CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
Code of Federal Regulations. 21 CFR 1271. Human cells, tissues, and cellular and tissue-based products. Accessed July 25, 2025. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271	Regulatory	n/a	n/a	n/a	n/a	FDA definitions of autologous tissue, establishment, minimal manipulation, storage, and others. Current good tissue practice requirements and tissue establishment registration requirements.	n/a
Guideline for specimen management. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:959-1002.	Guideline	n/a	n/a	n/a	n/a	Guideline for specimen management in the perioperative environment	IVA
3. US Food and Drug Administration, Center for Biologics Evaluation and Research. Same Surgical Procedure Exception Under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception. Guidance for Industry. November 2017. Accessed July 25, 2025. https://www.fda.gov/media/89920/download	Regulatory	n/a	n/a	n/a	n/a	Definition of "same surgical procedure" and exception language	n/a
4. Food and Drug Administration, HHS. Current good tissue practice for human cell, tissue, and cellular and tissue-based product establishments; inspection and enforcement. Final rule. Fed Regist. 2004;69(226):68611-68688.	Regulatory	n/a	n/a	n/a	n/a	FDA requirement for HCT/P establishments to follow current good tissue practice, which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; recordkeeping; and the establishment of a quality program.	n/a
5. Sable H, Patel MP, Shah KB. A prospective comparative study of different methods of cranioplasty: our institutional experience. Indian J Neurosurg. 2020;9(1):17-23.	Quasi- experimental	60 patients who underwent cranioplasty	method of cranioplasty. Group 1: ethylene oxidation sterilized autologous bone graft. Group 2: subcutaneously stored autologous bone graft. Group 3: titanium mesh.	n/a	surgical outcomes and complications	There was no statistically significant difference in postoperative complications between the three groups. There was no statistically significant difference in factors such as age, gender, initial diagnosis, interval between decompression craniectomy and cranioplasty, operative time, blood loss, method of fixation, and defect size on postoperative outcomes. All three methods are viable for cranioplasty. Subcutaneous placement is recommended for its lower complication rates and better properties.	IIB
Bader ER, Kobets AJ, Ammar A, Goodrich JT. Factors predicting complications following cranioplasty. J Craniomaxillofac Surg. 2022;50(2):134-139.	Nonexperime ntal	92 cranioplasties at a single center	n/a	n/a	factors associated with cranioplasty complications and graft removal.	Complication rate 16.3%. Variables that predict complication following cranioplasty including age, cranioplasty material, and craniectomy-cranioplasty interval. Titanium mesh associated with higher incidence of all-cause complication and cranioplasty removal. 3D-printed PEEK cranioplasties experienced higher rates of complication when compared with autologous bone, but not statistically significant. Longer intervals between craniectomy and cranioplasty increased the odds of graft removal. Authors recommend reducing the interval between craniectomy and cranioplasty to minimize complications.	IIIB
7. Al-Salihi MM, Ayyad A, Al-Jebur MS, et al. Subcutaneous preservation versus cryopreservation of autologous bone grafts for cranioplasty: a systematic review and meta-analysis. J Clin Neurosci. 2024;122:1-9.	Systematic Review w/ Meta-Analysis	n/a	n/a	n/a	Outcomes and complications for subcutaneous preservation and cryopreservation techniques in autologous bone flap preservation.	17 studies involving 1169 patients analyzed with no significant difference in SSI rates observed between SP and CP methods. SP associated with reduced hospitalization time, low infection rates, and a moderate need for revision.	IIIA
8. Cerveau T, Rossmann T, Clusmann H, Veldeman M. Infection- related failure of autologous versus allogenic cranioplasty after decompressive hemicraniectomy: a systematic review and meta- analysis. Brain Spine. 2023;3:101760.	Systematic Review w/ Meta-Analysis	n/a	n/a	n/a	n/a	14 studies included involving 2,569 patients. Infection-related failure rate: 6.9% for autologous and 8.3% for allogenic implants. No significant difference in infection-related failure between autologous and allogenic cranioplasty. Autologous bone flap is non-inferior to allogenic materials in preventing infection-related cranioplasty failure. Autologous cranioplasty remains a viable option, especially for patients with low risk of osteolysis.	IIIB



