



Clinical Evidence Report

December 2021



Digital Sedation™

An evidence-based safe, effective and patient-centric therapy for reducing pain and anxiety before, during and after interventions.

Major benefits of Oncomfort's Digital Sedation™ have been illustrated in 7 randomized controlled trials (RCT). These trials have demonstrated that **Digital Sedation™** enhances quality of care, improves work conditions and increases patient satisfaction.



Explore the scientific evidence proving the effectivity and benefits of Digital Sedation™



Better quality of care



Improved work conditions for practitioners



Higher patient satisfaction

1 Digital Sedation™ for better quality of care

Improved safety by reducing needed medication

- **Digital Sedation™ reduces or replaces the need for intravenous sedation (IVS).** Digital Sedation™ can completely replace IVS for 100% of patients undergoing prostate resection under spinal anesthesia. The intervention is safer and surgical conditions are optimized: apnea and involuntary movements are reduced and patients did not require oxygen supplementation (Moon et al., 2018). Digital Sedation™ reduces the need for IVS during locoregional anesthesia for orthopedic surgery by 90% (Chirnoaga et al., 2019).

- **Digital Sedation™ reduces analgesic consumption** by 56% during and after total knee arthroplasty (Depauw et al., 2020), which reduces the risk for side effects.

- **No adverse events nor side effects** have been reported using Digital Sedation™.

Improved patient experience

- **Digital Sedation™ reduces patient's pain** during procedure in pain clinic by 32%, compared to the control group (Joo et al., 2021). This drop in pain has been observed as from minute 1 of the procedure in adult and pediatric patients in the emergency room (Kavak et al., 2020). Digital Sedation™ also reduces patient's pain after intervention and during revalidation (Depauw et al., 2020).

- **Digital Sedation™ reduces patient's anxiety** before and after interventions. Cardiovascular surgical patients experienced a 47% reduction of anxiety after their preoperative Digital Sedation™ session (Rousseaux et al., 2022). In addition, Digital Sedation™ allowed a reduction of 21% of postprocedural anxiety compared to the control group after fluoroscopy-guided interventions (Joo et al., 2021). The anxiolytic effect lasted until discharge in patients undergoing oocytes puncture (Di Primio et al., 2018).

- **Digital Sedation™ ensures patient's comfort.** Patients undergoing regional anesthesia under Digital Sedation™ reported equivalent comfort as patients under IVS (Chirnoaga et al., 2019).

Improved health outcomes

- **Digital Sedation™ showed a positive impact on postprocedural and postsurgical health outcomes.** Patients who received Digital Sedation™ before oocytes puncture showed increased biological pregnancy rates (Di Primio et al., 2020). Digital Sedation™ also allows improved patient's mobilization after total knee arthroplasty (Depauw et al., 2020).

- **No adverse events nor side effects** have been reported using **Digital Sedation™**.

2 Digital Sedation™ for improved work conditions for practitioners

Improved workflow

- Digital Sedation™ allows a reduction of the duration of the surgery compared to IVS in prostate resection under spinal anesthesia (Moon et al., 2018).
- Digital Sedation™ reduces the need for additional local anesthesia during procedures, as illustrated in several procedures performed in emergency room (Kavak et al., 2020) and in pain clinics (Joo et al., 2021). This allows a smoother flow of the procedure as it improves practitioner's ability to focus on the intervention by reducing the need for interruptions.

Higher practitioners' satisfaction and better quality of the work environment

- 100% of anesthesiologists and surgeons are satisfied when using Digital Sedation™ and two times more anesthesiologists are extremely satisfied (Moon et al., 2018).
- Working with patients experiencing pain and anxiety impacts the quality of the work environment. Digital Sedation™ reduces patient's anxiety (Rousseaux et al., 2022; Jo et al., 2021; Di Primio et al., 2018) and pain (Kavak et al., 2020; Joo et al., 2021).



3 Digital Sedation™ for higher patient satisfaction

Patient satisfaction is significantly higher with Digital Sedation™ compared to intravenous sedation in patients undergoing prostate resection (Moon et al., 2018), and compared to standard of care in procedures in the emergency room (Kavak et al., 2020). Thanks to Digital Sedation™, patient's anxiety and pain are reduced (Joo et al., 2021) and patient's physical and emotional comfort are thus enhanced.

Digital Sedation™

Oncomfort Digital Sedation™ Randomized Controlled Trials



Replacement of intravenous sedation during urological surgery

Reference: Moon J., et al (2018), *Virtual Reality Distraction during endoscopic Urologic Surgery under Spinal Anesthesia: A Randomized Control Trial*, *Journal of Clinical medicine*, 8, 2 (NCT03055663)

Indication: Holmium laser enucleation of the prostate (HOLLEP) or transurethral resection of bladder tumor

Design: Prospective, controlled, randomized, monocentric
N=37, 2 arms

- Digital Sedation™ (DS) and spinal anesthesia
- Intravenous sedation (IVS) (MDZ 1-2 mg every 30 minutes) and spinal anesthesia

Results:

- 100% of patients under DS did not receive any IVS
- 94% of surgeries considered as under optimal surgical conditions (+49% compared to control group: 94,4% DS vs 63,2% IVS)
- 85% less apnea (5,6% DS vs 36,8% IVS)
- 65% fewer purposeless movements (11,1% DS vs 31,6% IVS)
- No oxygen supplied in DS group (vs 5L/min in IVS group)
- 100% patient satisfaction, (+49% of patients reported extreme satisfaction compared to IVS group)
- 100% anesthesiologists' and surgeons' satisfaction (2 times more extreme satisfaction of anesthesiologists compared to IVS group)
- Reduced average duration of the surgery (40 vs 45 min)

