The pain and fear of needles are increasingly barriers to health. In 1995, James Hamilton published one of the first papers evaluating the prevalence of needle fear and its effect on accessing healthcare. (1) At the time, he concluded that the estimated fear of needles was 10% in adults and 25% in children. By 2012, research showed 24% of adults and 63% of those born in 2000 feared injections. (2) We now know the increase in fear correlates with the advent in 1982 of multiple same-day booster injections given in the 4-6 year window. (3) At this age, children remember pain and fear, but do not have the abstract thought required to understand why people they trust are hurting them. Combination vaccines to lower the same-day total of injections are addressing the cause of needle fear. New evidence-based technology, “Buzzy”, reduces pain and fear to address the consequences on adherence, vaccination, and accessing health care.

The following references are all unfunded independent investigations of Pain Care Labs’ products Buzzy and/or DistrACTION Cards as of 9/16/2020. Studies by the inventor (Baxter) were funded by grants from Hope Street Kids and NICHD Grant Number 4R44HD056647-02.

**Adult and All-Age Studies Italicized; Pediatric Studies plain font.**

**Reviews and Meta-Analyses**

Ballard A Khadra C, Adler S, Doyon-Trottier E, Le May S. Efficacy of the Buzzy Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis. Clin J Pain. 2019 Feb 28 (N= 1138, pain reduction -1.11; 95% confidence interval [CI]: -1.52 to -0.70; P<0.0001), anxiety reduction (SMD -1.37; 95% CI: -1.77 to -0.96; P<0.00001) PMID: 30829735


Lee VY, Caillaud C, Fong J, Edwards KM. Improving vaccine-related pain, distress or fear in healthy children and adolescents—a systematic search of patient-focused interventions. Hum Vaccin Immunother. 2018;14(11):2737-2747 "CONCLUSION: Interventions using coolant and vibration together, as well as a combination of site-specific and patient-led interventions, showed the most consistent effects in reducing self-reported pain, fear or distress.” PMID: 29792557

**Buzzy is the Most Proven & Most Effective Solution for Needle Pain & Fear**

“Conclusion: Interventions using coolant and vibration together, as well as a combination of site-specific and patient-led interventions, showed the most consistent effects in reducing self-reported pain, fear or distress.” Lee VY, Caillaud C et al.

Ueki S, Yamagami Y, Makimoto K. Effectiveness of vibratory stimulation on needle-related procedural pain in children: a systematic review. JBI Database System Rev Implement Rep. 2019 Jul;17(7):1428-1463. Included Buzzy, Dental Vibe, Blaine Labs. "The effect size for the BUZZY tended to be higher than that for the other devices.” “Overall, vibratory stimulation was significantly effective: self-rated pain: - 0.55; 95% confidence interval (95% CI): -0.92 to -0.18) observer-rated pain outcomes (SMD: -0.47; 95% CI: -0.76 to -0.18). [With Buzzy] the effect on the child’s anxiety (SMD: -1.03; 95% CI: -1.85 to -0.20) was significant.” PMID: 31021972
Venipuncture

Abidin, N., Yahya, N., Izaham, A., Mat, W., Zain, J., Zainuddin, M., Mahdi, S. Assessing the Effectiveness of a Thermomechanical Device (Buzzy®) in Reducing Venous Cannulation Pain in Adult Patients. [PDF] Middle East Journal of Anesthesiology 2018 Feb 25(1):61-67. (N=184, Lowest w/ Buzzy Pain score 33.92 ± 15.59 (p = 0.016) 81.0% of patients satisfied w/ Buzzy)


Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. Clin J Pain. 2009 Oct;25(8):705-10. [Buzzy > cold spray, adult] (N=31, Reduced Pain (mean 9.9 mm, 95% confidence interval 0.82-19, P=0.035, SD 16) compared to vapocolant (mean 7.9 mm, 95% confidence interval -1.8-17.7, P=0.1, SD 16.9)) PMID: 19920721

Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department. Pediatr Emerg Care. 2011 Dec;27(12):1151-6. (N=81, Pain scores lower with Buzzy (-2; 95% CI, -4 to 0) than with vapocoolant (1; 95% CI, 0-2).Venipuncture success more likely w/ Buzzy (odds ratio, 3.05; 95% CI, 1.03-9.02), pediatric] PMID: 22134226


