those microorganisms sensitive to change in temperature (7, 86). The Mock I&D group had three subjects older than 60
years of age and the I&D group had one subject older than 60 years of age. None of the older subject’s temperatures exceeded 100°F. The age of the participants was not statistically significant between groups, so this variable is considered negligible.

Considering both means were below the average recorded body temperature of 98.6°F, they are not in range of a fever. This overall low average body temperature, and only one recording exceeding 100°F (100.6 °F, patient was 24 years of age, in the I&D group) out of all 81 patients, is congruent with the findings from Campanelli et al. where the vital signs (blood pressure, lymphadenopathy, and temperature) from a patient did not correlate with the presence or absence of a swelling (87). Poweski et al. (35) recorded two patients out of 82 that had a temperature greater than 100 °F (2%). Harrel et al (64) recorded three out of 89 patients that had a temperature exceeding 100 °F (3%) within their study. These are both similar to our findings of one patient out of 81 (1%) with a temperature warranting antibiotic administration by the Colleagues for Excellence (29). We can assume the statistical significance between groups of 0.02°F didn’t contribute to the success/failure outcomes of the groups.

The dimensions of the facial swellings were assessed using a flexible ruler extraorally to measure the greatest diameter of the swelling. Alternative forms of measuring swellings have been proposed for better accuracy. Ultrasound is a technique used for identification of fluid-filled cavities and measuring size. However, as reviewed in the introduction, ultrasound is not helpful in distinguishing between an abscess and a hematoma (34, 35). In addition, its accuracy in diagnosis is not significantly better than a clinician’s assessment. Qin et al. suggested the use of optical coherence tomography for a highly accurate representation of edema volumes in mouse models (50). The three
dimensional images are taken over time, overlaid, and run through an algorithm to determine increasing or decreasing fluid volume. Although other options may show promise for the future, we chose the cost-effective and readily available non-invasive ruler technique, which was kept consistent for all participants. In addition to this form of measurement, preoperative and postoperative photos were taken when the patient consented to image capture.

There was no statistical difference between the groups in terms of lesion diameter (Table 1). The initial lesion diameter had no effect on the outcome of success between groups.

Patients were asked about prior medication use including any pain medication (ibuprofen, acetaminophen, or narcotics) and antibiotics. The antibiotics recorded were clindamycin, amoxicillin, and penicillin. The majority of subjects in the I&D group reported no prior antibiotic usage (62%) and the majority of subjects in the Mock I&D group reported that they had taken antibiotics prior to treatment (55%). This difference, however, was not statistically significant between groups (p = 0.1419), which is a similar finding in Nusstein and Beck’s study examining subjects presenting to the emergency clinic and prior medication usage (88). Prior medication use is not considered to be a factor contributing to success in either group. Furthermore, when patients reported “yes” to prior antibiotics, most stated that they had recently started the medications one to two days prior to their presentation to the dental emergency clinic.

Pallasch (89) reviewed the pharmacokinetics for antibiotics, specifically relating to oral infections, stating the recommendations for management of an acute orofacial infection are to use an antibiotic loading dose, achieve blood levels of the antibiotic at 2-8
times the minimal inhibitory concentration, use frequent dosing intervals, and determine the duration of therapy by the remission of the disease. He determined that these guidelines were required to overcome the tissue barriers impeding penetration of the antibiotic, and that the acute nature of the infection within the mouth necessitates higher levels of antibiotic be reached and maintained to assist resolution of the infection (89). The consistent dosing maintenance is specifically indicated with cell wall inhibitors (beta-lactams) due to their slow-time dependent killing activity requiring that the bacteria grow and divide. Since bacteria have varying growth rates, it is ideal to have the antibiotic continuously present for optimum killing effectiveness. “The goal of dosing with beta-lactam drugs is to maximize the time of exposure to active drug levels and to maintain the tissue concentrations of the penicillins and cephalosporins above the minimal inhibitory concentration for as long as possible” (89). Most antibiotics used for orofacial infections have half-lives less than 3 hours (Penicillin V) and therapeutic doses are reached by 12 hours, but they need continued administration for effective microbe killing. In the current study, the short time frame reported by the participants indicates that the antibiotic would not have reached systemic levels that would change the outcome of success or failure between groups.

Another concern is that patients may have inaccurately reported their medication use. Fouad et al. and Henry et al. found that use of antibiotics did not predict better outcomes (less pain) in symptomatic patients (66, 90). When comparing improvement of odontogenic swellings, antibiotics have not been found to provide resolution of pain when compared with a placebo (66, 90, 91). In addition, when studying symptomatic patients with a diagnosis of a necrotic pulp and a periapical radiolucency, Henry et al.
found that penicillin administration did not significantly reduce “pain, pain on percussion, or the number of analgesic medications employed” (90). It is important to note that within the Henry et al. study, patients presented with minimal or no facial swelling which may prevent direct application to our study, as we were specifically studying patients with an acute apical abscess. Nonetheless, without statistical significance we can omit antibiotic use as a predictor of success within our study (Table 1). To minimize the effect of participants who presented with no antibiotic intervention, each patient was supplied with an antibiotic (and instructions for use - see Materials & Methods), even though the Endodontics: Colleagues for Excellence only recommends administering antibiotics in the cellulitis phase (29). As previously discussed, identifying exactly when a patient is in the cellulitis phase or is transitioning to the fluctuant stage is difficult (28, 31, 32, 35, 40). From an access-to-care standpoint, many providers may be providing an antibiotic in fear of missing an infection that would have the potential to continue to degrade the patient’s condition. We wanted to minimize the effect of antibiotics. Therefore, all patients were administered a clinically effective dose.

As for prior pain medication, it has been found that patients with a diagnosis of necrosis of the pulp with a symptomatic tooth who preoperatively take non-narcotic medication experience pain relief (88). Also, men, more so than women, obtain relief with non-narcotic medication administration prior to emergency treatment for odontogenic pain. This aligns with previous studies about gender differences and pain tolerance (73- 78, 88). Nusstein et al. recorded preoperative medications including analgesics (non-narcotic and narcotic) and antibiotics, but did not specifically record the dosing, type, or frequency of medications prior to arrival for treatment (88). In the
In the current study, twenty-one patients (54%) in the I&D group reported taking some form of pain medication to manage their symptoms, whereas 28 patients (55%) took pain medication in the Mock I&D group. As for prior pain medication usage, patients also reported more specifically the type and frequency for one to two days prior to procedural date. Since we could not rely on every patient accurately remembering the type, dosage, and frequency of previous medication management, we asked patients to simply answer “yes” or “no” to pain medication use. However, as a criterion for enrollment, no analgesic medication was taken 6 hours before the appointment. This ensured the participants were not under current pain medication management before treatment and would not have an effect on the outcomes in our study. Further investigations may want to collect more specific information regarding antibiotic and analgesic use to see if that results in significant outcomes. Both groups had the majority of patients reporting prior pain medication management with no statistically significant difference (p=0.2635) between the groups (Table 1).

In addition to the preliminary questions above, subjects were asked to complete the Corah Dental Anxiety questionnaire (68, 69). The mean anxiety recording was ten in the I&D group and ten in the Mock I&D group on a scale of 2-20 (Table 1), with no statistical difference between the groups (p = 0.7729). Both groups fell in the moderate anxiety category. This is notable as previous studies have shown agitated and nervous patients to have a lowered pain tolerance which could potentially affect their pain ratings during the procedure (57, 92, 93). In light of their similar ratings and lack of a statistically significant difference, we can remove this as a variable that would change the pain ratings during the anesthetic administration, access preparation, and incision and
drainage procedure.

**Success**

In the current study, success was defined as a pain recording of none to mild ($\leq 54$ mm on 170 mm Heft-Parker VAS) with no narcotic usage. We know from previous work by Sebastian et al. and Wells et al. that patients with a diagnosis of a symptomatic necrotic tooth and an initial pain rating of moderate-to-severe are expected to experience moderate pain postoperatively following emergency endodontic debridement (91, 94). Patients may choose to manage their pain with medication, including over-the-counter pain relievers (ibuprofen and/or acetaminophen) or prescription strength pain medication. Most often, ibuprofen and/or acetaminophen are sufficient to manage the postoperative pain, but some studies have found that patients require a narcotic pain medication (hydrocodone/acetaminophen combination) to relieve the pain (90, 91, 94). Narcotics were utilized in 20% of patients in the study by Wells et al. (94) Narcotics were employed by 20% of the endodontic debridement group and 12% of the no debridement group (with no statistically significant difference between the groups) in the study by Sebastian et al.

It is known that narcotics have undesirable side effects including dizziness, constipation, nausea, drowsiness, and impaired psychomotor function (95). Compton et al. states, “Because opioids, like other drugs that increase dopamine, can lead to conditioned responses, the use of the substance may become conditioned to the activities of daily living” (95). Therefore, opioids have the potential to become addictive and may lead to eventual abuse or even death. Many have studied options to decrease the overall
use and abuse of these drugs, starting first with trying to eliminate their necessity (95).

Our hope was that we could decrease the use of narcotic medication and minimize pain postoperatively following I&D after emergency debridement of a symptomatic necrotic tooth with an acute apical abscess.

**Procedural Pain**

Before the initial injection (the inferior alveolar block for a mandibular tooth, or an infiltration for a maxillary tooth) was completed, a topical 20% benzocaine was applied to the tissues after drying with 2x2 gauze. Studies have concluded that this practice is mostly effective in decreasing pain during the needle insertion phase of injection in the anterior maxilla (96). In the current study, the subjects’ swellings were in various areas of the mouth, so although this may not have been indicated for all patients, the display of compassion on the part of the provider in an effort to minimize pain has been thought to play a role in the patient’s comfort (97). In addition, the clinician was able to maintain consistency between all patients by applying topical anesthetic before every injection.

Previous studies report that pain of injection, whether experienced during a nerve block or at the mesial and distal aspects of an acute swelling, is in the moderate to severe range and is quite uncomfortable for patients (64, 67). The mean pain recordings were not statistically significant between either of our group, and thus are not believed to be of consequence with regard to successful outcomes.

