| REFERENCE # | CITATION | EVIDENCE TYPE | SAMPLE SIZE/ POPULATION | INTERVENTION(S) | CONTROL/ COMPARISON | OUTCOME MEASURE(S) | CONCLUSION(S) | CONSENSUS SCORE |
|---|---|---|---|---|---|---|---|---|
| 1 | 21 CFR 1271: Human cells, tissues, and cellular and tissue-based products. US Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1271. Accessed August 29, 2019. | Regulatory | n/a | n/a | n/a | n/a | Code of Federal Regulations regarding Human cells, tissues, and cellular and tissue-based products (HCT/P). | n/a |
| 2 | Guideline for specimen management. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:897-930. | Guideline | n/a | n/a | n/a | n/a | Guidance for specimen management in the perioperative setting. | IVA |
| 3 | Guideline for sterilization packaging systems. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019. | Guideline | n/a | n/a | n/a | n/a | Guidance for sterilization packaging systems in the perioperative setting. | IVA |
| 4 | Same surgical procedure exception under 21 CFR 1271.15(b): questions and answers regarding the scope of the exception. US Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/same-surgical-procedure-exception-under-21-cfr-127115b-questions-and-answers-regarding-scope. Published November 2017. Accessed August 29, 2019. | Regulatory | n/a | n/a | n/a | n/a | Clarification from the FDA on the definition of the "same surgical procedure" exception language. | n/a |
| 5 | Corliss B, Gooldy T, Vaziri S, Kubilis P, Murad G, Fargen K. Complications after in vivo and ex vivo autologous bone flap storage for cranioplasty: a comparative analysis of the literature. World Neurosurg. 2016;96:510-515. | Systematic Review | n/a | n/a | n/a | n/a | There was no significant difference between cryopreservation and abdominal subcutaneous preservation of autologous bone flaps for SSI, bone resorption, revision surgery, or cosmetic results. Both cryopreservation and storage in subcutaneous abdominal fat was safe. | IIIA |
| 6 | Cheah PP, Rosman AK, Cheang CK, Idris B. Autologous cranioplasty post-operative surgical site infection: does it matter if the bone flaps were stored and handled differently? Malays J Med Sci. 2017;24(6):68-74. | Quasi-experimental | 101 cranioplasty patients | cryopreservation of cranial bone flaps | subcutaneous abdominal preservation of cranial bone flaps | SSI | The method of bone flap preservation (ie, cryopreservation, subcutaneous abdomen) has no significant association with SSI. | IIB |
| 7 | Ernst G, Qeadan F, Carlson AP. Subcutaneous bone flap storage after emergency craniectomy: cost-effectiveness and rate of resorption. J Neurosurg. 2018;129(6):1604-1610. | Nonexperimental | 108 cranioplasty patients with subcutaneous preservation of the cranial bone flap in the abdomen | n/a | n/a | Bone resorption rates | The severe bone resorption rate was 9.62%. Supplemental cranioplasty material was needed in 24.07% of cases. Infections occurred in the subcutaneous pocket 2.60% of the time and infections in the pocket after cranioplasty were 9.26%. The cost of a custom implant was $35,118.60 +/- 2067.51. | IIIB |
| 8 | Fan MC, Wang QL, Sun P, et al. Cryopreservation of autologous cranial bone flaps for cranioplasty: a large sample retrospective study. World Neurosurg. 2018;109:e853-e859. | Nonexperimental | 946 cranioplasty patients | n/a | n/a | SSI rates and resorption rates | SSIs occurred in 4.06% of patients and that bone resorption occurred in 4.38% of patients. Storage of bone flaps longer than a year resulted in higher risk of bone resorption. Recommended performing cranioplasty prior to 1 year of flap preservation. | IIIA |
| 9 | Nobre MC, Veloso AT, Santiago CFG, et al. Bone flap conservation in the scalp after decompressive craniectomy. World Neurosurg. 2018;120:e269-e273. | Nonexperimental | 23 cranioplasty patients with cranial bone preserved in the subcutaneous tissue of the scalp. | n/a | n/a | SSI rates, bone resorption rates, and patient discomfort | Of the 23 patients, 5 died (21.7%). Of the patients that survived, the SSI rate was 0%, and there was no macroscopic evidence of bone resorption. The patients also did not report discomfort at the side of the cranial bone implant. | IIIC |
| 10 | Pasaoglu A, Kurtsoy A, Koc RK, et al. Cranioplasty with bone flaps preserved under the scalp. Neurosurg Rev. 1996;19(3):153-156. | Nonexperimental | 27 cranioplasty patients with the bone flap preserved under the scalp. | n/a | n/a | SSI rates, resorption rates, and cosmetic results | No infections or resorption was reported. Good cosmetic results were reported. | IIIC |

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|---|---|---|---|---|---|---|---|---|
| 11 | Lu Y, Hui G, Liu F, Wang Z, Tang Y, Gao S. Survival and regeneration of deep-freeze preserved autologous cranial bones after cranioplasty. Br J Neurosurg. 2012;26(2):216-221. | Nonexperimental | 16 cranioplasty patients with cranial bone flaps stored at -80° C. | n/a | n/a | SPECT Scans for cranial bone tomography results to show radioactivity compared to the non-excised skull at 2 weeks, 3 months, and 12 months. | The cranial bone was preserved at -80° C for an average of 111 days. The SPECT scans showed that the 16 cranial bone flaps survived the preservation process and regenerated in three and 12 months. | IIIC |
| 12 | Beez T, Sabel M, Ahmadi SA, Beseoglu K, Steiger H, Sabel M. Scanning electron microscopic surface analysis of cryoconserved skull bone after decompressive craniectomy. Cell Tissue Bank. 2014;15(1):85-88. | Nonexperimental | 5 cranial bone flaps | n/a | n/a | Structural integrity of cranial bone flaps after cryopreservation | When scanned with a electron microscope there were varying surface structures that did not correlate to the patient's age, gender or duration of cryopreservation. No microscopic cracks found. Cryopreservation for up to 8 months does not alter the surface structure of the preserved cranial bone flap. | IIIC |
| 13 | Elwatidy S, Elgamal E, Jamjoom Z, Habib H, Raddaoui E. Assessment of bone flap viability and sterility after long periods of preservation in the freezer. Pan Arab J Neurosurg. 2011;15(1):24-28. | Nonexperimental | 14 cranial bone flaps stored at -18° C. | n/a | n/a | Histological and microbiological results | Bone was found to be sterile in all specimens and viable for up to one year. | IIIC |
| 14 | Bhaskar IP, Yusheng L, Zheng M, Lee GY. Autogenous skull flaps stored frozen for more than 6 months: do they remain viable? J Clin Neurosci. 2011;18(12):1690-1693. | Quasi-experimental | 27 cranial bone flaps | Bone explant cell cultures from bone flaps stored at -30° C for more than 6 months. | Fresh (unpreserved) skull samples as controls | Growth of osteoblasts | The control samples of fresh skull biopsies showed growth of osteoblasts but the preserved group did not. The researchers concluded that cranial bone flaps preserved at -30° C for more than 6 months are not viable. | IIB |
| 15 | Cho TG, Kang SH, Cho YJ, Choi HJ, Jeon JP, Yang JS. Osteoblast and bacterial culture from cryopreserved skull flap after craniectomy: laboratory study. J Korean Neurosurg Soc. 2017;60(4):397-403. | Nonexperimental | 47 cryopreserved cranial bone flaps | n/a | n/a | Bone flap contamination and osteoblast viability. | There was no evidence of microbial contamination or any cultured osteoblasts from the cranial bone flaps cryopreserved an average of 83.2 months. Biological viability of cranial bone flaps after cryopreservation is low. | IIIC |
| 16 | Wui SH, Kim KM, Ryu YJ, et al. The autoclaving of autologous bone is a risk factor for surgical site infection after cranioplasty. World Neurosurg. 2016;91:43-49. | Nonexperimental | 80 cranioplasty patients | n/a | n/a | SSI rates and histological examination results | The only significant risk factor for increased risk of SSI was the use of autoclaved bone. Storage of the bone in the freezer at -70° C preserved viability but decreased the number of osteocytes. Long term preservation in the freezer followed by autoclaving the bone resulted in an almost complete loss of osteocytes. | IIIB |
| 17 | Bhaskar IP, Zaw NN, Zheng M, Lee GYF. Bone flap storage following craniectomy: a survey of practices in major Australian neurosurgical centres. ANZ J Surg. 2011;81(3):137-141. | Nonexperimental | 25 major, public teaching hospitals with neurosurgical centers were included in the survey | n/a | n/a | Survey results | Use of autologous cranial bone flaps was most common at 96%. Almost half of the facilities used a local tissue bank for preservation 48%, while 52% used freezers in their facility. The storage temperature ranged from -18 to -83 degrees C for varying durations ranging from 6 months until deceased. | IIIC |
| 18 | Schültke E, Hampl JA, Jatzwauk L, Krex D, Schackert G. An easy and safe method to store and disinfect explanted skull bone. Acta Neurochir (Wien). 1999;141(5):525-528. | Quasi-experimental | 20 pieces of cranial bone flaps | Immersion in H2O2, boiling in normal saline for 15 and 30 minutes | Prevacuum steam sterilization at 75° C for 20 min | Microbial Contamination | The bacterial contamination rate of bone flaps not purposefully contaminated was 20%. Only the prevacuum steam was able to eradicate all bacterial strains. | IIB |
| 19 | Iwama T, Yamada J, Imai S, Shinoda J, Funakoshi T, Sakai N. The use of frozen autogenous bone flaps in delayed cranioplasty revisited. Neurosurgery. 2003;52(3):591-596. | Nonexperimental | 49 cranioplasty patients | n/a | n/a | SSI rates, resorption rates, aesthetic results | There was one infection and one case of resorption that involved a bone flap that was in two pieces. Aesthetic results were reported to be highly satisfactory. | IIIB |