Binay Ş, Bilsin E, Gerçeker GÖ, Kahraman A, Bal-Yılmaz H. Comparison of the Effectiveness of Two Different Methods of Decreasing Pain During Phlebotomy in Children: A Randomized Controlled Trial. J Perianesth Nurs. 2019 Feb 20 S1089-9472(18)30414-3 (block randomization, 3-6 y/o, Pain scores were lower in the groups of external cold and vibration, and blowing soap bubbles than the control group.) PMID: 30797673

Bourdier S, Khelif N, Velasquez M, Usclada A, Rochette E et al. Cold Vibration (Buzzy) Versus Anesthetic Patch (EMLA) for Pain Prevention during cannulation in children: A randomized trial. Pediatr Emerg Care. 2019 Jun 6. N=607 children 18 months to 6 years. CHEOPS – eval pain relief, cannulation success, venous access times. Pain relief was not as effective with Buzzy; Time until cannulation was “effectively zero” with Buzzy, versus over one hour with EMLA. The cost of Buzzy for 1000 cannulations was equivalent to the cost of 25 EMLA patches. PMID: 31181022

Canbulat N, Ayhan F, Inal S. Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients. Pain Manag Nurs. 2015 Feb;16(1):33-9. (N=176, 7-12 y/o, significantly lower anxiety and pain in group using Buzzy.) PMID: 24912740(N=200, Mean age=8, Buzzy = to handheld computer distraction, both statistically significantly less pain than control.) PMID: 30601349


Gerçeker GÖ, Binay Ş, Bilsin E, Kahraman A, Yılmaz HB. Effects of Virtual Reality and External Cold and Vibration on Pain in 7- to 12-year-old Children During Phlebotomy: A Randomized Controlled trial. J Perianesth Nurs. 2018 Mar 17. (N=121, Buzzy = VR, both statistically significantly less pain than control.) PMID: 29559294

Inal S., Kelleci M. The Effect of External Thermomechanical Stimulation and Distraction on Reducing Pain Experienced by Children During Blood Drawing. Pediatr Emerg Care. 2020 Feb;36(2):66-69 (N=218, Control, Buzzy, Distraction cards, Buzzy + Distraction cards. All groups using Buzzy had significantly reduced pain (P < 0.001), Lowest pain measured w/ Buzzy in combination w/ Distraction Cards.) PMID: 28885392

Inal S, Kelleci M. Relief of pain during blood specimen collection in pediatric patients. MCN Am J Matern Child Nurs. 2012 Sep;37(5):339-45. [Buzzy v. control, pediatric] (N=120, 6-12y/o, Lower pain (p < .001) and anxiety (p < .001) w/ Buzzy) PMID: 22895207


Küçük Alemdar D, Yaman Aktaş Y. The use of the Buzzy, Jet lidocaine, bubble-blowing and aromatherapy for reducing pediatric pain, stress and fear associated with phlebotomy. J Pediatr Nurs. 2019 Jan 30 S0882-5963(18)30352-X (N=195, 5-10 y/o, Significant difference in intervention and control groups, Buzzy made the most impact on reducing fear and pain (p < 0.05)) PMID: 30711327


Schreiber S, Cozzi G, Rutigliano R, Assandro P, Tubaro M, Cortellazzo Wiel L, Ronfani L, Barbi E. Analgesia by cooling vibration during venipuncture in children with cognitive difficulties. Acta Paediatr. 2016 Jan;105(1):e12-6. [N=70, pediatric, severe cognitive impairment, "reported no or mild procedural pain in 32 cases (91.4%) in the Buzzy group and in 22 cases (61.1%) in the no-intervention group (p = 0.003)."] PMID: 26401633


Tork HM Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department. Am J Nursing Science 2017 Feb;6(2):26-32 (N=180, Pediatric, Lowest pain scores with Buzzy (1.90±1.34) vs Distracting cards (3.17 ±2.13) vs Balloon inflating (2.83 ±1.41) vs control (4.15±1.29), (p=0.012), Buzzy and distraction card groups had the greatest reduction in anxiety.)


*In Progress/Recruiting: Clark J. DHHS Buzzy for IV access pain relief in adults with cognitive difficulties.