For pain during endodontic access (dentin, pulp chamber, canal instrumentation), the majority of patients in all groups (male/female, I&D/Mock I&D) recorded pain in the
none-to-mild range. Sebastian et al. (91) also had pain recordings of none-to-mild within her study while accessing (dentin, chamber, canal instrumentation) teeth with a pulpal diagnosis of necrotic. Wells et al. (94) found no to mild pain for the dentin and chamber access during emergency endodontic procedure and no-to-moderate pain in the canal instrumentation step, he notes that between all three steps (dentin, chamber, canal instrumentation) no statistically significant difference is noted.

One may consider that if the tooth drained from the access opening that this would change the pain experienced postoperatively. Of the 81 teeth accessed, only 11 of them drained through the chamber (access opening). Nusstein et al. found that “obtaining short-term drainage upon access (average of 1.85 min) did not significantly reduce pain, percussion pain, swelling, or the number of analgesic medications taken for symptomatic necrotic teeth with periapical radiolucencies” (98) and thus this was not cause for concern in our study.

It is known that the incision and drainage procedure has been found to be very painful. Singer and co-authors conducted a study where 1,171 procedures were analyzed (51). A 100 mm VAS was marked by both patient and practitioner for the top 15 procedures completed within the emergency department and the type of anesthetics utilized with preference recorded, once again by both provider and patient. Correlation between groups was poor to fair. Patients rated nasogastric intubation, followed by incision and drainage of abscesses as the most painful procedures performed. Patients who didn’t receive local anesthetics for the procedure stated they would opt for local anesthetics in the future before another similar procedure is completed. This study was specifically looking at medical procedures within the hospital emergency department and
thus may not be directly applied to the results within our study. The actual measuring of
the pain experienced by the patient has been assessed with varying types of scales. We
chose to use the Heft-Parker 170 mm scale Visual Analog Scale with descriptors that
provide the patient the opportunity to best express their pain (63).

Balasco et al. utilized the 170 mm Heft-Parker scale in a study that compared
buffered 2% lidocaine vs. 2% lidocaine to ease the pain of the I&D procedure. There
were 81 patients within the study, with 41 patients randomly assigned to the buffered
group and 40 patients randomly assigned to the non buffered group. The incision pain for
the buffered lidocaine group measured in the moderate to severe category as did the non-
buffered group. The drainage procedure was reported to be quite painful for the patients
as well. In the buffered and non-buffered groups, patients recorded moderate to severe
pain. The final step, dissection, also had pain ratings of moderate to severe for both
groups (67). While both Balasco et al. and the present study utilized a 170 mm VAS,
Balasco’s patients did not receive an anesthetic block, nor was the offending tooth
debrided. These differences in study design may have contributed to differences in
results.

Harreld et al. also studied a 4% lidocaine vs. buffered 4% lidocaine in hope of
providing a less painful incision and drainage procedure. The majority of females who
received buffered 4% lidocaine with 1:100,000 epinephrine classified themselves as
having none to mild pain for incision, drainage, and dissection. Most of the females who
received 4% lidocaine with 1:100,000 epinephrine and most males in both groups rated
the pain of incision, drainage and dissection as mild to moderate. Harreld et al. found no
significant differences between groups in regards to pain when comparing the effects of a
buffered or unbuffered 4% lidocaine with 1:100,000 epinephrine solutions (64).

When considering Singer et al., Balasco et al., Harrel et al., and the present study, it stands true that the incision and drainage procedure is considered to be a painful procedure (51, 64, 67).

Females and males were represented in both groups (Table 1). It has been suggested that females and males interpretation of pain may differ. Females have been found to have a lower pain tolerance and greater intensity of response to pain compared with males (75, 77). Theories for this varied response have been attributed not to females actually feeling more or intense pain, but rather their social-emotional response with their surroundings during the experiment. Liddell and Locker, found women sought medical attention sooner than men because of their increased fear of pain and tendency to be more greatly affected by pain (78). Other researchers found no difference in pain responses between males and females regarding temporomandibular pain (79).

Within the current study’s findings regarding procedural pain, data aligned with the theory of females lowered pain threshold and more intense pain response during the Mock I&D procedure. When comparing the difference of pain responses during the I&D vs. Mock I&D procedure, the females’ recordings were not significantly different. These responses indicated that their perception of both procedures (I&D or Mock I&D) induced similar pain readings. As Fillingham suggested, females may have been influenced by social-emotional response cues (75) so that when told they were receiving the I&D, but were actually in the Mock I&D group, their expectation of pain led to their higher pain recordings during the simulated procedure. Different findings for the females may have also been found if we had a higher number of female participants.
Counterintuitively, males averaged higher pain recordings during each step (incision, drainage, and dissection) than females in the I&D group, but this was not found to be statistically significant. This opposes the theory of men having a higher pain threshold than women. Since our findings are not statistically significant, the difference was negligible which aligns with Bush’s findings where no difference between the genders was seen (79). Perhaps a significant difference would have been seen within a larger sample size or a more balanced group. In addition, some may speculate that the female investigator administering care to a male participant could have some effect on pain perception. A previous study by Perry et al. found that only female patients with a male operator, and only during the deposition phase of the injection, experienced significantly higher pain ratings. No other patient-operator combination had any significance (99).

Males recorded lower pain responses than females in the same three simulated steps in the Mock I&D group, however the differences were not significant. There was a significant difference noted between the male I&D vs. Mock I&D groups. Males in the I&D group responded with significantly higher pain intensity compared to the males in the Mock I&D group. Men respond to pain intensity of the I&D procedure (75, 76). Perhaps the anticipation of pain did not affect their actual pain responses.

The pain during incision and drainage or mock incision and drainage treatment was also measured on a Heft-Parker 170 mm Visual Analog Scale (Table 3, Figure 1, Table 20). The average pain during incision for females was $47.6 \pm 52.6$ mm and for males was $56.9 \pm 55.1$ mm. For females, average pain ratings were within the mild pain category, while males were also in the moderate category. When considering that the
males averaged higher pain assessments during this procedure, it is opposite of what we have seen in the past regarding higher pain tolerance in men (75, 76). Although males reported slightly more pain than females, they both fall within the mild to moderate range when considering their standard deviation. A similar finding was noted for the drainage procedure: women reported $45.1 \pm 50.5$ mm and men reported $72.1 \pm 55.5$ mm pain ratings. We see the same pattern where men averaged higher pain assessments. Men found drainage to be the most painful of the three procedural steps in the I&D group, whereas women found the dissection to be the most painful of the three steps. Both male and female subjects found dissection to be painful (moderate-to-severe pain range as measured on a 170 mm Heft-Parker VAS).

While it seems men may have reported lower pain threshold in the I&D group (Figure 1), when compared to the Mock I&D group the picture becomes clearer. There was no significant difference seen in females when comparing all three steps of the I&D to the Mock I&D. The statistically insignificant difference between the Mock I&D and I&D group for women may be an indication of lower pain threshold ($p > 0.05$ for all three steps). This finding is supported by literature that finds female patients have higher anxiety, contributing to their anticipation and avoidance of pain, and thus found a procedure in which no actual harm occurred somewhat painful (78). Female patients’ average pain recording of the mock incision was $22.5 \pm 31.1$ mm, while males recorded pain for the incision step as $10.1 \pm 17.6$ mm. This recording for males is lower than the females, as is expected, according to some literature (73-76). Both females and males in the Mock I&D group reported in the no to mild pain category the majority of the time (Table 20).
Why would the Mock I&D have a pain rating above none, considering no actual procedure was done? This may be attributed to the hyperalgesia of the tissues surrounding the swelling, as the inflammatory factors have lowered the threshold for the nerves to be activated. Also, allodynia may be experienced as a normally non-painful stimulus (Mock I&D) is now considered painful (7, 53, 57, 60).

**Postoperative Pain**

Before departing, participants were given a postoperative survey to measure their pain each day for four days. They were asked to mark the 170 mm Heft-Parker Visual Analog Scale each evening, answer two simple questions about their overall feeling of improvement, as well as comment on how they felt about the resolution of the swelling. The patients recorded any pain medication that was taken on a separate record, including which drug, the dosage, and time of day it was taken. Patients were given general instructions to take the provided non-narcotic pain medication when needed and to allow six hours between doses (one tablet of the 600 mg ibuprofen, and two tablets of 500 mg acetaminophen) to prevent overdosing. Maximum dosage of acetaminophen is 4000 mg/day and is 3200 mg/day for ibuprofen (100, 101). Specific regimens were not recommended because it has been found that there is no significant effect on pain whether the patient follows a strict regimen given by the provider, or takes pain medication on-demand (102). This way the patient could also choose whether or not they needed the narcotic and only took medication when truly in pain.

Patients returned on Day four for drain and suture removal and to return their postoperative survey. Whether a drain fell out without intervention, was not recorded.
Several patients stated it fell out one to two days after placement (in both the I&D group and the Mock I&D group), while some were completely unaware that it had come out on its own until we notified them at their return appointment. Thus the date of drain loss was not known. Colleagues for Excellence states that one to two days of drain placement is sufficient, therefore we can assume that loss of the drain did not have an effect on success (29). For our purposes, the drain was expected to be in place for at least one to two days. This is something that could be studied further to see if the loss of the drain affects treatment outcomes.

In observing both the female I&D and Mock I&D groups, the patients reported feeling “better” (BETTER = 2) with each passing day. Similar results were seen in the female patients’ perception of swelling over the four-day postoperative period. There was no statistically significant difference between the female groups for the pain or swelling questionnaire (p = 1.000). It isn’t surprising that over time both groups improved. After thorough debridement of the offending tooth, the patients were provided postoperative pain medication for managing discomfort, as well as antibiotics to assist in resolving the swelling.

The comparison of the males’ response in the four-day postoperative survey closely follows the females’ results, with improving response averages (2 = BETTER) for pain. On Day 0 for males in the I&D group average pain was 1.4 and improved to 1.6 by Day 3. The male Mock I&D group average pain response started at 1.7, increased to 1.6 on Day 2, and improved to 1.7 on Day 3. The swelling perception for Day 0 of the male I&D group is 1.5 improving to 1.8 by Day 3. The swelling perception for Day 0 of the Mock I&D group starts with 1.4 and progresses to 1.7. The difference between these
groups also was not statistically significant (p = ≥ 0.05). Overall, improvement was seen in both genders and in both groups. Females perceived the most resolution of pain and swelling but no statistical significance is noted whether in the I&D group vs. the Mock I&D group.