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| 20 | Shoakazemi A, Flannery T, McConnell RS. Long-term outcome of subcutaneously preserved autologous cranioplasty. Neurosurgery. 2009;65(3):505-510. | Nonexperimental | 110 cranioplasty patients who had the cranial bone flap stored in the subcutaneous abdominal wall pocket. | n/a | n/a | SSI rates and resorption rates | Patients that had to have the flap removed was 9%. Two of the 7 patients due to resorption and 5 patients due to infection. Storage in the subcutaneous abdominal has favorable long-term outcomes. | IIIB |
| 21 | Spijker R, Ubbink DT, Becking AG, et al. Autologous bone is inferior to alloplastic cranioplasties: safety of autograft and allograft materials for cranioplasties: a systematic review. World Neurosurg. 2018;117:443-452. | Systematic Review | n/a | n/a | n/a | n/a | Resorption only occurred in autologous bone flap patients. The authors concluded that autografts carry more patient risk than allografts. | IIIA |
| 22 | Malcolm JG, Mahmooth Z, Rindler RS, et al. Autologous cranioplasty is associated with increased reoperation rate: a systematic review and meta-analysis. World Neurosurg. 2018;116:60-68. | Systematic Review w/ Meta-Analysis | n/a | n/a | n/a | n/a | Autograft bone flaps had significantly more reoperations that were attributed to bone resorption. | IIIA |
| 23 | Kim SH, Kang DS, Cheong JH, Kim JH, Song KY, Kong MH. Comparison of complications following cranioplasty using a sterilized autologous bone flap or polymethyl methacrylate. Korean J Neurotrauma. 2017;13(1):15-23. | Nonexperimental | 127 cranioplasty patients using sterilized autologous bone flap or polymethyl methacrylate | n/a | n/a | SSI rates and bone flap resorption rates | Sterilized bone had a significant rate of bone flap resorption compared to polymethyl methacrylate. Polymethyl methacrylate to be safe with low rates of complications. | IIIB |
| 24 | Krishnan P, Bhattacharyya AK, Sil K, De R. Bone flap preservation after decompressive craniectomy—experience with 55 cases. Neurol India. 2006;54(3):291-292. | Organizational Experience | 55 cranioplasty procedures with autologous bone stored in the subgaleal pocket. | n/a | n/a | Skin breakdown and skin necrosis | There were 2 omplications out of 55 patients. One patient had skin breakdown attributed to a sharp piece of bone on the flap. A second patient had skin necrosing due to the pocket size being too small in comparison with the bone flap. Subgaleal preservation of the flap was cost effective with good outcomes. | VC |
| 25 | Wang WX, Jiang N, Wang JW, Kang X, Fu GH, Liu YL. Bone formation in subcutaneous pocket after bone flap preservation. Clin Case Rep. 2016;4(5):473-476. | Case Report | n/a | n/a | n/a | n/a | Bone formation found in the subcutaneous pocket used for preservation of the cranial bone flap 10 years after cranioplasty. | VB |
| 26 | Honeybul S, Morrison DA, Ho KM, Lind CRP, Geelhoed E. A randomised controlled trial comparing autologous cranioplasty with custom-made titanium cranioplasty: long-term follow-up. Acta Neurochir. 2018;160(5):885-891. | RCT | 64 patients having cranioplasty | Primary titanium implants | Autologous bone implants | Complications from surgery specifically bone resorption. | Patients that had primary titanium implants had reduced reoperations and hospital costs. However, the results were not statistically significant. | IB |
| 27 | Tahir MZ, Shamim MS, Sobani ZA, Zafar SN, Qadeer M, Bari ME. Safety of untreated autologous cranioplasty after extracorporeal storage at -26 degree Celsius. Br J Neurosurg. 2013;27(4):479-482. | Nonexperimental | 88 cranioplasty patients | n/a | n/a | SSI rates | Patients that developed infections were 3.4%. Two were resolved with oral antibiotics, the third patient required reoperation but all patients retained their autologous cranial bone flaps. Storage of the autologous bone in the freezer at -26 C had an acceptable rate of infection. The researchers questioned the need to keep the cranial bone flaps at deep freezer temperatures. | IIIB |
| 28 | Daou B, Zanaty M, Chalouhi N, et al. Low incidence of bone flap resorption after native bone cranioplasty in adults. World Neurosurg. 2016;92:89-94. | Nonexperimental | 114 cranioplasty patients with autologous cranial bone flaps used | n/a | n/a | Complications, specifically bone resorption | Bone resorption occurred in 2.7% of patients. Two of the three patients with bone resorption eventually had synthetic implants replace their bone flap. The researchers concluded that bone resorption rates are low after 6 months. | IIIB |

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|---|---|---|---|---|---|---|---|---|
| 29 | Sundseth J, Sundseth A, Berg-Johnsen J, Sorteberg W, Lindegaard KF. Cranioplasty with autologous cryopreserved bone after decompressive craniectomy: complications and risk factors for developing surgical site infection. Acta Neurochir (Wein). 2014;156(4):805-811. | Nonexperimental | 47 cranioplasty patients | n/a | n/a | SSI rates and bone resorption rates | The SSI rate was 12.8% and the bone resorption rate was 4.3%. No statistically significant factors were correlated to risk of SSI. This study had limited statistical power due to a low N. | IIIB |
| 30 | Cheng CH, Lee HC, Chen CC, Cho DY, Lin HL. Cryopreservation versus subcutaneous preservation of autologous bone flaps for cranioplasty: comparison of the surgical site infection and bone resorption rates. Clin Neurol Neurosurg. 2014;124:85-89. | Nonexperimental | 290 cranioplasty patients | n/a | n/a | SSI rates and bone resorption rates | The SSI rates were found to be similar between groups. The incidence of bone flap resorption was higher in the cryopreservation group. | IIIA |
| 31 | Herteleer M, Ectors N, Duflou J, Van Calenbergh F. Complications of skull reconstruction after decompressive craniectomy. Acta Chir Belg. 2017;117(3):149-156. | Nonexperimental | 74 cranioplasty patients | n/a | n/a | Complication rates | The study found that 29.7% of patients had to have the original cranial bone flap removed and replaced with a synthetic substitute. The researchers found a significantly high rate complications in patients 20-40 years of age. | IIIB |
| 32 | Inamasu J, Kuramae T, Nakatsukasa M. Does difference in the storage method of bone flaps after decompressive craniectomy affect the incidence of surgical site infection after cranioplasty? Comparison between subcutaneous pocket and cryopreservation. J Trauma. 2010;68(1):183-187. | Nonexperimental | 70 cranioplasty patients, 39 using subcutaneous storage, and 31 using cryopreservation | n/a | n/a | SSI rates | There was no significant difference in between groups. Both subcutaneous and cryopreservation storage methods are effective. | IIIB |
| 33 | Chan DYC, Mok YT, Lam PK, et al. Cryostored autologous skull bone for cranioplasty? A study on cranial bone flaps' viability and microbial contamination after deep-frozen storage at -80°C. J Clin Neurosci. 2017;42:81-83. | Nonexperimental | 18 cranial bone flaps | n/a | n/a | Osteoblast viability and microbial contamination | There was no viable osteoblast growth for any of the bone flaps. There was a 27.8% rate of microbial contamination. Large flaps that were stored for longer durations tended to be more likely to be contaminated but the study was too small to reach statistical significance. | IIIC |
| 34 | Standards for Tissue Banking. 14th ed. McLean, VA: American Association of Tissue Banks; 2016. | Consensus | n/a | n/a | n/a | n/a | AATB standards | IVC |
| 35 | Schoekler B, Trummer M. Prediction parameters of bone flap resorption following cranioplasty with autologous bone. Clin Neurol Neurosurg. 2014;120:64-67. | Nonexperimental | 58 cranioplasty patients | n/a | n/a | Risk factors of cranioplasty. | Patients with a defect size greater than 120 cm and delayed reimplantation tend to have bone flap resorption. Patients with large defects and delayed implantation, the surgeon should consider a patient-specific synthetic implant instead. | IIIC |
| 36 | Morton RP, Abecassis IJ, Hanson JF, et al. Predictors of infection after 754 cranioplasty operations and the value of intraoperative cultures for cryopreserved bone flaps. J Neurosurg. 2016;125(3):766-770. | Nonexperimental | 754 cranioplasty procedures | n/a | n/a | Culture results and SSI rates | The only thing that significantly predicted SSI rates was the length of time between the craniectomy and cranioplasty procedures. Discontinuing routine culturing of cranial bone flaps without the presence of clinical symptoms because it is not a useful predictor and can increase costs associated with use of synthetic prostheses. | IIIA |
| 37 | Piedra MP, Thompson EM, Selden NR, Ragel BT, Guillaume DJ. Optimal timing of autologous cranioplasty after decompressive craniectomy in children. J Neurosurg Pediatr. 2012;10(4):268-272. | Nonexperimental | 61 pediatric cranioplasty patients | n/a | n/a | Complications of cranioplasty including bone resorption | Bone resorption was significantly more likely in the patients who had cranioplasties six weeks or longer after the initial craniectomy. Cranioplasties performed prior to six weeks after craniectomy will reduce the risk of bone flap resorption. | IIIB |
| 38 | Bowers CA, Jay Riva-Cambrin, Hertzler DA, Walker ML. Risk factors and rates of bone flap resorption in pediatric patients after decompressive craniectomy for traumatic brain injury. J Neurosurg Pediatr. 2013;11(5):526-532. | Nonexperimental | 54 pediatric cranioplasty patients | n/a | n/a | Bone flap resorption rates | The length of time a bone flap was in the freezer was not found to be associated with bone flap resorption rates. | IIIC |