*In Progress/Completed: Stein K. Buzzy Use for IV access in Dentistry. University of Iowa College of Dentistry. NCT03619135

Injections

Alshawan M. A Prospective comparison between skin cooling and skin vibration in reducing the pain of local anesthetic injection. J Cosmet Dermatol 2019 Sept 26 e pub ahead of print. “Skin vibration may be more effective than skin cooling in alleviating the pain caused by local anesthetic infiltration. (Buzzy without ice). PMID: 31556234


Canbulat Sahiner N, Turkmen AS, Acikgoz et al. Effectiveness of Two Different Methods for Pain Reduction During Insulin Injection in Children with Type 1 Diabetes: Buzzy and Shotblocker. Worldviews Evid Based Nurs 2018 Oct 11. Epub ahead of print. (N=60, Buzzy and Shotblocker both reduced pain compared to control.) PMID: 30307692

Redfern RE, Chen JT2, Sibrel S3. Effects of Thermomechanical Stimulation during Vaccination on Anxiety, pain, and Satisfaction in Pediatric Patients: A Randomized Controlled Trial. J Pediatr Nurs. 2018 JanFeb;38:1-7 [N=50, pain significantly less (3.56 vs 5.92, p=0.015), pediatric] PMID: 29167074
Redfern RE, Micham J, Seegert S, Chen JT. Influencing Vaccinations: A Buzzy Approach to Ease the Discomfort of a Needle Stick – a Prospective, Randomized Controlled Trial. Pain Management Nursing. 2019 Apr;20(2):164-169. (N=497 pain 0.87 v 1.12 p=.035, better than previous experiences 62% Buzzy 23.9% control p<.0001.) PMID: 30425014

Rundell JD, Sebag JA, Kihm CA, Herpen RW, Vlahovic TC. Use of an external vibratory device as a pain management adjunct for injections to the foot and ankle. The Foot and Ankle Online Journal 2016 9 (4): 6 (N=108, 31.3% decrease in pain associated w/ injections in treatment vs control group)


Sahin M. Effect of Buzzy® application on pain and injection satisfaction in adult patients receiving intramuscular injections. Pain Management Nurs 2018 Dec;19(6):645. Diclofenac, (N=65, average age 52, Pain 74% reduced, satisfaction 95 v. 84. P<.001 both) PMID: 30318424


Yilmaz G, Alemdar DK. Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear caused by intramuscular injection. A Randomized Controlled Trial. J Emerg Nurs. 2019 Sep;45(5):502-511. “Pain and fear were notably less in the group of children receiving the Buzzy intervention. DISCUSSION: The Buzzy intervention should be used when children are undergoing IM injections to reduce their levels of pain and fear.” PMID: 31257044

*In Progress: Katia L, Joret I. Nantes University Hospital, France. Efficacy of the Buzzy® Device on the Prevention of Health Care Induced Pediatric Pain in a Vaccination Center (DOLVAX) NCT03220555

*In Progress: Mesterman R. Pain Perception of Children and Youth Receiving Non-sedated Botulinum Toxin-A Injections Using the Buzzy®. NCT02273284

*In Progress: Feasibility, Acceptability and Satisfaction of a New Device (Buzzy®) for Pediatric Procedural Pain and Anxiety Management During SQ, IV, and IM Needle-Related Procedures: A Pilot Study. NCT02771600

*In Progress: Steiner SJ, Riley Children’s Hospital. Buzzy for patients with IBD – improvement of treatment with Humira or Remicade. Presentation at ImproveCareNow.

*In Progress: Marcio Boniatti, Hospital Nossa Senhora da Conceicao Rio Grande Do Sul, Brazil, Minimizing pain during childhood vaccination. Infants, outcome crying in seconds NCT03540589

*In Progress: Pfieffer Jennifer; Evaluation of Pain Alleviating Strategies During Allergy Shots Nemours Jackson Florida Buzzy v. Shotblocker NCT04181632

*In Progress: Ryan Cobb MD: Thermomechanical distraction and social anesthesia in interventional radiology Temple University, Philadelphia

*In Progress: Seda CEVHEROĞLU: The Effect of Three Different Local Cold Applications on Pain and Ecchymosis in Subcutaneous Heparin Injections: NCT04235244