Differences between genders were also noted with regard to postoperative pain. Table 8 reviews the female patients’ postoperative pain, and this reflects the data for overall improvement by day in both groups with no statistical significance between the I&D and Mock I&D group (Table 6). On Day 0 the females in the I&D group averaged 104.8 ± 47.7 mm. This placed female patients in the moderate to severe category on Day 0. By Day 3 ratings had dropped to 50.1 ± 37.7 mm, placing the majority in the mild to moderate category (Table 21). For the Mock I&D group Day 0 began with an average of 87.0 ± 50.8 mm (moderate to severe category). By Day 3 ratings had decreased to 39 ± 35.4 mm (mild to moderate category). As you can see, they too started in the moderate to severe range and then dropped to the mild to moderate rating by Day 3 (Table 21).

Males had similar trends with Day 0 of the I&D group beginning in the moderate to severe category and decreasing to the mild to moderate classification by Day 3. For the male Mock I&D group, Day 0 began with an average pain rating in the moderate to severe pain range, and ended on Day 3 with average pain in the no to mild pain range. The categorical data also shows the decreased classification of both the groups, being rated as mild to moderate by Day 3. All categorical data by group, day, and gender can be seen in Table 21. There was not a statistically significant difference in the VAS scores between genders for the I&D vs. Mock I&D, yet there was a decreasing slope seen
in Figure 2 as all groups reported less and less pain as the four days passed. Once again, as stated above, this isn’t surprising as we expected patients to improve with proper clearing of the source of the infection (36, 90, 91). No current literature addresses the outcome when comparing incision and drainage to mock incision and drainage following emergency endodontic debridement.

Each pain recording was analyzed and categorized as successful if the recording was within the no to mild pain range and no narcotics were taken the same day as that recording. When the count (representing the total recordings for each day of the total 81 subjects, whether in the I&D or Mock I&D group) of these successful readings were tallied, men were found to have significantly higher success rates than women (49% vs. 30%) (p = 0.0007). This may also be attributed to men’s increased pain tolerance and/or women’s higher threshold to pain that was described earlier (75, 78).

The average perception of improvement postoperatively for all participants, whether male or female, I&D or Mock I&D ameliorated over the four days following the procedure. The patient perception of improvement is expected as proper care has been administered, primarily by mechanically and chemically debriding bacteria from the tooth and proper pain medication along with antibiotics has been supplied.

One participant recorded an increase in swelling and symptoms over the four postoperative days. He had been randomly assigned to the incision and drainage group. Following thorough endodontic debridement of tooth #18, an incision and drainage of his vestibular swelling was performed with drain placement. The patient returned on day four postoperatively for drain removal and evaluation of healing. His symptoms did not resolve and he was escorted to the oral and maxillofacial clinic for assessment due to
difficulty swallowing. His antibiotics were then changed to Augmentin by the oral surgery resident and follow up was conducted by the research provider. During a phone call to inquire about patient status on day five the patient’s difficulty swallowing had worsened and due to concern for the patient’s airway, the investigator advised the patient to go to the emergency department for evaluation. The patient reported that he was admitted to the hospital that evening and had intravenous antibiotics administered with surgical decompression due to Ludwig’s angina. Patient returned to our offices two weeks later for evaluation of healing, patient reported significant improvement and plans to have root canal therapy finished in future.

The question remains, how could both groups overall feel they were improving in both pain and swelling status when one group never had the swelling drained? The placebo effect has been a theory for centuries and been studied to identify just how the body employs healing when no real medication, or in our case, procedure was administered. Colloca et al. began mapping out how the brain communicates back to the peripheral nervous system and utilizes endogenous opioids and negative feedback mechanisms to dull pain (104). This may be a reason patients perceive they are getting better, although the initiation of root canal therapy with adjunctive calcium hydroxide medicament and identifying and treating the source is a primary goal when a patient presents with an infection of odontogenic origin should not be discounted.

**Postoperative Statistically Significant Variables**

In terms of success, three variables were found to be significant: Gender (male vs. female), Day (particularly Day 0 vs. Day 2, Day 0 vs. Day 3, Day 1 vs. Day 2, and Day 1 vs. Day 3).
vs. Day 3), and Group (I&D vs. Mock I&D). First, there was a statistically significant difference in success related to gender \((p = 0.0007)\). Each day that was recorded as no to mild pain in conjunction with no narcotic use was identified as a success (Table 12). Females had 51/168 (30%) recordings of success. Males had 74/151 (49%), recordings of success (5 responses were missing). Thus, if you were a male in this study you had a better chance of experiencing success. This coincides with all the literature discussed earlier about men’s higher pain tolerance and women’s heightened pain anxiety and expectation (73-75, 78). It should be noted that there were some postoperative questionnaire recordings that show that males were not “feeling better” as quickly as the females. We consider the better reliability of the VAS daily recordings and self-administered pain medication to be more accurate reflections of pain experienced.

Another significant factor is the Day. Success by day is shown in Table 11, with the percentage of success on Day 0 as 16%, 25% on Day 1, 52% on Day 2, and further increasing by Day 3 to 66% \((p = \leq 0.0001)\). A significant difference for success was seen when comparing these specific days: Day 0 vs. Day 2, Day 0 vs. Day 3, Day 1 vs. Day 2, and Day 1 vs. Day 3. This isn’t surprising, for as the days progress and are compared to the initial days, the participants recorded lower VAS scores and used less pain medication because they felt better.

The final condition to discuss in relation to success is Group assignment. The success summary for the I&D group was 51/154 (33%) counts of success (2 responses were missing). The Mock I&D group had 74/165 (45%) counts of success (3 responses missing). This was found to be statistically significant \((p = 0.0037)\).

The big question is: How could something that is classically taught as optimal
treatment for swellings (incision and drainage) (26, 29) result in significantly higher pain ratings and more narcotic usage? The answer may lie in the procedure itself. When a patient presents with a non-life threatening swelling accompanied by severe pain, we sincerely give our best efforts to identify the problem and provide a resolution by draining the swollen area. The area that is hyperinflamed due to the presence of bacteria, and inflammatory byproducts heightens the nerves response, increasing pain (7, 53). We further wound the tissues with an I&D procedure, believing that this may be beneficial because we are “relieving the pressure”. If it is a cellulitis, we have now introduced a foreign object (the drain) into the area, leaving an open wound exposed to the oral environment. Most swellings of odontogenic origin contain bacteria that are found in the oral environment (12, 13, 29), so this may be of no consequence if you let more bacteria have access to the site of the infection. Once the drain is placed, does it actually remain patent to the environment? In the author’s clinical observations, once the area had been drained and the T-drain placed, the incision area appeared to have collapsed due to the cheek and mouth movements from the patient. However, would the area of the I&D “clot” and close over within a short period of time? Or does the drain provide an open avenue for continued drainage?

There are studies that have looked at the other steps utilized by medical professionals and evaluated their necessity, or rather, lack of necessity in conjunction with incision and drainage. Just recently, the use of irrigation as a predictor of treatment success was argued in Annals of Emergency Medicine. Chinnock, et al. conducted a prospective, non-blinded, randomized, single-center study of patients presenting to the emergency department for incision and drainage of a cutaneous abscess (42). There were
95 patients in the irrigation group and 92 patients in the no-irrigation group. Patients recorded their postprocedural pain on a 100 mm VAS. Telephone calls, after 30 days of collecting data, regarding if further intervention was required, “predefined as repeated incision and drainage, change in antibiotics (addition or change not related to allergy or non-abscess-related infection), and admission for abscess-related condition” was their primary outcome identifier. They found that there was no difference in pain or need for further intervention whether the incision and drainage was completed with or without irrigation (42). This suggests that the added step of irrigation may be unnecessary.

In a review of the medical literature, some authors have studied the effect of wound packing following incision and drainage procedures in pediatric patients. Kessler et al (46) found no statistical significance in failure rates of 57 patients followed for 15 months after packing or not packing the wound. Seventy percent of the packed group required intervention within 48 hours versus only 59% of participants in the non-packed group needing an intervention within the same time frame (p = .03). Pain scores were measured with a color analog scale (due to age of patients enrolled in study). Pain scores among the packed and non-packed wounds did not differ significantly. Kessler et al concluded, “Wound packing does not lead to a difference in the rate of interventions needed at 48-hour wound check, pain scores, rate of healing, or recurrences in children with simple cutaneous abscesses in the pediatric emergency department.” Within the study it was noted that the number of participants was not high enough and further studies would need to be conducted to study this topic. The conclusion states that wound packing does not appear to significantly impact the failure or recurrence rates after simple I&D (46).
O’Malley also conducted a study regarding wound packing vs. no wound packing. Subjects were randomly assigned to two groups, one with packing (¼-inch non–iodophor-impregnated ribbon-gauze) following incision and drainage of the cutaneous abscess, and the other without packing following the incision and drainage. Patients assigned to the packing group reported significantly higher pain scores immediately after the procedure and 48 hours postoperatively, as well as using more ibuprofen and oxycodone/acetaminophen to manage their pain. This finding may indicate that the pain induced during and immediately after the procedure makes wound packing to be unnecessary (47).

Within the current study we did not employ irrigation or wound packing and we did not intend to cross-compare those adjuncts to our study of incision and drainage. Rather, the idea that adding treatment to a process where we were not sure of its current development stage may have been more of a detriment than an aid. Sticking with a logical and trusted resolve, removing the source of the infection via either extraction or endodontic therapy, instead of addressing the symptoms with the infliction of more wounds (incision and drainage) may be our best course of action. Gronholm et al. found that “thorough canal debridement during the first session is essential for minimizing the risk for spread of infection in addition to incision and drainage of the abscess. If this cannot be achieved, tooth extraction should be considered.”(36). Pallasch agreed, stating, “Acute orofacial infections have a rapid onset and relatively short duration of 2-7 days or less, particularly if the offending cause is treated and/or eliminated” (89). Although Gronholm states that treatment of the origin of infection is essential ‘in conjunction with the incision and drainage,’ this alludes to the fact that we know incision and drainage
alone may not be the ideal treatment for these acute apical abscesses.