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|---|---|---|---|---|---|---|---|---|
| 39 | Baust JM, Campbell LH, Harbell JW. Best practices for cryopreserving, thawing, recovering, and assessing cells. In Vitro Cell Dev Biol Anim. 2017;53(10):855-871. | Expert Opinion | n/a | n/a | n/a | n/a | Discussion on cryopreservation and cryoprotectants. | VA |
| 40 | Takeuchi H, Higashino Y, Hosoda T, et al. Long-term follow-up of cryopreservation with glycerol of autologous bone flaps for cranioplasty after decompressive craniectomy. Acta Neurochir (Wien). 2016;158(3):571-575. | Nonexperimental | 40 cranioplasty patients | n/a | n/a | SSI rates and bone resorption rates | There was one case of mild bone resorption but no cases of infection. The researchers concluded that use of cryopreservation with glycerol is a safe method for preservation. | IIIC |
| 41 | Zhang J, Peng F, Liu Z, et al. Cranioplasty with autogenous bone flaps cryopreserved in povidone iodine: a long-term follow-up study. J Neurosurg. 2017;127(6):1449-1456. | Nonexperimental | 188 cranioplasty patients involving 211 cranial bone flaps | n/a | n/a | Short and log term complication rates | Short term complications included infection (3.8%), epidural hematomas (7.6%), and extradural seroma collection (9.0%). The long term complications included bone flap thinning (59.1%), reduced bone density (11.8%), and osteolysis of the bone flap (29.0%). Because the rates of infection and severe bone flap resorption were low the use of povidone-iodine in cryopreservation is safe and effective. | IIIB |
| 42 | Matsuno A, Tanaka H, Iwamuro H, et al. Analyses of the factors influencing bone graft infection after delayed cranioplasty. Acta Neurochir (Wien). 2006;148(5):535-540. | Nonexperimental | 206 cranioplasty procedures, 54 using of autologous bone that was preserved in 100% ethanol at -20˚ C and then sterilized prior to cranioplasty. | n/a | n/a | Bone graft infection rates defined by the need for bone flap removal | The overall infection rate was 12.1% for all materials used for cranioplasty in the study. The rate of infection for autologous bone was 25.9%. | IIIB |
| 43 | Cheng Y, Weng H, Yang J, Lee M, Wang T, Chang C. Factors affecting graft infection after cranioplasty. J Clin Neurosci. 2008;15(10):1115-1119. | Nonexperimental | 84 cranioplasty procedures done on 75 patients using either autologous cryopreserved bone or polymethyl methacrylate | n/a | n/a | SSI rates. | The infection rate was 10.7%. The positive bone flap cultures did not have the same bacteria as the cultures taken from the infected wounds. Bone flap cultures should only be done for patients with confirmed infections after craniectomy. Routine bone flap culturing does not prevent SSIs and is not cost efficient. | IIIC |
| 44 | Piitulainen JM, Kauko T, Aitasalo KMJ, Vuorinen V, Vallittu PK, Posti JP. Outcomes of cranioplasty with synthetic materials and autologous bone grafts. World Neurosurg. 2015;83(5):708-714. | Nonexperimental | 84 cranioplasty patients | n/a | n/a | Complication rates | The complication rate was 32%. Minor complications occured in 13 patients and 19 patients had major complications that required reoperation. There were less complications in the synthetic materials groups compared to the autologous group. | IIIC |
| 45 | Ronholdt CJ, Bogdansky S. The appropriateness of swab cultures for the release of human allograft tissue. J Ind Microbiol Biotechnol. 2005;32(8):349-354. | RCT | 168 human allograft tissues consisting of cut tissues and soft tissues | Two different types of swab systems | Positive controls = inoculated swabs. Negative controls = noninnoculated swabs | Microbial recovery | Swab systems exhibited low and highly variable recoveries from the seeded allograft tissues. | IB |
| 46 | Dennis JA, Martinez OV, Landy DC, et al. A comparison of two microbial detection methods used in aseptic processing of musculoskeletal allograft tissues. Cell Tissue Bank. 2011;12(1):45-50. | Nonexperimental | 78 from musculoskeletal donors | n/a | Liquid and swab cultures | Microbial detection | The liquid culture method is superior to swab cultures in microbial detection. | IIIB |

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| 47 | Nguyen H, Morgan DAF, Cull S, Benkovich M, Forwood MR. Sponge swabs increase sensitivity of sterility testing of processed bone and tendon allografts. J Ind Microbiol Biotechnol. 2011;38(8):1127-1132. | Quasi-experimental | 81 bone and tendon allografts from cadaveric donors | Nasco sponges | Swab Cultures | Microbial detection | Sponge sampling should be applied as the standard for sterility testing of structural bone and tendon allografts. | IIB |
| 48 | 42 CFR 493: Laboratory requirements. Government Publishing Office. https://www.govinfo.gov/app/details/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part493. Published October 1, 2011. Accessed August 29, 2019. | Regulatory | n/a | n/a | n/a | n/a | Laboratory requirements | n/a |
| 49 | Abdelfatah MA. Management of dropped skull flaps. Turk Neurosurg. 2017;27(6):912-916. | Nonexperimental | 31 dropped cranial bone flaps | n/a | n/a | Reasons for dropped cranial bone flap, decontamination treatments, and patient complications | The reasons for the dropped bone flap included elevation (51.6%), insertion (32.2%), and drilling the bone while it was on the OR table (16.1%). After contamination the following treatments were applied soaking in povidone-iodine and antibiotic solution (54.8%), autoclave (35.4%), and discarded and replaced with mesh (9.6%). No SSIs were noted during the 20 month follow up period. | IIIC |
| 50 | Jankowitz BT, Kondziolka DS. When the bone flap hits the floor. Neurosurgery. 2006;59(3):585-589. | Nonexperimental | 14 cranial bone flaps dropped in a 16 year period at one institution | n/a | n/a | Amounts dropped, treatments given, SSI rates, and survey results. | The reason for dropping included elevation, handing off the field, during plating, and unknown (two cases). The management dropped bone flaps included soaking in betadine and or antibiotic solution, autoclaving, discarding, and unknown (one case). There were no infections reported. During a poll, 66% of neurosurgeons reported have experienced a dropped flap and 83% would replace the bone flap after disinfection. | IIIB |
| 51 | Presnal BP, Kimbrough EE. What to do about a dropped bone graft. Clin Orthop Relat Res. 1993;296:310-311. | Quasi-experimental | 100 pieces of autologous bone from neurosurgical and orthopedic procedures | Place 50 pieces of bone placed on the OR floor by the instrument table for 1 minute | Bone was not placed on the floor | Microbial contamination | There was no microbial contamination found in either the intervention or control group except for a purposefully contaminated specimen to check the veracity of the culture process. Even 1 minute would be longer than the bone would likely be on the floor and that the rates of subsequent microbial contamination do not warrant sterilization which could damage the bone. | IIB |
| 52 | Bruce B, Sheibani-Rad S, Appleyard D, et al. Are dropped osteoarticular bone fragments safely reimplantable in vivo? J Bone Joint Surg Am. 2011;93(5):430-438. | Quasi-experimental | Phase one: 162 osteoarticular bone fragments dropped on the OR floor. Phase 2: 340 osteoarticular bone fragments for decontamination | Decontamination was performed using 10% povidone-iodine solution, 4% CHG, 70% isopropyl alcohol with 2% CHG (Chloropropyl), or 0.9% normal saline solution. First, the bone was immersed in a solution for either 5 or 10 minutes followed by mechanical decontamination with done through 1 minute lavage with a bulb syringe with normal saline or a 1 minute mechanical scrub with a bristled scrub brush. | 28 pieces of purposefully inoculated bone had no decontamination procedures. | Culture results and chondrocyte viability from cell counts. | In phase 1 the contamination rate for dropped bone was 70%. In the inoculated and decontaminated specimens the use of a five minute bath with povidone-iodine solution followed by a 1 minute bulb syringe lavage with normal saline was found to sufficiently decontaminate osteoarticular bone fragments. The use of chlorehexidine gluconate and alcohol together was not recommended because it failed to completely sterilize the grafts even after 10 minutes of exposure. | IIB |