**Teaching Buzzy Technique, Lab Values and pharmacokinetic considerations**


Baxter AL, Lawson ML. Concerns with the methodology, analysis and discussion of the Buzzy® and transillumination comparison article Blood Transfus. 2014 Jan; 12(Suppl 1): s3–s5 PMID: 24599904


**Dermatology**

Alshawan M. A Prospective comparison between skin cooling and skin vibration in reducing the pain of local anesthetic injection. J Cosmet Dermatol 2019 Sept 26 e pub ahead of print. “Skin vibration may be more effective than skin cooling in alleviating the pain caused by local anesthetic infiltration. (Buzzy without ice).” PMID: 31556234

**Itching**

**Musculoskeletal**


**Dental Injections**


**DistrACTION Cards**


Sahiner NC, Turkmen AS. *The effect of DistrACTION Cards on reducing pain and anxiety during intramuscular injection in children*. Worldviews on Evidence-Based Nursing 2019;1-6. (N=120, self-reported pain cards 5.67+/−3.5 v. control 7.65 +/- 2.77, p=.001. Anxiety Parent-reported cards 1.73 v. control 2.53 p=.003.) PMID: 30997744

### Pain Relief Options for IV and Injections

<table>
<thead>
<tr>
<th>Pain Reliever</th>
<th>Cost/use $USD</th>
<th>Prep time</th>
<th>Ease of use</th>
<th>Duration</th>
<th>Needle Pain Relief</th>
<th>Stinging Pain Relief†</th>
<th>RCTs for fear/anxiety*</th>
<th>RCTs IVs*</th>
<th>RCTs for injections*</th>
<th>Meta-analyses</th>
<th>Head to head trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buzzy®</td>
<td>$0.20/0.01</td>
<td>1 min</td>
<td>****</td>
<td>60 seconds</td>
<td>****</td>
<td>Y</td>
<td>****+X</td>
<td>***</td>
<td>**+</td>
<td>***</td>
<td>Potts: LMX = Buzzy for IV; Canbulat: Buzzy &gt; Shotblocker IM; Bilgin Buzzy &gt; Shotblocker</td>
</tr>
<tr>
<td>DistrACTION® Cards</td>
<td>0.01</td>
<td>10 sec</td>
<td>****</td>
<td>n/a</td>
<td>***</td>
<td>Y</td>
<td>***</td>
<td>X*</td>
<td>*</td>
<td>97% say better phlebotomy experience</td>
<td></td>
</tr>
<tr>
<td>EMLA®</td>
<td>$6.00</td>
<td>60 min</td>
<td>*</td>
<td>2 hours</td>
<td>***</td>
<td>N</td>
<td>X*</td>
<td>***X</td>
<td>**+</td>
<td>Emla&gt; Buzzy for IV &lt;6 year olds; not effective injections &gt;1 year</td>
<td></td>
</tr>
<tr>
<td>LMX-4®</td>
<td>$4.00</td>
<td>20 min</td>
<td>**</td>
<td>20 min</td>
<td>***</td>
<td>N</td>
<td>***++</td>
<td>Bahorski, Potts: Buzzy = for IV</td>
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</tr>
<tr>
<td>Ice</td>
<td>$.10</td>
<td>1 min</td>
<td>***</td>
<td>30 seconds</td>
<td>**</td>
<td>N</td>
<td>***</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shotblocker®</td>
<td>$.05</td>
<td>1 min</td>
<td>****</td>
<td>0 seconds</td>
<td>**</td>
<td>N</td>
<td>*+XXX</td>
<td>SB = Buzzy for insulin; SB &lt; Buzzy vaccines</td>
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</tbody>
</table>

Each * indicates one peer reviewed publication for the procedure indicated with statistically improved outcomes compared to control. X is trials **without** improvement compared to no intervention, + is each trial with equivalent outcome compared to another proven intervention.

Injections are defined as delivery of medication into soft tissue, thus studies evaluating microneedling, dermatologic scalp steroid injections, lumbar punctures etc. are not included. Adult only or adult + pediatric studies indicated in **BOLD**

†Buzzy is FDA 510K indicated for control of needle pain from injections, lab draws, and temporary relief of stinging among other indications.