It can be argued that emergency endodontic treatment alone may not be the choice of treatment at the initial appointment. In a study by Sebastian et al. (91) the efficacy of initial endodontic therapy vs. no initial endodontic therapy on postoperative pain was compared in patients with a symptomatic necrotic tooth. Both groups were taking antibiotic pain medication, and were given a five-day postoperative survey and pain medication (ibuprofen 600 mg to be taken every six hours and acetaminophen 500 mg to be taken every six hours, as well as a hydrocodone/acetaminophen 5/500 mg q6h prescription as the escape medication if the non-narcotic didn’t provide pain relief). Sebastian et al. found the emergency endodontic debridement group to have statistically less pain postoperatively on the fifth day. “The debridement group reached a mild pain level on day one compared to day three in the non-debridement group.” Yet, no statistically significant difference in escape medication usage was seen in the debridement vs. no debridement groups. They concluded, “emergency endodontic debridement of a symptomatic necrotic tooth did not lead to a statistically significant difference in postoperative pain or medication use.” Overall, both groups within Sebastian et al’s study improved over the five days postoperatively (91). It should be noted that when comparing their study to the current study, they did not study patients with swellings. Had swollen patients been included in the study of debridement vs. no debridement that may have led to different findings, due to the status of the spread of infection.

The findings of Schmitz et al. may shed more light. Their study found various methods are currently being practiced to treat abscesses in hospital emergency
departments such as packing vs. not packing, irrigation vs. no irrigation, drain placement vs. no drain placement (41). Flynn’s prospective study proved the length of hospital stay for patients that underwent incision and drainage, whether it was for a cellulitis or fluctuant swelling, did not statistically differ (40). Shanti concludes, “Today, there is no universal agreement on issues, such as optimal timing for surgical drainage and the duration of antibiotic therapy for the management of deep neck infections.” (32). Currently, practitioners make clinical decisions on whether or not to drain based on anecdotal reports or personal preference, rather than on sound scientific evidence.

**Overall Treatment Pain and Satisfaction**

The overall treatment pain for the entire procedure, including the anesthetic administration, root canal access, debridement, and incision and drainage/mock incision and drainage was rated by each patient. The I&D group reported average pain in the moderate-to-severe category. The Mock I&D group recorded average pain in the moderate level. This represents a statistically significant difference ($p = 0.0271$). When considering that the mock procedure did not create a wound comparable to the real I&D procedure, it is logical that the mock procedure would not be rated as highly as the known painful procedure (actual I&D) (51, 67, 64).

At the end of all the procedures patients were asked to rate their satisfaction on a 100 mm VAS. The majority of patients were completely satisfied with treatment whether in the I&D group or the Mock I&D group, with no statistical significance noted ($p = 0.3114$). Both the I&D and Mock I&D groups reported being “completely satisfied” with their treatment. This finding is noteworthy, as the pain recordings during the I&D
procedure were found to be in the moderate-to-severe range, yet participants remained satisfied. This could be due to hope and gratitude for the possibility of pain reduction and/or relief. They were also financially compensated as a participant of the study, which could contribute to their satisfaction of receiving care for something they would have had to have treated regardless of participating in a study.

A caring attitude and attention to patient communicative styles can also affect the satisfaction of the patient, regardless of a painful procedure. Gale et al. found when a provider is kind and sympathetic to a patient’s needs and answers concerns thoroughly, this results in satisfied patients, no matter the pain experienced during treatment (104). This is effective because they feel that providers do not intend to cause pain, which their goal is to relieve patients of their pain. Clearly communicating with your patient and understanding their form of communication has a positive effect on a patient’s satisfaction with treatment, even when that treatment is something that is known to cause pain, such as root canal therapy, or incision and drainage (105, 106). Finally, the anticipation of resolution from the uncomfortable state they arrived in is thought to have some bearing on their satisfaction with treatment. It gives the patient hope for healing, which may be priceless. Most patients in this study reported that they were completely satisfied, which is most likely due to our close attention to addressing their needs and clearly communicating in a way that put them at ease (107).

Conclusions and Future Direction

In conclusion, the I&D procedure proved to be more painful during all three procedure steps for both genders and the difference was statistically significant for males. The I&D
procedure also resulted in higher VAS pain recordings, and pain perception over the four days postoperatively. The statistically significant finding of the Mock I&D group experiencing more successful outcomes when compared to the I&D group indicates the I&D procedure may be unnecessary in these mild to moderately painful, localized, intraoral swellings of odontogenic origin.

Perhaps, until there is more evidence to support the methods of how, when, and with what to perform the incision and drainage, it is best to only intervene when the spread is known to be of medical necessity in order to remove the source of infection, or in cases where the swelling becomes life-threatening. It is clear that there are situations where incision and drainage is warranted (Ludwig’s angina, for example), and as dental professionals we are expected to recognize these signs and advise the patient to the appropriate care that is found in the emergency department. However, for these mild to moderate, localized, intraoral swellings of odontogenic origin perhaps we can serve our patients best by removing the source of the infection, supplying antibiotics when appropriate, and prescribing sufficient pain medication for patient comfort during healing.

If the study were to be repeated, it would be beneficial to include a larger sample size. We did not directly measure the volume of the swellings for reasons stated earlier, but if future measuring options that are reliable and convenient are developed these may help more directly identify swelling status, as well as accurately assessing resolution of the swelling. These measurements could provide more information regarding the clinical necessity of the I&D procedure in these mild to moderate, localized, intraoral swelling of odontogenic origin. Further investigations may also want to collect more specific
information regarding antibiotic and analgesic use to see if that provides significance in outcome.
Chapter 5: Summary and Conclusions

This investigation evaluated the efficacy of incision and drainage and mock incision and drainage in postoperative pain status and narcotic use. Adult patients presenting to the emergency clinic at The Ohio State University with a diagnosis of pulpal necrosis with associated facial swelling of either an acute apical abscess or cellulitis were included in the study. Patients had emergency endodontic debridement performed on the offending tooth prior to undergoing an I&D or Mock I&D procedure. Each of the steps of the I&D or Mock I&D (incision, drainage, and dissection) pain and postoperative pain were recorded and statistically analyzed. Additionally, pain perception, and swelling perception were recorded. Success was defined as no-to-mild pain recordings on a 170 mm Heft-Parker VAS and no narcotic usage.

There were statistically significant differences between gender, day, and group for the postoperative pain assessment. Males had a statistically significant difference in pain measurements between the I&D vs. the Mock I&D procedure, whereas female pain recordings were not significant for the I&D vs. Mock I&D. These findings suggest that the I&D procedure induced more pain during the procedure and postoperatively in males, when compared with the Mock I&D in the studied patient population.

Furthermore, statistically significant differences were found in success when analyzing the postoperative pain ratings and narcotic use with regard to gender, day, and
group assignment. Forty-nine percent of male patient recordings were successful postoperatively. In comparison, 30% of female patient recordings were successful in the four postoperative days. Males had significantly higher success than females postoperatively. The percentage of successful recordings increased with each passing day (16% Day 0, 24.7% Day 1, 51.9% Day 2, 65.8% Day 3) and the difference was statistically significant. A statistically significant difference between the postoperative success recordings was noted between the I&D and Mock I&D group. The Mock I&D group reported 44.8% of the responses as successful. Thirty-three percent of the responses in the I&D group were recorded as successful. This difference in pain ratings may suggest that an I&D is a less efficacious procedure than not performing an I&D for patients experiencing an acute apical abscess or cellulitis undergoing emergency endodontic debridement.

In conclusion, Mock Incision and Drainage, when compared with Incision and Drainage, significantly reduced the pain of the procedure, as well as, pain and narcotic use four days postoperatively in patients with a diagnosis of pulpal necrosis and an acute apical abscess or cellulitis.
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Appendix A: Tables
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<th>Incision and Drainage</th>
<th>Mock Incision and Drainage</th>
<th>p-value</th>
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<td>42</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td>0.5865*</td>
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<td>Female 23/42 (55%)</td>
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<td>37.3 (+/−14.7)</td>
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<td>25 (64%)</td>
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<td>10</td>
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Table 1. Preliminary Data for Incision and Drainage vs. Mock Incision and Drainage.

*Chi-square test
**Mann-Whitney-Wilcoxon test
***Randomization Test. Step-down Bonferroni method of Holm
****Fisher Exact Test
<table>
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Table 2. Initial Injection Pain and Treatment Pain as Rated on a 170 mm Heft-Parker VAS.
***Randomization Test. Step-down Bonferroni method of Holm
Table 3. Pain During Incision and Drainage vs. Mock Incision and Drainage as Rated on a 170 mm Heft-Parker VAS.

***Randomization Test. Step-down Bonferroni method of Holm

Table 4. Female Postoperative Pain Status.

Day 0 Question: Compared to before treatment, do you feel the swelling is
Day 1-3 Question: Compared to yesterday, do you feel the swelling is
0 = WORSE
1 = THE SAME
2 = BETTER

**Mann-Whitney-Wilcoxon test. Step-down Bonferroni method of Holm
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<td></td>
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<td>1.3</td>
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Table 5. Female Postoperative Swelling Status.

Day 0 Question: Compared to before treatment, do you feel the swelling is
Day 1-3 Question: Compared to yesterday, do you feel the swelling is
0 = WORSE
1 = THE SAME
2 = BETTER

**Mann-Whitney-Wilcoxon test. Step-down Bonferroni method of Holm

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<td>1.7</td>
<td>0.7</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Day 1</td>
<td>1.7</td>
<td>0.5</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Day 2</td>
<td>1.6</td>
<td>0.8</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Day 3</td>
<td>1.7</td>
<td>0.6</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Table 6. Male Postoperative Pain Status.

Day 0 Question: Compared to before treatment, do you feel the swelling is
Day 1-3 Question: Compared to yesterday, do you feel the swelling is
0 = WORSE
1 = THE SAME
2 = BETTER

**Mann-Whitney-Wilcoxon test. Step-down Bonferroni method of Holm

<table>
<thead>
<tr>
<th>GROUP</th>
<th>N Obs</th>
<th>Variable</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I&amp;D</td>
<td>20</td>
<td>Day 0</td>
<td>1.5</td>
<td>0.7</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1.0000**</td>
</tr>
<tr>
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<td>20</td>
<td>Day 1</td>
<td>1.6</td>
<td>0.7</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1.0000**</td>
</tr>
<tr>
<td></td>
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<td>Day 2</td>
<td>1.7</td>
<td>0.7</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1.0000**</td>
</tr>
<tr>
<td></td>
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<td>Day 3</td>
<td>1.8</td>
<td>0.6</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1.0000**</td>
</tr>
<tr>
<td>MOCK</td>
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<td>Day 0</td>
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<td>0.6</td>
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<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Day 1</td>
<td>1.7</td>
<td>0.6</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Day 2</td>
<td>1.7</td>
<td>0.6</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Day 3</td>
<td>1.7</td>
<td>0.6</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Table 7. Male Postoperative Swelling Status.