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| 53 | Bhandari M, Schemitsch EH, Adili A, Lachowski RJ, Shaughnessy SG. High and low pressure pulsatile lavage of contaminated tibial fractures: an in vitro study of bacterial adherence and bone damage. J Orthop Trauma. 1999;13(8):526-533. | Quasi-experimental | 10 sections of human tibiae contamination with *Staphylococcus aureus* | Treatment with high and low pressure pulsatile lavage | No treatment | Microbial detection and identification and evaluation of bone structure | Low pressure pulsatile lavage led to less structural damage and was equally effective in removing bacteria within a 3 hour debridement delay. | IIB |
| 54 | Cruz NI, Cestero HJ, Cora ML. Management of contaminated bone grafts. Plast Reconstr Surg. 1981;68(3):411-414. | Quasi-experimental | Multiple part experiment. The first part of the study included 120 rib bone grafts, the second part included 60 iliac bone fragments, and the third part of the study included 40 rib grafts. | Decontamination with normal saline solution, povidone-iodine solution, or cefazolin 1gm/liter. | No treatment performed | Presence of infection noted by erythema, inflammation, or pus. | Minimal contamination was caused by OR floor contact. Cleansing with any of the solutions was effective in preventing infection. Since all the solutions showed an almost equal effectiveness it is the mechanical decontamination that is important. Contaminated bone does not have to be discarded, but should be mechanically decontaminated with a solution prior to implantation. | IIB |
| 55 | Hirn M, Laitinen M, Pirkkalainen S, Vuento R. Cefuroxime, rifampicin and pulse lavage in decontamination of allograft bone. J Hosp Infect. 2004;56(3):198-201. | Quasi-experimental | 30 femoral heads from healthy primary total hip arthroplasty procedures rubbed on the OR floor and left for 60 minutes. | Treatment by soaking in antibiotic solution or low-pressure pulsatile lavage with normal saline. | Soaking in normal saline solution. | Mircobial detection and identification | Low-pressure pulsatile lavage with sterile saline solution is very effective in removing bacteria from the bone graft, when compared with antibiotic solutions. | IIB |
| 56 | Bhandari M, Adili A, Schemitsch EH. The efficacy of low-pressure lavage with different irrigating solutions to remove adherent bacteria from bone. J Bone Joint Surg Am. 2001;83(3):412-419. | Quasi-experimental | 6 Calvarial cells from newborn mice | Exposure to equivalent concentrations of five different irrigation solutions after three different time periods. | Exposure to normal saline solution | Function of osteoblasts and osteoclasts in vitro and amount of adherent bacteria removed from bone | Certain solutions may be more effective in removing bacteria from bone than mechanical irrigation with saline alone. Low pressure lavage with the soap solution resulted in the greatest removal of adherent bacertia from bone. | IIB |
| 57 | Bhandari M, Adili A, Lachowski RJ. High pressure pulsatile lavage of contaminated human tibiae: an in vitro study. J Orthop Trauma. 1998;12(7):479-484. | Quasi-experimental | 9 Human tibias from above the knee amputations contaminated with two bacterial strains | Treatment with high-pressure pulsatile lavage | No treatment | Microbial detection, identification, and evaluation of bone structure | High pressure pulsatile lavage resulted in bacterial seeding into the intramedulary canal and signifigant damage to the structure of the bone. | IIB |
| 58 | Yaman F, Unlü G, Atilgan S, Celik Y, Ozekinci T, Yaldiz M. Microbiologic and histologic assessment of intentional bacterial contamination of bone grafts. J Oral Maxillofac Surg. 2007;65(8):1490-1494. | Quasi-experimental | 160 rate femora conatminated with bacteria | Immersion in various decontamination solutions for specified periods of time | No treatment | Microbial detection, identification, and evaluation of bone structure | Rifamycin seems to be the most suitable agent for elimination of contamination introduced into bone grafts during surgery. | IIB |
| 59 | Kaysinger KK, Nicholson NC, Ramp WK, Kellam JF. Toxic effects of wound irrigation solutions on cultured tibiae and osteoblasts. J Orthop Trauma. 1995;9(4):303-311. | Quasi-experimental | 6 per group, osteoblasts isolated from 17-day chick embryo calvariae/Tibiae harvested from 18-day chick embryos. | Exposure to three antiseptic and one antibiotic solutions at various concentrations for two minutes. | Exposure to normal saline solution | Cytotoxicity to bones and cells | A wound irrigation solution containing bacitracin may be safer than one containing an antiseptic solution, although other antibiotic agents should be tested regarding their effects on osteoblast function. Three common antiseptic solutions: hydrogen peroxide, povidone-iodine solution, and povidone-iodine scrub were shown to cause frank toxicity in bone at concentrations used clincally. | IIB |
| 60 | Guideline for sterile technique. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:931-972. | Guideline | n/a | n/a | n/a | n/a | Perioperative practice recommendations on the application of sterile technique. | IVA |