Replacement of intravenous sedation during regional anesthesia

Reference: Chirnoaga D., Van Hecke, D., Pandin, P., Truong, H-N., Van Obbergh, L, *Virtual reality hypnosis distraction to improve tolerance to regional anaesthesia performance [Poster presentation]. ESA 2019 Convention, Vienna, Austria. (NCT04024904)*

Indication: Regional anesthesia (RA) before orthopedic surgery

Design: Prospective, controlled, randomized, monocentric
N=60, 3 arms

- Digital Sedation™ (DS) before and during RA and intravenous sedation (IVS) if behavioral pain score (BPS)>3
- DS during RA and IVS only if behavioral pain score BPS>3
- Standard IVS (SUF 5 µg + MDZ 2 mg)

Results:

- 90% of patients under DS without IVS
- The need for IVS is reduced by an additional 60% when DS session before and during procedure (10% IVS when DS is provided before and during, vs 25% IVS only during procedure)
- Equivalent patients' comfort and satisfaction

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Anxiety management before and after cardiovascular surgery

Reference: Rousseaux F, Dardenne N, Massion PB, Ledoux D, Bicego A, Donneau AF, Faymonville ME, Nyssen AS, Vanhauwenhuysse A. Virtual reality and hypnosis for anxiety and pain management in intensive care units: A prospective randomised trial among cardiac surgery patients. *Eur J Anaesthesiol.* 2022 Jan 1;39(1):58-66. doi: 10.1097/EJA.0000000000001633. PMID: 34783683. (NCT03820700)

Indication: Aortic valve replacement, mitral valve, coronary artery deviation

Design: Prospective, controlled, randomized, monocentric
N=100, 4 arms

- Digital Sedation™ (DS)
- Clinical Hypnosis (HYP)
- Virtual reality (VR) distraction
- Standard of care (SOC)

Results:

- 47% reduction of preoperative anxiety before/ after DS
- 26% increased preoperative relaxation before/ after DS
- Lower anxiety in the DS group as compared to the HYP group

Pain management for interventions in the emergency room

Reference: Kavak, E., van Berlaer, G., Diltoer, M., Malbrun, M. Medical hypnosis and virtual reality glasses are safe and effective tools to alleviate pain and anxiety in patients undergoing medical procedures. [Poster presentation]. ISICEM 2020, Brussels, Belgium

Indication: Blood sample, wound suture, other interventions

Design: Prospective, randomized, monocentric
N=240 (6-86 years old), 3 arms

- Digital Sedation™ (DS) and local or topical anesthesia if needed
- Individual clinical hypnosis (HYP) and local or topical anesthesia if needed
- Standard of care (SOC) and local or topical anesthesia if needed

Results:
(intermediate: n=104)

- Significant reduction in pain during the procedure (after 1 min) in HYP and DS groups
- -74% patients need complement of local anesthesia compared with SOC group (16% DS vs 64% SOC)
- -45% patients need complement of local anesthesia compared with HYP group (16% DS vs 38% HYP)
- Significantly increased patient satisfaction in the DS group

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Anxiety management in fertility clinics

Reference: Di Primio, S., Pirard, C., Laurent, P., Watremez, C., Momeni, M., Roelants, F. Impact of Virtual Reality (VR) with hypnosis and VR distraction on anxiety and pregnancy rate before sedation for oocytes retrieval (OR): a double blinded randomized study. [Poster presentation]. Euroanesthesia 2018, Copenhagen, Denmark. (NCT03064061)

Indication: Preparation for oocytes retrieval

Design: Prospective, controlled, randomized, monocentric
N=600, 2 arms

- Digital Sedation™ (DS) before oocytes puncture
- Non-therapeutic virtual reality (VR) before oocytes puncture

Results:
Intermediate n=100

- 45% anxiety reduction after the session
- 65% anxiety reduction at discharge
- 119% higher biological pregnancy rate in the DS group (evaluated by blood HCG at day 14 after pick-up) (45.7% DS vs 20.8% VR)

Procedural pain and anxiety management in outpatient pain clinic

Reference: Joo Y., Kim E-K, Song H-G, Jung H., Park H., Moon J.Y. Effectiveness of virtual reality immersion on procedure related pain and anxiety in outpatient pain clinic: an exploratory randomized controlled trial, Korean Journal of Pain, 34 (3): 304-314 (NCT03599479)

Indication: Fluoroscopy-guided minimally-invasive interventions in prone position at an outpatient clinic

Design: Prospective, controlled, randomized, monocentric
N=38, 2 arms

- Control group (CON): Inactive VR goggles + local anesthesia (LA)
- Digital Sedation™ (DS) + LA

Results:

- -32% procedural pain (3.7 DS vs 5.5 CON)
- -21% postprocedural anxiety (2.5 DS vs 3.2 CON)
- -69% patients received additional LA during procedure (21.1% DS vs 68.4% CON)
- DS is adequately used in prone position



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Pain management after orthopedic surgery

Reference: Depauw L., et al (2020), *Virtual reality hypnosis for postoperative pain after total knee arthroplasty*, *Acta Anaest Belg*, 71, 73-77 (NCT03665233)

Indication: Postoperative pain after total knee arthroplasty

Design: Prospective, controlled, randomized, monocentric
N=11, 2 arms

- Non-therapeutic virtual reality (VR) and standard of care
- Digital Sedation™ (DS) and standard of care

Results:

- Rapid decrease of pain after intervention (mean pain=2.5 at D3)
- 50% of patients: improved degree of flexion
- 56% decrease in consumption of analgesics
- No VR-induced nausea or vomiting