Day 0 Question: Compared to before treatment, do you feel the swelling is
Day 1-3 Question: Compared to yesterday, do you feel the swelling is
0 = WORSE
1 = THE SAME
2 = BETTER

**Mann-Whitney-Wilcoxon test. Step-down Bonferroni method of Holm
<table>
<thead>
<tr>
<th>GROUP</th>
<th>N Obs</th>
<th>Variable</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I&amp;D</td>
<td>19</td>
<td>Day 0</td>
<td>104.8</td>
<td>47.7</td>
<td>112</td>
<td>0</td>
<td>170</td>
<td>0.7345***</td>
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<tr>
<td>I&amp;D</td>
<td>19</td>
<td>Day 1</td>
<td>88.5</td>
<td>38.3</td>
<td>97</td>
<td>0</td>
<td>142</td>
<td>0.7345***</td>
</tr>
<tr>
<td>I&amp;D</td>
<td>19</td>
<td>Day 2</td>
<td>70.6</td>
<td>44.2</td>
<td>61</td>
<td>0</td>
<td>170</td>
<td>0.1981***</td>
</tr>
<tr>
<td>I&amp;D</td>
<td>19</td>
<td>Day 3</td>
<td>50.1</td>
<td>37.7</td>
<td>39</td>
<td>0</td>
<td>142</td>
<td>0.7345***</td>
</tr>
<tr>
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<td>23</td>
<td>Day 0</td>
<td>87.0</td>
<td>50.8</td>
<td>90</td>
<td>0</td>
<td>170</td>
<td></td>
</tr>
<tr>
<td>MOCK</td>
<td>23</td>
<td>Day 1</td>
<td>73.9</td>
<td>42.0</td>
<td>64</td>
<td>0</td>
<td>149</td>
<td></td>
</tr>
<tr>
<td>MOCK</td>
<td>23</td>
<td>Day 2</td>
<td>47.3</td>
<td>29.8</td>
<td>48</td>
<td>0</td>
<td>113</td>
<td></td>
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<tr>
<td>MOCK</td>
<td>23</td>
<td>Day 3</td>
<td>39.0</td>
<td>35.4</td>
<td>35</td>
<td>0</td>
<td>153</td>
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</table>

Table 8. Pain by Group and Day for Female Subjects (170 mm Heft-Parker VAS).
***Randomization Test. Step-down Bonferroni method of Holm

<table>
<thead>
<tr>
<th>GROUP</th>
<th>N Obs</th>
<th>Variable</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I&amp;D</td>
<td>20</td>
<td>Day 0</td>
<td>100.0</td>
<td>54.4</td>
<td>88</td>
<td>21</td>
<td>170</td>
<td>0.2871***</td>
</tr>
<tr>
<td>I&amp;D</td>
<td>20</td>
<td>Day 1</td>
<td>66.2</td>
<td>50.2</td>
<td>58</td>
<td>0</td>
<td>170</td>
<td>0.2871***</td>
</tr>
<tr>
<td>I&amp;D</td>
<td>20</td>
<td>Day 2</td>
<td>53.0</td>
<td>45.9</td>
<td>44</td>
<td>0</td>
<td>170</td>
<td>0.2871***</td>
</tr>
<tr>
<td>I&amp;D</td>
<td>20</td>
<td>Day 3</td>
<td>39.3</td>
<td>44.2</td>
<td>24.5</td>
<td>0</td>
<td>160</td>
<td>0.2871***</td>
</tr>
<tr>
<td>MOCK</td>
<td>19</td>
<td>Day 0</td>
<td>68.1</td>
<td>52.6</td>
<td>59</td>
<td>0</td>
<td>170</td>
<td></td>
</tr>
<tr>
<td>MOCK</td>
<td>19</td>
<td>Day 1</td>
<td>46.0</td>
<td>33.6</td>
<td>58</td>
<td>0</td>
<td>109</td>
<td></td>
</tr>
<tr>
<td>MOCK</td>
<td>19</td>
<td>Day 2</td>
<td>34.5</td>
<td>28.0</td>
<td>37</td>
<td>0</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>MOCK</td>
<td>19</td>
<td>Day 3</td>
<td>20.5</td>
<td>18.1</td>
<td>21</td>
<td>0</td>
<td>58</td>
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</table>

Table 9. Pain by Group and Day for Male Subjects (170 mm Heft-Parker VAS).
***Randomization Test. Step-down Bonferroni method of Holm

<table>
<thead>
<tr>
<th>GROUP</th>
<th>SUCCESS</th>
<th>COUNT</th>
<th>PERCENT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I&amp;D</td>
<td>MISSING</td>
<td>2</td>
<td>0.0037*</td>
<td></td>
</tr>
<tr>
<td>I&amp;D</td>
<td>NO</td>
<td>103</td>
<td>67</td>
<td></td>
</tr>
<tr>
<td>I&amp;D</td>
<td>YES</td>
<td>51</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>MOCK</td>
<td>MISSING</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOCK</td>
<td>NO</td>
<td>91</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>MOCK</td>
<td>YES</td>
<td>74</td>
<td>45</td>
<td></td>
</tr>
</tbody>
</table>

Table 10. Success** Summary by Group.
*Chi-square test
** Success defined by no or mild pain (≤54 mm on Heft-Parker VAS) and no narcotic use.

<table>
<thead>
<tr>
<th>DAY</th>
<th>SUCCESS</th>
<th>COUNT</th>
<th>PERCENT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>NO</td>
<td>68</td>
<td>84</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>0</td>
<td>YES</td>
<td>13</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NO</td>
<td>61</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>YES</td>
<td>20</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NO</td>
<td>39</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>YES</td>
<td>42</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>MISSING</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NO</td>
<td>26</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>YES</td>
<td>50</td>
<td>66</td>
<td></td>
</tr>
</tbody>
</table>

Table 11. Success** Summary by Day.
*Chi-square test
**Success defined by no or mild pain (≤54 mm on Heft-Parker VAS) and no narcotic use.
<table>
<thead>
<tr>
<th>GENDER</th>
<th>SUCCESS</th>
<th>COUNT</th>
<th>PERCENT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEMALE</td>
<td>NO</td>
<td>117</td>
<td>70</td>
<td>0.0007*</td>
</tr>
<tr>
<td>FEMALE</td>
<td>YES</td>
<td>51</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>MALE</td>
<td>MISSING</td>
<td>5</td>
<td>.</td>
<td></td>
</tr>
<tr>
<td>MALE</td>
<td>NO</td>
<td>77</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>MALE</td>
<td>YES</td>
<td>74</td>
<td>49</td>
<td></td>
</tr>
</tbody>
</table>

Table 12. Success** Summary by Gender.
*Chi-square test
**Success defined by no or mild pain (≤54 mm on Heft-Parker VAS) and no narcotic use.

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Estimate</th>
<th>DF</th>
<th>95% Confidence Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP I&amp;D vs MOCK</td>
<td>0.414</td>
<td>300</td>
<td>0.228 - 0.752</td>
</tr>
<tr>
<td>DAY 0 vs 1</td>
<td>0.647</td>
<td>300</td>
<td>0.254 - 1.649</td>
</tr>
<tr>
<td>DAY 0 vs 2</td>
<td>0.146</td>
<td>300</td>
<td>0.064 - 0.334</td>
</tr>
<tr>
<td>DAY 0 vs 3</td>
<td>0.075</td>
<td>300</td>
<td>0.032 - 0.175</td>
</tr>
<tr>
<td>DAY 1 vs 2</td>
<td>0.226</td>
<td>300</td>
<td>0.099 - 0.517</td>
</tr>
<tr>
<td>DAY 1 vs 3</td>
<td>0.116</td>
<td>300</td>
<td>0.049 - 0.271</td>
</tr>
<tr>
<td>DAY 2 vs 3</td>
<td>0.511</td>
<td>300</td>
<td>0.249 - 1.047</td>
</tr>
<tr>
<td>GENDER FEMALE vs MALE</td>
<td>0.361</td>
<td>300</td>
<td>0.2 - 0.651</td>
</tr>
</tbody>
</table>

Table 13. Odds Ratio Estimates for Success**.
**Success defined by no or mild pain (≤54 mm on Heft-Parker VAS) and no narcotic use.

<table>
<thead>
<tr>
<th>Effect*</th>
<th>Num DF</th>
<th>Den DF</th>
<th>Chi-Square</th>
<th>F Value</th>
<th>Pr &gt; ChiSq</th>
<th>Pr &gt; F ***</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP</td>
<td>1</td>
<td>300</td>
<td>8.44</td>
<td>8.44</td>
<td>0.0037</td>
<td>0.0039</td>
</tr>
<tr>
<td>DAY</td>
<td>3</td>
<td>300</td>
<td>48.48</td>
<td>16.16</td>
<td>&lt;.0001</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>GROUP*DAY</td>
<td>3</td>
<td>300</td>
<td>0.61</td>
<td>0.2</td>
<td>0.8939</td>
<td>0.8938</td>
</tr>
<tr>
<td>GENDER</td>
<td>1</td>
<td>300</td>
<td>11.54</td>
<td>11.54</td>
<td>0.0007</td>
<td>0.0008</td>
</tr>
<tr>
<td>GROUP*GENDER</td>
<td>1</td>
<td>300</td>
<td>0.03</td>
<td>0.03</td>
<td>0.8545</td>
<td>0.8546</td>
</tr>
<tr>
<td>GENDER*DAY</td>
<td>3</td>
<td>300</td>
<td>1.2</td>
<td>0.4</td>
<td>0.7535</td>
<td>0.7535</td>
</tr>
<tr>
<td>GROUP<em>GENDER</em>DAY</td>
<td>3</td>
<td>300</td>
<td>1.64</td>
<td>0.55</td>
<td>0.651</td>
<td>0.6514</td>
</tr>
</tbody>
</table>

Table 14. Adjusted Odds Ratio for Success**.
**Success defined by no or mild pain (≤54 mm on Heft-Parker VAS) and no narcotic use.
*Type III test of fixed effects.
****Fisher Exact Test