| REFERENCE # | CITATION | EVIDENCE TYPE | SAMPLE SIZE/ POPULATION | INTERVENTION(S) | CONTROL/ COMPARISON | OUTCOME MEASURE(S) | CONCLUSION(S) | CONSENSUS SCORE |
|---|---|---|---|---|---|---|---|---|
| 61 | Lacey RW. Antibacterial activity of povidone iodine towards non-sporing bacteria. J Appl Bacteriol. 1979;46(3):443-449. | Quasi-experimental | Four cultures of bacterial strains spread over three centimeter circles on the forarms of healthy volunteers | Treatment with povidone-iodine | No treatment | Microbial detection and identification | Hemaglobin inactivates povidone-iodine. | IIB |
| 62 | Surgical site infection (SSI) event. In: National Healthcare Safety Network (NHSN) Patient Safety Component Manual. Atlanta GA: National Healthcare Safety Network, Centers for Disease Control and Prevention; 2018. | Regulatory | n/a | n/a | n/a | n/a | Description of CDC Wound Class. | n/a |
| 63 | Anto D, Manjooran RP, Aravindakshan R, Lakshman K, Morris R. Cranioplasty using autoclaved autologous skull bone flaps preserved at ambient temperature. J Neurosci Rural Pract. 2017;8(4):595-600. | Nonexperimental | 72 cranioplasty patients with bone flaps autoclaved and preserved under ambient conditions. | n/a | n/a | Clinical outcome, including osteomyelitis, bone resorption, and bone fragmentation or fracture. | There was satisfactory clinical outcomes in 86.11% of patients, osteomyeltis was 5.56%, bone resorption was 1.39% and bone fragmentation or fracture was 6.94%. Storage of cranial bone flaps at ambient temperature had good outcomes. | IIIB |
| 64 | Mracek J, Hommerova J, Mork J, Richtr P, Priban V. Complications of cranioplasty using a bone flap sterilised by autoclaving following decompressive craniectomy. Acta Neurochir (Wein). 2015;157(3):501-506. | Nonexperimental | 149 cranioplasty patients with sterilized cranial bone flaps | n/a | n/a | SSI rates and bone flap resorption rates | SSIs developed in 5 patients (3.3%) and bone flap resorption occurred in 20% of patients. | IIIB |
| 65 | Missori P, Marruzzo D, Paolini S, et al. Autologous skull bone flap sterilization after decompressive craniectomy: an update. World Neurosurg. 2016;90:478-483. | Quasi-experimental | 45 cranioplasty patients | 33 patients had cranial bone flaps that were preserved with ethylene oxide (EO) sterilization. | 7 patients had cranial bone flaps sterilized with hydrogen peroxide gas plasma and 5 patients had bone flaps sterilized at 121° C for 45 min. | SSI rates and bone flap resorption rates | Overall complication rate was 4.4%. A single patient developed an infection (2%) and one child had partial resorption of the flap after 12 months. Both EO and high- or low-temperature autoclaving was safe and inexpensive for preservation of cranial bone flaps. | IIC |
| 66 | Jho DH, Neckrysh S, Hardman J, Charbel FT, Amin-Hanjani S. Ethylene oxide gas sterilization: a simple technique for storing explanted skull bone: technical note. J Neurosurg. 2007;107(2):440-445. | Nonexperimental | 103 cranioplasty patients with ethylene oxide (EO) gas sterilization of the cranial bone flap for preservation and room temperature storage | n/a | n/a | SSI rates, aesthetic results. | The infection rate was 7.8%. The mean preservation interval was 3.8 months in uninfected patients and 6.4 months in infected patients. Therefore, patients with preservation durationss over 10 months were more likely to develop an infection. Discard or re-sterilize bone flaps after 10 months of storage. | IIIB |
| 67 | Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:973-1002. | Guideline | n/a | n/a | n/a | n/a | Practice recommendations for sterilization in the perioperative practice setting. | IVA |
| 68 | Herrera MF, Grant CS, van Heerden JA, Jacobsen D, Weaver A, Fitzpatrick LA. The effect of cryopreservation on cell viability and hormone secretion in human parathyroid tissue. Surgery. 1992;112(6):1096-1102. | Quasi-experimental | 18 cryopreserved parathyroid tissue specimens and 10 fresh abnormal parathyroid glands | Different lengths of cryopreservation | Fresh specimens | Viable cells and functional studies, including PTH release | No difference in viability found between fresh and cryopreserved tissue regardless of the length of cryopreservation. Cell viability and function remained unchanged due to cryopreservation. | IIC |
| 69 | Schneider R, Ramaswamy A, Slater EP, Bartsch DK, Schlosser K. Cryopreservation of parathyroid tissue after parathyroid surgery for renal hyperparathyroidism: does it really make sense? World J Surg. 2012;36(11):2598-2604. | Nonexperimental | 15 patients who received autologous cryopreserved parathyroid tissue | n/a | n/a | Cell viability | Cryopreservation was successful but facilities should determine patient's should have parathyroid tissue stored because there were high rates of cryopreservation, high costs associated with cryopreservation, and low autotransplantation rates. | IIIB |

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|---|---|---|---|---|---|---|---|---|
| 70 | McHenry CR, Stenger DB, Calandro NK. The effect of cryopreservation on parathyroid cell viability and function. Am J Surg. 1997;174(5):481-484. | Quasi-experimental | N was not reported but was over 52 bovine parathyroid specimens | Cryopreserved dispersed cells | Non-cryopreserved control and minced cryopreserved parathyroid specimens | Live cell yield and cellular response to calcium | The cryopreservation process decreased live cell yield by 70-90%. Maximizing the amount of parathyroid tissue for autotransplantation may increase the total amount of live cells and increase the success of the graft. | IIC |
| 71 | Cohen MS, Dilley WG, Wells SA Jr, et al. Long-term functionality of cryopreserved parathyroid autografts: a 13-year prospective analysis. Surgery. 2005;138(6):1033-1040. | Nonexperimental | 29 parathyroidectomy patients who had autologous parathyroid autotransplantation | n/a | n/a | Autograft function | The mean cryopreservation period was 7.9 months in patients with fully functioning grafts while the mean storage duration was 15.3 months in non functioning autografts. The difference in time was statistically significant. Shorter cryopreservation times may show a better functional outcome. | IIIB |
| 72 | Saxe AW, Spiegel AM, Marx SJ, Brennan MF. Deferred parathyroid autografts with cryopreserved tissue after reoperative parathyroid surgery. Arch Surg. 1982;117(5):538-543. | Nonexperimental | 12 patients receiving autotransplantation of cryopreserved parathyroid | n/a | n/a | Parathyroid viability | There was no correlation between the duration of cryopreservation and the function of a patient's autograft. | IIIC |
| 73 | Wagner PK, Rumpelt HJ, Krause U, Rothmund M. The effect of cryopreservation on hormone secretion in vitro and morphology of human parathyroid tissue. Surgery. 1986;99(3):257-264. | Quasi-experimental | Parathyroid tissue from 6-10 patients depending on the test. | Cryopreserved parathyroid tissue | Fresh parathyroid tissue | PTH secretion, cell morphology | Cryopreservation did impact cell morphology. When cryopreserving tissue the surgeon should take into account the increased risk of cell necrosis from the process when deciding how much tissue to autotransplant (eg, more cryopreserved tissue potentially then when autotransplanting fresh tissue). | IIB |
| 74 | Guerrero MA, Evans DB, Lee JE, et al. Viability of cryopreserved parathyroid tissue: when is continued storage versus disposal indicated? World J Surg. 2008;32(5):836-839. | Nonexperimental | 106 cryopreserved parathyroid specimens | n/a | n/a | Cell viability | Only 10% of the specimens examined were found to be viable. Only 1% of the specimens stored longer than 24 months was found to be viable. Recommended storing only for 24 months. | IIIB |
| 75 | Agarwal A, Waghray A, Gupta S, Sharma R, Milas M. Cryopreservation of parathyroid tissue: an illustrated technique using the Cleveland Clinic protocol. J Am Coll Surg. 2013;216(1):e1-9. | Organizational Experience | 630 cryopreserved parathyroid tissue specimens. 9 of the patients with cryopreserved parathyroid tissue had it autotransplanted | n/a | n/a | n/a | Described the complete protocol used for cryopreservation of parathyroid glands and the rational. | VA |
| 76 | Barreira CE, Cernea CR, Brandão LG, Custodio MR, Caldini ET, de Menezes Montenegro FL. Effects of time on ultrastructural integrity of parathyroid tissue before cryopreservation. World J Surg. 2011;35(11):2440-2444. | Quasi-experimental | 11 total parathyroidectomy patients | Storage in cell culture medium at 4 degrees C for 2, 6, 12 & 24 hours. | No storage | Structural integrity consistent with cell viability | Storage in a cell culture medium @ 4 degrees C for up to 12 hours maintained structural integrity of the tissue. | IIC |
| 77 | Alvarez-Hernandez D, Gonzalez-Suarez I, Carrillo-Lopez N, Naves-Diaz M, Anguita-Velasco J, Cannata-Andia JB. Viability and functionality of fresh and cryopreserved human hyperplastic parathyroid tissue tested in vitro. Am J Nephrol. 2008;28(1):76-82. | Quasi-experimental | 18 specimens of parathyroid tissue from 18 patients split into 2 groups | Calcium culture for 60 hours | Calcitriol culture for 60 hours | PTH secretion | Cell viability measured for fresh and cryopreserved parathyroid tissue was higher than 85% in all cases showing no difference between fresh and cryopreserved parathyroid tissue. | IIC |
| 78 | Brennan MF, Brown EM, Sears HF, Aurbach GD. Human parathyroid cryopreservation: in vitro testing of function by parathyroid hormone release. Ann Surg. 1978;187(1):87-90. | Quasi-experimental | Parathyroid tissue from 19 patients | cryopreservation | fresh (tested in only 8 patients) | PTH Secretion | No difference was found in PTH secretion between fresh and cryopreserved tissue (200 days). | IIC |