<table>
<thead>
<tr>
<th>Label</th>
<th>Num DF</th>
<th>Den DF</th>
<th>F Value</th>
<th>Pr &gt; F***</th>
</tr>
</thead>
<tbody>
<tr>
<td>I&amp;D VS MOCK I&amp;D</td>
<td>1</td>
<td>300</td>
<td>8.44</td>
<td>0.0039</td>
</tr>
<tr>
<td>FEMALE VS MALE</td>
<td>1</td>
<td>300</td>
<td>11.54</td>
<td>0.0008</td>
</tr>
<tr>
<td>DAY0 VS DAY1</td>
<td>1</td>
<td>300</td>
<td>0.84</td>
<td>0.3609</td>
</tr>
<tr>
<td>DAY0 VS DAY2</td>
<td>1</td>
<td>300</td>
<td>21.02</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>DAY0 VS DAY3</td>
<td>1</td>
<td>300</td>
<td>36.04</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>DAY1 VS DAY2</td>
<td>1</td>
<td>300</td>
<td>12.51</td>
<td>0.0005</td>
</tr>
<tr>
<td>DAY1 VS DAY3</td>
<td>1</td>
<td>300</td>
<td>24.87</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>DAY2 VS DAY3</td>
<td>1</td>
<td>300</td>
<td>3.39</td>
<td>0.0665</td>
</tr>
</tbody>
</table>

Table 15. Success Contrasts.
****Fisher Exact Test
<table>
<thead>
<tr>
<th>GROUP</th>
<th>N</th>
<th>Variable</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>p***</th>
</tr>
</thead>
<tbody>
<tr>
<td>I&amp;D</td>
<td>39</td>
<td>SATISFAC</td>
<td>94.5</td>
<td>10.5</td>
<td>100</td>
<td>66</td>
<td>100</td>
<td>0.3114</td>
</tr>
<tr>
<td>MOCK</td>
<td>42</td>
<td>SATISFAC</td>
<td>97.0</td>
<td>11.4</td>
<td>100</td>
<td>33</td>
<td>100</td>
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</tr>
</tbody>
</table>

Table 16. Satisfaction with procedures as rated on 100 mm VAS.
***Randomization Test. Step-down Bonferroni method of Holm

<table>
<thead>
<tr>
<th>GROUP</th>
<th>N</th>
<th>Variable</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>p***</th>
</tr>
</thead>
<tbody>
<tr>
<td>I&amp;D</td>
<td>39</td>
<td>TXPAIN</td>
<td>81.6</td>
<td>47.6</td>
<td>84</td>
<td>0</td>
<td>170</td>
<td>0.0271</td>
</tr>
<tr>
<td>MOCK</td>
<td>42</td>
<td>TXPAIN</td>
<td>55.9</td>
<td>43.0</td>
<td>54.5</td>
<td>0</td>
<td>159</td>
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</tr>
</tbody>
</table>

Table 17. Overall treatment pain for procedure as rated on 170 mm Heft-Parker VAS.
***Randomization Test. Step-down Bonferroni method of Holm
<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th></th>
<th>Male</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dentin</td>
<td>Pulp Chamber</td>
<td>Instrumentation</td>
<td>Dentin</td>
</tr>
<tr>
<td>I&amp;D N</td>
<td>19</td>
<td>19</td>
<td>19</td>
<td>20</td>
</tr>
<tr>
<td>None</td>
<td>18</td>
<td>16</td>
<td>18</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>(95%)</td>
<td>(84%)</td>
<td>(95%)</td>
<td>(65%)</td>
</tr>
<tr>
<td>Mild</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>(0%)</td>
<td>(16%)</td>
<td>(5%)</td>
<td>(35%)</td>
</tr>
<tr>
<td>Moderate</td>
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<td>0</td>
<td>0</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>(5%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td>(0%)</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Severe</td>
</tr>
<tr>
<td></td>
<td>(0%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td>(0%)</td>
</tr>
<tr>
<td>Mock I&amp;D N</td>
<td>23</td>
<td>23</td>
<td>23</td>
<td>Mock I&amp;D N</td>
</tr>
<tr>
<td>None</td>
<td>14</td>
<td>19</td>
<td>14</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>(61%)</td>
<td>(83%)</td>
<td>(61%)</td>
<td>(74%)</td>
</tr>
<tr>
<td>Mild</td>
<td>9</td>
<td>4</td>
<td>7</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>(39%)</td>
<td>(17%)</td>
<td>(30%)</td>
<td>(26%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>(0%)</td>
<td>(0%)</td>
<td>(9%)</td>
<td>(0%)</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Severe</td>
</tr>
<tr>
<td></td>
<td>(0%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td>(0%)</td>
</tr>
</tbody>
</table>

Table 18. Categorical Summary of Pain during Tooth Access (170 mm Heft-Parker VAS).
<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th></th>
<th>Male</th>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Insertion</td>
<td>Placement</td>
<td>Deposition</td>
<td>Insertion</td>
<td>Placement</td>
<td>Deposition</td>
<td></td>
</tr>
<tr>
<td>I&amp;D</td>
<td>N</td>
<td>19</td>
<td>19</td>
<td>19</td>
<td>I&amp;D</td>
<td>N</td>
<td>20</td>
</tr>
<tr>
<td>None</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
<td>None</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Mild</td>
<td>7 (37%)</td>
<td>2 (11%)</td>
<td>0 (0%)</td>
<td>Mild</td>
<td>7 (35%)</td>
<td>6 (30%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>7 (37%)</td>
<td>13 (68%)</td>
<td>10 (53%)</td>
<td>Moderate</td>
<td>8 (40%)</td>
<td>11 (55%)</td>
<td>12 (60%)</td>
</tr>
<tr>
<td>Severe</td>
<td>3 (16%)</td>
<td>2 (11%)</td>
<td>7 (37%)</td>
<td>Severe</td>
<td>4 (20%)</td>
<td>2 (10%)</td>
<td>2 (10%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Mock I&amp;D</th>
<th>N</th>
<th>23</th>
<th>23</th>
<th>23</th>
<th>Mock I&amp;D</th>
<th>N</th>
<th>19</th>
<th>19</th>
<th>19</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0 (0%)</td>
<td>3 (13%)</td>
<td>0 (0%)</td>
<td>None</td>
<td>2 (11%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>13 (57%)</td>
<td>7 (30%)</td>
<td>8 (35%)</td>
<td>Mild</td>
<td>10 (53%)</td>
<td>6 (32%)</td>
<td>4 (21%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>8 (35%)</td>
<td>11 (48%)</td>
<td>9 (39%)</td>
<td>Moderate</td>
<td>7 (37%)</td>
<td>11 (58%)</td>
<td>11 (58%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>2 (9%)</td>
<td>2 (9%)</td>
<td>6 (26%)</td>
<td>Severe</td>
<td>0 (0%)</td>
<td>2 (11%)</td>
<td>4 (21%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 19. Categorical Summary of Pain during Anesthetic Administration (170 mm Heft-Parker VAS).
<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th></th>
<th></th>
<th>Male</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incision</td>
<td>Drainage</td>
<td>Dissection</td>
<td>Incision</td>
<td>Drainage</td>
<td>Dissection</td>
</tr>
<tr>
<td>I&amp;D</td>
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<td>N</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>5 (26%)</td>
<td>5 (26%)</td>
<td>None</td>
<td>1 (5%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>6 (32%)</td>
<td>8 (42%)</td>
<td>Mild</td>
<td>10 (50%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>7 (37%)</td>
<td>7 (37%)</td>
<td>Moderate</td>
<td>6 (30%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>3 (16%)</td>
<td>4 (21%)</td>
<td>Severe</td>
<td>3 (15%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>Mock I&amp;D</td>
<td>N</td>
<td>23</td>
<td>23</td>
<td>N</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>8 (35%)</td>
<td>7 (31%)</td>
<td>None</td>
<td>10 (53%)</td>
<td>10 (53%)</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>12 (52%)</td>
<td>12 (52%)</td>
<td>Mild</td>
<td>8 (42%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>1 (4%)</td>
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<td>Moderate</td>
<td>1 (5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>Severe</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Table 20. Categorical Summary of Pain during Incision & Drainage or Mock Incision and Drainage procedure (170 mm Heft-Parker VAS).
<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Male</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DAY0</td>
<td>DAY1</td>
<td>DAY2</td>
<td>DAY3</td>
<td></td>
<td>DAY0</td>
<td>DAY1</td>
<td>DAY2</td>
<td>DAY3</td>
<td></td>
</tr>
<tr>
<td>I&amp;D</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td>I&amp;D</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
<td>2 (11%)</td>
<td>None</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
<td>4 (20%)</td>
<td>4 (20%)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>1 (5%)</td>
<td>2 (11%)</td>
<td>5 (26%)</td>
<td>9 (47%)</td>
<td>Mild</td>
<td>5 (25%)</td>
<td>5 (25%)</td>
<td>8 (40%)</td>
<td>11 (55%)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>10 (53%)</td>
<td>13 (68%)</td>
<td>10 (53%)</td>
<td>7 (37%)</td>
<td>Moderate</td>
<td>7 (35%)</td>
<td>10 (50%)</td>
<td>7 (35%)</td>
<td>4 (20%)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>7 (37%)</td>
<td>3 (16%)</td>
<td>3 (16%)</td>
<td>1 (5%)</td>
<td>Severe</td>
<td>8 (40%)</td>
<td>3 (15%)</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mock I&amp;D</td>
<td>N</td>
<td>23</td>
<td>23</td>
<td>23</td>
<td>23</td>
<td>Mock I&amp;D</td>
<td>N</td>
<td>19</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>None</td>
<td>2 (9%)</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
<td>4 (18%)</td>
<td>None</td>
<td>3 (16%)</td>
<td>4 (21%)</td>
<td>4 (21%)</td>
<td>6 (32%)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>3 (13%)</td>
<td>5 (22%)</td>
<td>14 (61%)</td>
<td>12 (52%)</td>
<td>Mild</td>
<td>4 (21%)</td>
<td>5 (26%)</td>
<td>11 (58%)</td>
<td>11 (58%)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>13 (56%)</td>
<td>14 (61%)</td>
<td>8 (35%)</td>
<td>6 (26%)</td>
<td>Moderate</td>
<td>9 (47%)</td>
<td>10 (53%)</td>
<td>4 (21%)</td>
<td>2 (10%)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>5 (22%)</td>
<td>3 (13%)</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
<td>Severe</td>
<td>3 (16%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 21. Categorical Data of Pain by Day and Group and Gender (170 mm Heft-Parker VAS).
<table>
<thead>
<tr>
<th></th>
<th>DAY0</th>
<th>DAY1</th>
<th>DAY2</th>
<th>DAY3</th>
</tr>
</thead>
<tbody>
<tr>
<td>I&amp;D</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1 (3%)</td>
<td>3 (8%)</td>
<td>5 (13%)</td>
<td>6 (16%)</td>
</tr>
<tr>
<td>Mild</td>
<td>6 (15%)</td>
<td>7 (18%)</td>
<td>13 (33%)</td>
<td>20 (51%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>17 (44%)</td>
<td>23 (59%)</td>
<td>17 (44%)</td>
<td>11 (28%)</td>
</tr>
<tr>
<td>Severe</td>
<td>15 (38%)</td>
<td>6 (15%)</td>
<td>4 (10%)</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Mock I&amp;D</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>5 (12%)</td>
<td>5 (12%)</td>
<td>5 (12%)</td>
<td>10 (24%)</td>
</tr>
<tr>
<td>Mild</td>
<td>7 (17%)</td>
<td>10 (24%)</td>
<td>25 (60%)</td>
<td>23 (55%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>22 (52%)</td>
<td>24 (57%)</td>
<td>12 (28%)</td>
<td>8 (19%)</td>
</tr>
<tr>
<td>Severe</td>
<td>8 (19%)</td>
<td>3 (7%)</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

Table 22. Categorical Data of Pain by Day and Group (170 mm Heft-Parker VAS).

<table>
<thead>
<tr>
<th></th>
<th>DAY0</th>
<th>DAY1</th>
<th>DAY2</th>
<th>DAY3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe Pain I&amp;D</td>
<td>32 (82%)</td>
<td>29 (74%)</td>
<td>21 (54%)</td>
<td>13 (33%)</td>
</tr>
<tr>
<td>Moderate-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe Pain Mock I&amp;D</td>
<td>30 (71%)</td>
<td>27 (64%)</td>
<td>12 (29%)</td>
<td>9 (21%)</td>
</tr>
</tbody>
</table>

Table 23. Categorical Data of combined moderate to severe pain by Day and Group (Heft-Parker VAS).
Appendix B: Figures
Figure 1. Procedural Pain by Gender and Group (170 mm Heft-Parker VAS)

Figure 2. Pain by Day and Gender (Heft-Parker 170 mm VAS)
Figure 3. Pain by Day and Group (Heft-Parker 170 mm VAS)

Figure 4. Success** Summary by Group (recorded over 4 days post operatively)

** Success defined by no or mild pain (≤54 mm on Heft-Parker VAS) and no narcotic use.
Appendix C: Consent Form
The Ohio State University Consent to Participate in Research

Study Title: Does incision and drainage need to be done following emergency root canal treatment?
Principal Investigator: Dr. Sara Fowler
Sponsor: Not applicable

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. **Why is this study being done?**

   The purpose of this study is to determine the clinical value of the incision (cut) and drainage procedure in patients who are undergoing root canal treatment due to pain, clinical swelling, and a diagnosis of pulpal necrosis (dead tooth).

2. **How many people will take part in this study?**

   One hundred and twenty (120) people will take part in this study.

3. **What will happen if I take part in this study?**

   If you choose to participate in this study, you will receive an incision (cut) and drainage
or mock (simulated) incision and drainage in conjunction with your standard root canal therapy to assess if the incision (cut) and drainage procedure is helpful. After you consent to participate and sign a HIPAA (privacy) form, you will be required to complete a medical history questionnaire.

You will then be randomly assigned (like flipping a coin) to one of two groups to determine whether you will receive an incision (cut) and drainage or mock (simulated) incision and drainage, with your root canal therapy. You will not know which procedure you are receiving. The doctor will know which procedure you are receiving. Both groups will still have the standard of care emergency root canal therapy to address the swelling and pain.

**Root Canal Therapy**: This procedure will be completed the same as it would if you were not participating the in study.

**Incision & Drainage or Mock Incision and Drainage**: Prior to injection, topical anesthetic will be placed at each injection site for 60 seconds. You then will receive an infiltration (injection) of 0.9 mL (one half anesthetic cartridge) of 4% articaine in front of the swelling over a one minute time period. Next, you will receive a second infiltration (injection) of 0.9 mL (one half anesthetic cartridge) of the anesthetic solution behind the swelling over a one minute time period. Following each of these two injections, you will be asked to rate the amount of pain you feel when the injections are being given. You will do this by marking your pain experience on a line graph with a pen. Following the administration of the appropriate anesthetic solution, an incision and drainage or mock incision and drainage procedure will be performed on the swelling. Following this procedure, you will again be asked to rate your pain experience on a line graph with a pen.

At the end of the study visit, you will be asked to rate your degree of satisfaction with the procedure on another line graph. You will receive a diary for the day (Day 0) of the appointment and 3 days postoperatively to daily record any pain you are having and the pain medication you are taking. You will also be allowed to take and submit to the investigator (Hannah Beus) any pictures of the swelling or drain area. You will return the diary when you return to the clinic on day 4 (3rd day postoperatively) for drain removal and evaluation to determine if any further treatment if necessary. This will conclude your study participation. Any additional treatment will be performed outside of the study.

4. **How long will I be in the study?**

You will have two appointments, Day 0 (treatment and drain placement) and Day 3 (drain removal) during day 1 to day 3 you will have diary entry each day about your pain and healing. The first appointment, where we start root canal therapy with incision and drainage or mock incision and drainage, will last approximately 60 minutes. The second appointment, where we will remove the drain and collect the diary will last approximately 20 minutes.
5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

You may have pain associated with the local anesthetic (numbing solution) or soreness at the site of the injections (shots) for approximately two days. Where you receive the injection, you may have swelling (hematoma—a collection of blood in your mouth) or a bruise may develop. You may experience a feeling of anxiety, lightheadedness or fainting, and or a temporary increase in your heart rate. You may have an allergic reaction to the local anesthetic (itching or hives) which is very rare, or have an unexpected infection (also rare) which could result in permanent nerve damage. You may have soreness of your gum tissue for a few days or a possible altered sensation of your lip or tongue that may last up to a few weeks.

If you are a woman able to have children, you will be questioned regarding pregnancy or suspected pregnancy and will not be allowed to participate if pregnant, suspect a pregnancy, trying to become pregnant, or nursing. The reason for excluding pregnant or potentially pregnant women is an attempt to minimize this population in the study because the potential risks to the fetus and nursing baby are unknown.

7. What benefits can I expect from being in the study?

You may not directly benefit from participating in this study. We do not know if there is any difference in terms of pain or comfort of healing in patients who receive an incision (cut) and drainage verses those who do not.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. You may elect to have your root canal treatment performed outside of this study.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal
information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

• Office for Human Research Protections or other federal, state, or international regulatory agencies;
• U.S. Food and Drug Administration;
• The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
• The sponsor supporting the study, their agents or study monitors; and
• Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician’s office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

There will be no additional costs associated with the study participation. You (or your insurance company) will be responsible for the cost of your standard root canal therapy. The incision and drainage procedure will be performed at no cost.

11. Will I be paid for taking part in this study?

You will receive $50 cash at the end of the root canal emergency treatment/incision and drainage appointment. At the second visit, upon the completion and return of the daily diary and presentation for drain removal, you will receive an additional $50 cash.

By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses.
for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Sara Fowler or Dr. Hannah Beus at 657-229-2387.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Sara Fowler or Dr. Hannah Beus at 657-229-2387.
**Signing the consent form**

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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<th>Printed name of subject</th>
<th>Signature of subject</th>
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<th>Printed name of person authorized to consent for subject (when applicable)</th>
<th>Signature of person authorized to consent for subject (when applicable)</th>
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**Investigator/Research Staff**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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<th>Printed name of person obtaining consent</th>
<th>Signature of person obtaining consent</th>
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**Witness(es) - May be left blank if not required by the IRB**

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Appendix D: Privacy Form
THE OHIO STATE UNIVERSITY
AUTHORIZATION TO USE
PERSONAL HEALTH INFORMATION IN RESEARCH

Title of the Study: Does an incision and drainage need to be done following emergency root canal treatment?

OSU Protocol Number:

Principal Investigator: Dr. Sara Fowler

Subject Name__________________________________________________________

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, x-ray or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the University’s Notice of Privacy Practices or the study before signing this form.

Initials/Date: _______________
Those Who May Use, Share and Receive Your Information as Part of This Study

- Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Other Ohio State University staff not involved in the study but who may become involved in your care for study-related treatment will have access to your information.
- Those who oversee the study will have access to your information, including:
  - Members and staff of the Ohio State University’s Institutional Review Boards, including the Western Institutional Review Board
  - The Office for Responsible Research Practices
  - University data safety monitoring committees
  - The Ohio State University Research Foundation
- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:
  - The Food and Drug Administration
  - The Office for Human Research Protections
  - The National Institutes of Health
  - The Ohio Department of Human Services

These researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study:

- NONE

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Initials/Date________________
Authorization Period

This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Signing the Authorization

- You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.
- You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.
- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to:
  Dr. Sara Fowler at the College of Dentistry, 305 W. 12th Avenue, The Ohio State University, Columbus, Ohio 43210 or Dr. Fonda Robinson at the College of Dentistry, 305 W. 12th Avenue, The Ohio State University, Columbus, Ohio 43210.

- Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

- If you have any questions relating to your privacy rights, please contact Dr. Fonda Robinson at the College of Dentistry, 305 w 12th avenue, the Ohio State University, Columbus, Ohio 43210.
- If you have any questions relating to the research, please contact Dr. Sara Fowler at the College of Dentistry, 305 W. 12th Avenue, The Ohio State University, Columbus, Ohio 43210.
Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Dr. Sara Fowler and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature________________________________________________________
(Subject or Legally Authorized Representative)

Name __________________________________________________________
(Print name above)
(If legal representative, also print relationship to subject.)