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|---|---|---|---|---|---|---|---|---|
| 79 | Stotler BA, Reich-Slotky R, Schwartz J, et al. Quality monitoring of microbial contamination of cryopreserved parathyroid tissue. Cell Tissue Bank. 2011;12(2):111-116. | Organizational Experience | 47 parathyroid specimens for cryopreservation | n/a | n/a | Bacterial contamination | The specimen contamination rate was 23%. Contamination was present at the time of cryopreservation in 10 of 11 cases. However, in only 3 cases was contamination present before and after cryopreservation . | VB |
| 80 | Monchik JM, Cotton TM. Technique for subcutaneous forearm transplantation of autologous parathyroid tissue. Surgery. 2017;161(5):1451-1452. | Expert Opinion | n/a | n/a | n/a | n/a | Discusses a forearm technique of autologous parathyroid transplantation. | VB |
| 81 | Leite AK, Junior CP, Arap SS, et al. Successful parathyroid tissue autograft after 3 years of cryopreservation: a case report. Arq Bras Endocrinol Metabol. 2014;58(3):313-316. | Case Report | n/a | n/a | n/a | n/a | Discussed one successful case of autotransplantation of parathyroid tissue after 36 months of cryopreservation. | VB |
| 82 | de Menezes Montenegro FL, Custodio MR, Arap SS, et al. Successful implant of long-term cryopreserved parathyroid glands after total parathyroidectomy. Head Neck. 2007;29(3):296-300. | Case Report | 2 patients | n/a | n/a | n/a | Discussed two cases of successful cryopreserved autografts one after 22 months and one at 30 months. | VB |
| 83 | Ciudad P, Date S, Orfaniotis G, et al. Delayed grafting for banked skin graft in lymph node flap transfer. Int Wound J. 2017;14(1):125-129. | Nonexperimental | 10 split-thickness skin grafts | n/a | n/a | Graft take and complications | The flap survival rate was 100% and the graft take rate was more than 97% .No complications were reported except one patient needing slightly more medication at bedside during the graft transfer. Cost effective method. | IIIB |
| 84 | Sheridan R, Mahe J, Walters P. Autologous skin banking. Burns. 1998;24(1):46-48. | Nonexperimental | 42 skin grafts onto 28 patients in 5 years | n/a | n/a | Successful engraftment with vascularization | In 12 of the 42 cases documentation about the engraftment success rate was found. The documentation from the 12 cases showed a 70% successful vascularization rate. | IIIC |
| 85 | DeBono R, Rao GS, Berry RB. The survival of human skin stored by refrigeration at 4 degrees C in McCoy's 5A medium: does oxygenation of the medium improve storage time? Plast Reconstr Surg. 1998;102(1):78-83. | Quasi-experimental | 80 3mm split-thickness skin grafts | Storage in oxygenated McCoy's 5A medium | Storage in McCoy's 5A medium, in 0.9% normal saline solution, and in carbon dioxide supplemented McCoy's 5A medium. | Skin viability through skin culture | All specimens were refrigerated at 4 degrees C. Storage in McCoy's 5A medium and McCoy's 5A medium supplemented with oxygen both survived 4 weeks. Skin stored in saline solution was only viable for one week and skin stored in McCoy's 5A medium supplemented with CO2 did not survive the first week. | IIB |
| 86 | Turhan-Haktanır N, Dilek FH, Köken G, Demir Y, Yılmaz G. Evaluation of amniotic fluid as a skin graft storage media compared with RPMI and saline. Burns. 2011;37(4):652-655. | Quasi-experimental | 15 pieces of split-thickness skin grafts from different patients separated into three groups. | Storage in amniotic fluid or RPMI-1640 | Storage in saline | histological changes | Storage in amniotic fluid and RPMI-1640 was significantly better than storage in saline. | IIA |
| 87 | Boekema BK, Boekestijn B, Breederveld RS. Evaluation of saline, RPMI and DMEM/F12 for storage of split-thickness skin grafts. Burns. 2015;41(4):848-852. | Quasi-experimental | 15 donors (8 living and 7 deceased) | Submerged storage at 4 degrees C in one of the following - DMEM/F12 or RPMI | Submerged storage at 4 degrees C in 0.9% NaCl | Skin viability assessed through MTT-based activity assay | RPMI was better for skin storage at 4 degrees C than DMEM/F12 on days 3 and 10 and was better than saline and DMEM/F12 on days 14 and 21. It is not possible to determine a cutoff point at which grafts should no longer be used because of the gradual decline in viability index of stored skin. | IIB |
| 88 | Sterne GD, Titley OG, Christie JL. A qualitative histological assessment of various storage conditions on short term preservation of human split skin grafts. Br J Plast Surg. 2000;53(4):331-336. | Quasi-experimental | 42 Split-thickness skin grafts | Meshed and stored in a rolled fashion in a fluctuating refrigerator. | Not meshed, stored flat, and in a stable temperature controlled refrigerator. | Skin viability through histological assessment at time 0 and after 4, 14, 21, and 28 days of storage | The researchers recommend storing the skin as a rolled sheet at a uniform temperature of 4° C. | IIC |

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|---|---|---|---|---|---|---|---|---|
| 89 | Knapik A, Kornmann K, Kerl K, et al. Practice of split-thickness skin graft storage and histological assessment of tissue quality. J Plast Reconstr Aesthet Surg. 2013;66(6):827-834. | Nonexperimental | 17 split-thickness skin grafts in saline soaked gauze over 14 days | N/A | N/A | Skin integrity, cell viability, cell proliferation, apoptosis, and vascularity. | Cell viability decreased by 50% after day 3 of storage. While it is clear that superior methods of storage exist the saline soaked gauze method is still the most commonly used method in Switzerland, Germany, Austria, Great Britain, and France. | IIIB |
| 90 | Titley OG, Cooper M, Thomas A, Hancock K. Stored skin—stored trouble? Br J Plast Surg. 1994;47(1):24-29. [ | Nonexperimental | 102 spilt-thickness skin grafts | n/a | n/a | Bacterial contamination and graft take rates | There was a correlation between bacterial growth and the rates of graft take failure. Skin should be stored in refrigerators that are industrial not domestic, with temperature monitor, and consideration for other items stored in the same location to prevent bacterial cross-contamination. | IIIB |
| 91 | Li Z, Overend C, Maitz P, Kennedy P. Quality evaluation of meshed split-thickness skin grafts stored at 4°C in isotonic solutions and nutrient media by cell cultures. Burns. 2012;38(6):899-907. | Quasi-experimental | 30 meshed split-thickness skin grafts | Storage in Hartmann's solution, Dulbecco's Modified Eagle Medium (DMEM), or DMEM/Ham F12 at 4 degrees C for 28 days. | Storage in saline at 4 degrees C for 28 days. | Cell viability and microbial contamination. | DMEM or DMEM/Ham F12 should be used for storage of grafts at 4 degrees C instead of saline or Hartmann's solution. The meshed grafts should be used within 7 days. Graft contamination is of concern and interventions to minimize contamination should be performed during skin harvest and storage. Recommend the inclusion of antimicrobial agents in storage solution and microbial testing. | IIA |
| 92 | Rosenquist MD, Kealey GP, Lewis RW, Cram AE. A comparison of storage viability of nonmeshed and meshed skin at 4 degrees C. J Burn Care Rehabil. 1988;9(6):634-636. | Quasi-experimental | 6 split-thickness skin grafts divided into 2 storage groups. | Meshing | No Meshing | Graft take and complication rates | The difference in storage viability expressed in graft take rates was not statistically significant between groups. Meshing the skin prior to preservation does not affect the viability of banked skin and that short-term preservation of skin for 20-30 days at 4 degrees C in nutrient medium can be achieved if skin is stored under optimal conditions. | IIB |
| 93 | Mardini S, Agullo FJ, Salgado CJ, Rose V, Moran SL, Chen HC. Delayed skin grafting utilizing autologous banked tissue. Ann Plast Surg. 2009;63(3):311-313. | Case Report | 10 patients with split-thickness skin grafting stored at the donor site for delayed autotransplantation | n/a | n/a | n/a | Preservation of spit-thickness skin grafts at the donor site for delayed autotransplantation between days 3-8 postoperatively at the bedside resulted in 95% of graft take rates at patient discharge and 100% healed grafts between 5-12 months. This was a reliable and cost effective method of skin preservation. | VB |
| 94 | Wilbring M, Tugtekin SM, Zatschler B, et al. Preservation of endothelial vascular function of saphenous vein grafts after long-time storage with a recently developed potassium-chloride and N-acetylhistidine enriched storage solution. Thorac Cardiovasc Surg. 2013;61(8):656-662. | Nonexperimental | 19 saphenous vein segments split between two groups | n/a | n/a | Wall tension, endothelium-dependent vasodilation, and endothelium-independent vasodilation | Storage in cold normal saline after 96 hours resulted in nearly complete loss of function. However, storage in TiProtect was significantly better in at 24 hours and 96 hours. | IIIB |
| 95 | Ebner A, Poitz DM, Augstein A, Strasser RH, Deussen A. Functional, morphologic, and molecular characterization of cold storage injury. J Vasc Surg. 2012;56(1):189-198. | Quasi-experimental | 6 mouse aorta | Placed in ice-cold TiProtec solution for up to a maximum or 7 days at 4 degrees C. | Placed in ice-cold TiProtec solution for 2 hours at 4 degrees C. | Aorta morphology changes (vessel tone) and changes in gene RNA | Cold storage for 2 days results in a decline or vasorelaxation and vasoconstriction. However, RNA changes occurred after 2 hours of cold storage. Molecular level changes occur before morphologic and functional changes are obvious. | IIB |
| 96 | Garbe S, Zatschler B, Muller B, et al. Preservation of human artery function following prolonged cold storage with a new solution. J Vasc Surg. 2011;53(4):1063-1070. | RCT | 133 patients with harvested internal mammary artery | Storage for up to 25 days in TiProtec, Histidine-tryptophan-ketoglutarate (HTK) solution, or phosphate-buffered saline | Storage for up to 25 days in 0.9% normal saline solution | Vessel function | The use of TiProtect permits safe storage of human and animal vessels for 7 to 14 days. | IB |