Date___________ Time __________ AM / PM
Appendix E: Medical History Form
Medical History

1. Do you have or have you had any of the following?
   a. rheumatic fever or rheumatic heart disease……………………. NO YES
   b. heart murmur or mitral valve prolapse…………………………. NO YES
   c. heart disease or heart attack……………………………………… NO YES
   d. artificial heart valve…………………………………………… NO YES
   e. irregular heart beat……………………………………………… NO YES
   f. pacemaker………………………………………………………… NO YES
   g. high blood pressure…………………………………………….. NO YES
   h. chest pains or angina…………………………………………… NO YES
   i. stroke……………………………………………………………… NO YES
   j. artificial joint……………………………………………………… NO YES
   k. hepatitis/liver disease……………………………………………. NO YES
   l. tuberculosis………………………………………………………. NO YES
   m. thyroid problem…………………………………………………… NO YES
   n. kidney disease…………………………………………………… NO YES
   o. diabetes (sugar)…………………………………………………… NO YES
   p. asthma……………………………………………………………… NO YES
   q. HIV or other immunosuppressive disease………………………. NO YES
   r. radiation or cancer therapy………………………………………. NO YES

2. Do you or have you had any disease, condition, or problem not listed here? NO YES

3. Have you ever been hospitalized? NO YES

4. Have you had excessive or prolonged bleeding requiring special treatment? NO YES

5. Have you had an allergic reaction to any drugs or medications?
   (Circle all that apply: penicillin; codeine; aspirin; anesthetics; other) NO YES

6. Are you currently under the care of a physician (M.D., D.O.)? NO YES
   When were you last seen by a physician?________________________
   Name of Physician___________________________________________
   Street address_______________________________________________
   City, State, and Zip Code_______________________________________
   Phone______________________________________________________

7. Are you pregnant or nursing? Estimated date of delivery____________ NO YES
8. Have you had any trouble associated with previous dental treatment? NO YES

9. How often do you have dental check ups? ___________ Date of last Exam ___________

10. Do you have any lumps or sores in your mouth now? NO YES

11. Do you smoke or use smokeless tobacco? NO YES

12. Are you currently taking any drugs or medications (such as antibiotics, heart medicine, birth control pills?) NO YES

**Current Medications**

<table>
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<th>Trade Name</th>
<th>Generic Name</th>
<th>Dose/Frequency</th>
<th>Reason</th>
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**Summary of Patient’s Medical Status:**

______________________________________________________________________________
______________________________________________________________________________

**Medical Risk Assessment**

ASA I (healthy individual) ASA III (severe disease but not incapacitating)
ASA II (mild systemic disease) ASA IV (incapacitating systemic disease)

**Medical Consultation Required**

No (healthy and/or stabilized disease)

Yes (ASA III or IV; cardiac murmur; vague hx; recent major disease; recent diagnosis/operation; uncontrolled disease; blood pressure; etc.)

To the best of my knowledge, the above information is correct and complete.
Appendix F: Corah’s Dental Anxiety Scale
Date: _______________ Code #: _______________

For each question, please circle the letter (and only one letter) that best approximates how you feel.

1. If you had to go to the dentist tomorrow, how would you feel about it?
   a) I would look forward to it as a reasonably enjoyable experience.
   b) I wouldn’t care one way or the other.
   c) I would be a little uneasy about it.
   d) I would be afraid that it would be unpleasant and painful.
   e) I would be very frightened of what the dentist might do.

2. When you are waiting in the dentist’s office for your turn in the chair, how do you feel?
   a) Relaxed.
   b) A little uneasy.
   c) Tense.
   d) Anxious.
   e) So anxious that I sometimes break out in a sweat or almost feel physically sick.

3. When you are in the dentist’s chair waiting while he gets his drill ready to begin working on your teeth, how do you feel?
   a) Relaxed.
   b) A little uneasy.
   c) Tense.
   d) Anxious.
   e) So anxious that I sometimes break out in a sweat or almost feel physically sick.

4. You are in the dentist’s chair to have your teeth cleaned. While you are waiting and the dentist is getting out the instruments which he will use to scrape your teeth around the gums, how do you feel?
   a) Relaxed.
   b) A little uneasy.
   c) Tense.
   d) Anxious.
   e) So anxious that I sometimes break out in a sweat or almost feel physically sick.
Appendix G: Pretreatment Interview
Pretreatment Interview

1. Swelling measurement (maximum diameter) : __________________

2. How long has it been swollen? When did it start?
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________

3. Taking an antibiotic? What? For how long? Dosage?
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________

4. Pain meds? What and for how long, dosages?
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________

5. Patient’s temperature: __________

6. Pretreatment: fluctuant or cellulitis?____________________________

7. Posttreatment: fluctuant or cellulitis?____________________________
Appendix H: Initial Pain Rating Visual Analog Scale
Initial Pain Rating

Code #: __________

8. Please place an “X” on the line below to rank the level of pain that brought you here today.

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.
Appendix I: Initial Injection Visual Analog Scale
**Injection Information Sheet**

**Needle Insertion**

9. Please place an “X” on the line below to rank the level of pain felt during needle insertion.

![Visual Analog Scale for Needle Insertion]

**Needle Placement**

10. Please place an “X” on the line below to rank the level of pain felt during needle placement.

![Visual Analog Scale for Needle Placement]

**Solution Deposition**

11. Please place an “X” on the line below to rank the level of pain felt during solution deposition.

![Visual Analog Scale for Solution Deposition]

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.
Appendix J: Access Pain Visual Analog Scale
Emergency Treatment
Access Dentin

Mark an “X” on the line below to rank the level of pain experienced.

None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum Possible

Emergency Treatment
Access Pulp Chamber

Mark an “X” on the line below to rank the level of pain experienced.

None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum Possible

Emergency Treatment
Canal Instrumentation

Mark an “X” on the line below to rank the level of pain experienced.

None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum Possible

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.
Appendix K: Incision and Drainage Visual Analog Scale
Treatment Pain Sheet

Incision

Please place an “X” on the line below to rank the level of pain felt during the incision procedure.

None               Faint       Weak       Mild       Moderate       Strong       Intense       Maximum       Possible

Drainage

Please place an “X” on the line below to rank the level of pain felt during the drainage procedure.

None               Faint       Weak       Mild       Moderate       Strong       Intense       Maximum       Possible

Dissection

Please place an “X” on the line below to rank the level of pain felt during the dissection procedure.

None               Faint       Weak       Mild       Moderate       Strong       Intense       Maximum       Possible

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.
Appendix L: Satisfaction and Overall Treatment Pain VAS
Code Number:____________________

**Satisfaction Rating**

Mark a vertical line “|” on the point on the scale line that best describes your satisfaction.

```
Not Satisfied ┌───┐Somewhat Satisfied ┌───┐Moderately Satisfied ┌───┐Completely Satisfied ┌───┐
```

**Treatment Pain Rating**

Do you remember feeling pain during the treatment? If you did, what was the greatest amount of pain you felt?

12. Please place an “X” on the line below to rank the level of pain.

```
None ┌───┐Faint ┌───┐Weak ┌───┐Mild ┌───┐Moderate ┌───┐Strong ┌───┐Intense ┌───┐Maximum Possible
```

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.
Appendix M: Postoperative Survey
Post-Op Survey

Please answer the following questions regarding the area of your mouth that was treated today.

DAY 0

A. Please rate the discomfort, soreness, or pain in the area of your mouth that was treated today. (Place an “X” on the line.)

None               Faint       Weak        Mild       Moderate                Strong       Intense       Maximum       Possible

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.

B. How do you feel now compared to before treatment? (check one of the following to answer):
   o   better
   o   worse
   o   the same

C. Compared to before treatment, do you feel the swelling is (check one of the following to answer):
   o   smaller
   o   bigger
   o   the same
D. Have you taken any pain medication since your appointment?  **Yes / No**  
If yes, please complete the following table indicating the time and number of tablets since your treatment.

<table>
<thead>
<tr>
<th>Time</th>
<th>Number of Ibuprofen (yellow)</th>
<th>Number of Acetaminophen (white)</th>
<th>Number of escape medication (if needed)</th>
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Comments about why you took pain medication or what happened to your pain after you took medication:

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

125
Post-Op Survey

Please answer the following questions regarding the area of your mouth that was treated yesterday.

DAY 1

A. Please rate the discomfort, soreness, or pain in the area of your mouth where the drain was placed. (Place an “X” on the line.)

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.

B. How do you feel today compared to yesterday? (check one of the following):
   - better
   - worse
   - same

C. Compared to yesterday, do you feel the swelling is (check one of the following):
   - smaller
   - bigger
   - same
D. Have you taken any pain medication in the past 24 hours?  **Yes / No**

If yes, please complete the following table indicating the time and number of tablets since your treatment.

<table>
<thead>
<tr>
<th>Time</th>
<th>Number of Ibuprofen (yellow)</th>
<th>Number of Acetaminophen (white)</th>
<th>Number of escape medication (if needed)</th>
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Comments about why you took pain medication or what happened to your pain after you took medication:

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

127
Post-Op Survey

Please answer the following questions regarding the area of your mouth that was treated two days ago.

DAY 2

A. Please rate the discomfort, soreness, or pain in the area of your mouth where the drain was placed. (Place an “X” on the line.”)

| None | Faint | Weak | Mild | Moderate | Strong | Intense | Maximum Possible |

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.

B. How do you feel today compared to yesterday? (check one of the following):
   - better
   - worse
   - same

C. Compared to yesterday, do you feel the swelling is (check one of the following):
   - smaller
   - bigger
   - same
D. Have you taken any pain medication in the past 24 hours?  Yes / No

If yes, please complete the following table indicating the time and number of tablets since your treatment.

<table>
<thead>
<tr>
<th>Time</th>
<th>Number of Ibuprofen (yellow)</th>
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Comments about why you took pain medication or what happened to your pain after you took medication:

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

129
Post-Op Survey

Please answer the following questions regarding area of your mouth that was treated three days ago.

DAY 3

A. Please rate the discomfort, soreness, or pain in the area of your mouth where the drain was placed. (Place an “X” on the line.”)

B. How do you feel today compared to yesterday? (check one of the following):
   - better
   - worse
   - same

C. Compared to yesterday, do you feel the swelling is (check one of the following):
   - smaller
   - bigger
   - same
D. Have you taken any pain medication in the past 24 hours?  **Yes / No**

If yes, please complete the following table indicating the time and number of tablets since your treatment.

<table>
<thead>
<tr>
<th>Time</th>
<th>Number of Ibuprofen (yellow)</th>
<th>Number of Acetaminophen (white)</th>
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Comments about why you took pain medication or what happened to your pain after you took medication:

________________________________________________________________________

________________________________________________________________________

General Comments about your experience:

________________________________________________________________________

________________________________________________________________________