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|---|---|---|---|---|---|---|---|---|
| 97 | Zatschler B, Dieterich P, Muller B, Kasper M, Rauen U, Deussen A. Improved vessel preservation after 4 days of cold storage: experimental study in rat arteries. J Vasc Surg. 2009;50(2):397-406. | Quasi-experimental | Varying vessels from rats, N not reported. | Compared vessel function at 96 hours with storage in physiologic saline solution, histidine-tryptophan-ketoglutarate (HTK) solution, and a new solution comprised of N-acetyl histidine-buffered, potassium-chloride enriched, or solution 8 which comprised amino acid fortified solution augmented with iron chelators deferoxamine (100 µmol/L) and LK 614 (20µmol/L). | Compared vessel function at 2 hours with storage in physiologic saline solution, histidine-tryptophan-ketoglutarate (HTK) solution, and a new solution comprised of N-acetyl histidine-buffered, potassium-chloride enriched, or solution 8 which comprised amino acid fortified solution augmented with iron chelators deferoxamine (100 µmol/L) and LK 614 (20µmol/L). | Vessel tone, endothelium-dependent and independent vessel relaxation, and eNOS expression | Solution 8 protected the vessels significantly better than HTK or saline solution. Use of the new solution allows for vessel storage for a minimum of 4 days while retaining endothelial function and coupling to smooth muscle. | IIC |
| 98 | Cavallari N, Abebe W, Hunter WJ 3rd, et al. University of Wisconsin solution effects on intimal proliferation in canine autogenous vein grafts. J Surg Res. 1995;59(4):433-440. | RCT | Veins from 11 canines | University of Wisconsin solution for vessel storage for 24 hours | Autologous whole blood or normal saline solution for vessel storage for 24 hours. One vein segment was immediately re-anastomosed as a control. | Morphology and functional vessel responses | Storage in University of Wisconsin solution is better than storage in blood or normal saline. | IB |
| 99 | Thatte HS, Biswas KS, Najjar SF, et al. Multi-photon microscopic evaluation of saphenous vein endothelium and its preservation with a new solution, GALA. Ann Thorac Surg. 2003;75(4):1145-1152 | Quasi-experimental | 5 saphenous vein segments from 9 patients | Storage in a heparinized physiologic buffered salt solution containing glutathione, ascorbic acid, and L-arginine (GALA) | Storage in heparin, lidocaine, and sodium chloride (HLS), autologous heparinized blood, tissue culture medium (TCM), minimum essential medium (MEM), RPMI 1640, or Hanks balanced salt solution (HBSS), | Endothelial cell viability | Veins may be stored in GALA for up to 24 hours. Standard solutions used to store veins today led to a rapid decline in vein endothelial cell viability. | IIB |
| 100 | Policy 16: Organ and extra vessel packaging, labeling, shipping, and storage. Organ Procurement and Transplantation Network. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Effective date August 15, 2019. Accessed August 29, 2019. | Accreditation | n/a | n/a | n/a | n/a | Policy of the OPTN on labeling and management of vessels used for human transplantation. | n/a |

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|---|---|---|---|---|---|---|---|---|
| 101 | Molnar GF, Nemes A, Kekesi V, Monos E, Nadasy GL. Maintained geometry, elasticity and contractility of human saphenous vein segments stored in a complex tissue culture medium. Eur J Vasc Endovasc Surg. 2010;40(1):88-93. | RCT | 72 vein segments from 32 patients | Segments stored in one of the following ways - normal Kreb-Ringer's solution, physiological salt solution at 0-4 degrees C for 1 and 2 weeks, stored in X-Vivio 10 medium solution stored for 1, 2, 3, and 4 weeks at 0-4 degrees C, and cryopreserved segments stored for a few weeks at -140 degrees C | Fresh segments tested after the operation | Biomechanical graft properties (eg, contractility, lumen pressure, inner lumen diameter) | Storage for 1 week in physiological salt solution distends the segments and decreased contractility and distensibility. Cryopreservation diminished high-pressure contractility but increases wall thickness. X-vivo was found to preserve contractility for up to 4 weeks with only a slight reduction in wall thickness and no change in elastic properties. | IB |
| 102 | Harskamp RE, Alexander JH, Schulte PJ, et al. Vein graft preservation solutions, patency, and outcomes after coronary artery bypass graft surgery: follow-up from the PREVENT IV randomized clinical trial. JAMA Surg. 2014;149(8):798-805. | RCT | 3014 patients from 107 US facilities | Intraoperative preservation in either buffered saline solution or blood-based solutions | Intraoperative preservation in saline solution | Vein graft failure rates and patient outcomes (ie, 5-year all-cause mortality, myocardial infarction [MI], revascularization). | While most patients have veins stored intraoperatively in saline, the study found lower vein graft failure rates and better long-term patient outcomes for patient's whose veins were stored in buffered saline solution. | IA |
| 103 | Chang SK, Lau JW, Chui CK. Changes in mechanical, structural integrity and microbiological properties following cryopreservation of human cadaveric iliac arteries. Ann Acad Med Singapore. 2014;43(10):492-498. | Quasi-experimental | 7 pairs of cadaver iliac arteries | Cryopreservation | No cryopreservation | Mechanical vessel function | Cryopreservation increased vessel stiffness as duration of storage increased but also that the mechanical properties of the vessels were similar prior to and after cryopreservation. Atherosclerotic areas of the cryopreserved arteries were more likely to have fragmentation. | IIB |
| 104 | Coppi G, Ragazzi G, Cataldi V, Corvi V, Silingardi R. Cryopreserved autologous saphenous vein for staged treatment of bilateral popliteal aneurysms: report of three cases. Ann Vasc Surg. 2014;28(5):1322.e13-1322.e17. | Case Report | n/a | n/a | n/a | n/a | Report on three cases of cryopreservation of autologous saphenous vein. There were no occlusions or aneurysmal dilations were found during the follow-up period. Vascular and cardiac patients that undergo multiple procedures may be more likely to have vessel disease limiting the number of vessels available for grafting or may have vessels used during a previous procedure that could be cryopreserved for a future procedure as a method of longer-term storage than refrigeration. | VB |
| 105 | Shinar AA, Harris WH. Bulk structural autogenous grafts and allografts for reconstruction of the acetabulum in total hip arthroplasty. Sixteen-year-average follow-up. J Bone Joint Surg Am. 1997;79(2):159-168. | Nonexperimental | 70 total hip arthroplasty procedures from 62 patients. | n/a | n/a | Patient outcomes after hip surgery including loosening, Harris hip score, and the need for revision procedure. | Regression analysis showed that a younger age at the time of surgery was correlated to the need for revision but that 60% of hips with allograft tissue used and 29% of hips using autologous tissue had been revised. | IIIB |

| REFERENCE # | CITATION | EVIDENCE TYPE | SAMPLE SIZE/ POPULATION | INTERVENTION(S) | CONTROL/ COMPARISON | OUTCOME MEASURE(S) | CONCLUSION(S) | CONSENSUS SCORE |
|---|---|---|---|---|---|---|---|---|
| 106 | Hing CB, Ball RY, Tucker JK. Autobanking of femoral heads for revision total hip replacement, a preliminary report of a new surgical technique. Surgeon. 2004;2(1):37-41. | Organizational Experience | 13 THA patients that showed evidence of loosening of their THA on the other side had the femoral head placed in an iliac fossa subperiosteal pouch. 6 of the patients had revisions where the femoral head was used up to eight years and 11 months later | n/a | n/a | n/a | No morbidity was found at the implant site. Radiologic and histologic examination showed the femoral heads to be viable. Microbiologic specimens showed no contamination. Tissue viability appeared to be dependent of the distance from the ilium. | VB |
| 107 | Mohan MD, Sandeep RB, Roshan MW. Auto bone banking: innovative method for bone preservation. J Orthop Case Rep. 2014;4(4):16-18. | Case Report | n/a | n/a | n/a | n/a | Report on 17 total hip arthroplasty procedures where the femoral head was implanted in a pouch within the patient for future use if necessary. | VB |
| 108 | Faramarzi M, Roosta S, Dianat M. Outcome of incus interposition after preservation in soft tissue. Iran J Otorhinolaryngol. 2017;29(2):83-88. | Nonexperimental | 199 (including 92 left ears and 107 right ears) | n/a | n/a | After 12 months, postoperative pure tone audiometry was completed for assessment of a 20 dB air-bone gap (ABG). | A 20 dB ABG was achieved in 78.9% of patients. The researchers concluded that preservation of the autologous incus in the postauricular space between surgeries was safe and effective. | IIIB |
| 109 | Gyo K, Hato N, Shinomori Y, Hakuba N. Storage of the incus in the mastoid bowl for use as a columella in staged tympanoplasty. Auris Nasus Larynx. 2007;34(1):5-8. | Nonexperimental | 24 | n/a | n/a | At least one of the following postoperative conditions: ABG within 15 dB, hearing gain more than 15 dB, or air conduction hearing within 30 dB | The ossicular chain reconstruction procedure used the preserved incus in 79.1% of the procedures. The five procedures that did not use the preserved incus included only one patient whose incus was severely atrophied. The hearing testing showed that the reconstruction was successful in 65% of procedures. The follow-up period 5 to 9 years after the procedure showed continued successful hearing outcomes in 57% of the patients. | IIIC |
| 110 | Fritsch MH, Moberly AC. Tragal storage of autograft middle-ear ossicles. Otolaryngol Head Neck Surg. 2010;143(1):161-162. | Case Report | n/a | n/a | n/a | n/a | The incus was placed in the soft tissue of the posterior tragus until the second stage ossicular chain reconstruction procedure. Upon removal the incus was found to be intact with no resorption and was placed successfully during the second procedure with good results. | VC |
| 111 | Ha KY, Park H, Park SH, et al. The relationship of a combination of human adipose tissue-derived stem cells and frozen fat with the survival rate of transplanted fat. Arch Plast Surg. 2015;42(6):677-685. | Quasi-experimental | 40 nude mice | Subcutaneous injection of fresh fat and adipose tissue-derived stem cells (ASCs) , fat cryopreserved for 1 month and ASCs, or fat cryopreserved for 2 months and ASCs. | Same groups used without ASCs | Resorption rates | The researchers concluded that the use of ASCs can increase graft survival rates. | IIB |

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|---|---|---|---|---|---|---|---|---|
| 112 | Ibrahiem SMS, Farouk A, Salem IL. Facial rejuvenation: serial fat graft transfer. Alex J Med. 2016;52(4):371-376. | Organizational Experience | 104 patients receiving 364 autologous fat grafts, most from frozen tissue | n/a | n/a | n/a | Article reported good clinical results with a few poor outcomes. Authors suggested small amounts of fat grafts over a period of time. | VB |
| 113 | Ma H, Fang YH, Lin CH, Perng CK, Tsai CH, Hsiao FY. Facial recontouring with autologous cryopreserved fat graft. Formosan J Surg. 2018;51(2):58-62. | Nonexperimental | 32 autologous cryopreserved fat graft patients with 84 fresh grafts and 178 autologous cryopreserved grafts | n/a | n/a | Patient satisfaction and postoperative complication rate | Complication rate for cryopreserved grafts was 1/178 (0.6%). The patient satisfaction questionnaire revealed no statistical difference in rating between fresh and cryopreserved tissue. There was a significant difference in convenience of using cryopreserved versus fresh tissue on the questionnaire. | IIIB |
| 114 | Conti G, Jurga M, Benati D, et al. Cryopreserved subcutaneous adipose tissue for fat graft. Aesthetic Plast Surg. 2015;39(5):800-817. | Nonexperimental | 26 mice | n/a | n/a | MRI analysis | Further research is needed for clinical applications of cryopreserved adipose tissue. | IIIB |
| 115 | Guideline for team communication. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:1061-1092. | Guideline | n/a | n/a | n/a | n/a | Guidance for team communication in the perioperative setting. | IVA |
| 116 | Wax MK, Futran ND, Rosenthal EL, Blackwell KE, Cannady S. Accidental dropping or misplacement of free flaps. Laryngoscope. 2015;125(8):1807-1810. | Nonexperimental | 13 free flaps (0.15%) of 8,382 free flaps performed were dropped or misplaced. | n/a | n/a | The flaps were dropped or wrapped in a towel/sponge and placed in the trash. The reasons included 9 instances of miscommunication and 4 instances of dropped flaps. | All flaps were retrieved washed with saline and iodophors and autoimplanted back into the patient. There were no altered outcomes. Miscommunication was identified as the root cause of 9 of the 13 errors (69.2%). Staff changes during long procedures may have also played a role in misplacement or dropped flaps. | IIIB |
| 117 | Ask HRC: Best practices for specimen handling. ECRI Institute. https://www.ecri.org/components/HRC/Pages/AskHRC072417.aspx. Published July 24, 2017. Accessed August 29, 2019. | Expert Opinion | n/a | n/a | n/a | n/a | Report on best practices for specimen handling which details results from a 2013 analysis on lab errors. | VB |
| 118 | Greenberg CC, Regenbogen SE, Studdert DM, et al. Patterns of communication breakdowns resulting in injury to surgical patients. J Am Coll Surg. 2007;204(4):533-540. | Nonexperimental | 444 surgical liability malpractice claims | n/a | n/a | Communication breakdown rates | Most communication breakdowns happened in verbal communication compared to written. Suggested the use of a read back system to ensure information is correctly received. | IIIB |
| 119 | Guideline for transmission-based precautions. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019. | Guideline | n/a | n/a | n/a | n/a | Guidance for transmission-based precautions in the perioperative setting. | IVA |
| 120 | 29 CFR 1910.1030: Bloodborne pathogens. Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS. Accessed August 29, 2019. | Regulatory | n/a | n/a | n/a | n/a | OSHA Bloodborne pathogens standards. | n/a |
| 121 | Lost surgical specimens, lost opportunities. PA PSRS Patient Saf Advis. 2005;2(3):1-5. | Expert Opinion | n/a | n/a | n/a | n/a | Pennsylvania Patient Safety Advisory on the reasons for lost surgical specimens. | VB |
| 122 | Where do most lab errors occur? Not the lab. ECRI PSO Monthly Brief. June 2012. ECRI Institute. https://www.ecri.org/EmailResources/PSO_Monthly_Brief/2012/PSO_Brief_Jun12.pdf. Accessed August 29, 2019. | Expert Opinion | n/a | n/a | n/a | n/a | Brief by ECRI discusses where lab errors occur and some strategies to prevent them. | VB |

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|---|---|---|---|---|---|---|---|---|
| 123 | Program: Ambulatory. Transplant safety. TS.03.01.01: The organization uses standardized procedures for managing tissues. In: Comprehensive Accreditation Manual. E-dition ed. Oakbrook Terrace, IL: The Joint Commission; 2019. | Accreditation | n/a | n/a | n/a | n/a | Joint Commission accreditation document for ambulatory that outlines standard procedures for transplant and tissue management. | n/a |
| 124 | Program: Hospital. Transplant safety. TS.03.01.01: The hospital uses standardized procedures for managing tissues. In: Comprehensive Accreditation Manual. E-dition ed. Oakbrook Terrace, IL: The Joint Commission; 2019. | Accreditation | n/a | n/a | n/a | n/a | Joint Commission accreditation document for hospitals that outlines standard procedures for transplant and tissue management. | n/a |
| 125 | Guideline for patient information management. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:371-400. | Guideline | n/a | n/a | n/a | n/a | Guidance of patient information management in the perioperative setting. | IVA |
| 126 | 45 CFR parts 160 and 164: Modifications to the HIPAA privacy, security, enforcement, and breach notification rules under the health information technology for economic and clinical health act and the genetic information nondiscrimination act; other modifications to the HIPAA rules; final rule. Fed Regist. 2013;78(17):5566-5702. | Regulatory | n/a | n/a | n/a | n/a | HIPAA modifications. | n/a |
| 127 | Standards of perioperative nursing. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015. | Position Statement | n/a | n/a | n/a | n/a | Standards of Perioperative Nursing | IVB |
| 128 | Program: Hospital. Transplant safety. TS.03.02.01: The hospital traces all tissues bi-directionally. In: Comprehensive Accreditation Manual. E-dition ed. Oakbrook Terrace, IL: The Joint Commission; 2019. | Accreditation | n/a | n/a | n/a | n/a | Joint Commission accreditation document for hospitals that outlines tissue traceability for transplant and tissue management. | n/a |
| 129 | Program: Ambulatory. Transplant safety.TS.03.02.01: The organization traces all tissues bi-directionally. In: Comprehensive Accreditation Manual. E-dition ed. Oakbrook Terrace, IL: The Joint Commission; 2019. | Accreditation | n/a | n/a | n/a | n/a | Joint Commission accreditation document for ambulatory that outlines tissue traceability for transplant and tissue management. | n/a |