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Dowlati E, Pasko KBD, Molina EA, et al. Decompressive hemicraniectomy and cranioplasty using subcutaneously preserved autologous bone flaps versus synthetic implants: perioperative outcomes and cost analysis. J Neurosurg. 2022;137(6):1831-1838.	Nonexperime ntal	248 decompressive hemicraniectomy patients divided into two groups: flaps preserved in SQ tissue and flap discarded	n/a	n/a	SSI, postoperative complications, operative costs, length of stay, and blood loss	Patients in the discarded bone flap group were more likely to have a diagnosis of TBI. Patients in the SQ preservation group were more likely to have a diagnosis of malignant stroke. Abdominal surgical site infection rate was 5.2% and abdominal hematomas occurred in 5.8%. Autologous cranioplasties had a significantly higher reoperation rate with 11% attributable to abdominal reoperations. There were no significant differences in complications or surgical site infections. Reoperation rates associated with SQ preservation increase the mean operative costs.	IIIB
10. Gerstl JVE, Rendon LF, Burke SM, et al. Complications and cosmetic outcomes of materials used in cranioplasty following decompressive craniectomy: a systematic review, pairwise meta-analysis, and network meta-analysis. Acta Neurochir (Wien). 2022;164(12):3075-3090.	Systematic Review w/ Meta-Analysis	n/a	n/a	n/a	cosmetic outcomes and complications (resorption, dehiscence, infection, migration, hematoma, seizures)	Overall complications were statistically significantly higher for autologous bone compared to alloplasts, hydroxyapatite, polymethacrylate, and titanium. Resorption occurred only in autologous bone and not in alloplasts. No overall difference in complications between autologous bone and combined alloplasts, nor between individual materials. Dehiscence is higher in alloplasts compared to autologous bone. No significant difference in satisfactory cosmetic outcomes between autologous bone and alloplasts. Individual material outcome profiles should be considered in the individual patient.	IIIA
11. Rosinski CL, Chaker AN, Zakrzewski J, et al. Autologous bone cranioplasty: a retrospective comparative analysis of frozen and subcutaneous bone flap storage methods. World Neurosurg. 2019;131:e312-e320.	Nonexperime ntal	94 patients who underwent cranioplasty with autologous bone stored subcutaneously or frozen			surgical outcomes	The mean operation time was greater within the subcutaneous group. No significant differences in complications, readmissions, unplanned reoperations, or length of stay. Similar risk profile for both frozen and subcutaneous autologous bone graft storage. Overall low complication and resorption rates with autologous bone cranioplasty.	IIIB
12. Alkhaibary A, Alharbi A, Abbas M, et al. Predictors of surgical site infection in autologous cranioplasty: a retrospective analysis of subcutaneously preserved bone flaps in abdominal pockets. World Neurosurg. 2020;133:e627-e632.	Nonexperime ntal	103 patients who underwent cranioplasty from subcutaneously preserved bone flaps	n/a	n/a	SSI and possible risk factors	TBI was the most frequent indication for decompressive craniotomy. SSI occurred in 15.7% of patients. The most significant predictors of infection were blood glucose levels and large skull defect size. Storing bone flaps in subcutaneous abdominal pockets is a cost-effective therapeutic measure that carries considerable risk of infection. Identifying predictors of infection will enable neurosurgeons to risk stratify, predict complications, and assess prognoses in patients requiring cranioplasty.	IIIB
13. Shafiei M, Sourani A, Saboori M, Aminmansour B, Mahram S. Comparison of subcutaneous pocket with cryopreservation method for storing autologous bone flaps in developing surgical wound infection after cranioplasty: a randomized clinical trial. J Clin Neurosci. 2021;91:136-143.	RCT	143 patients who underwent primary decompressive craniectomy	subcutaneous pocketing preservation of autologous bone flap	cryopreservation of autologous bone flap	surgical site infection and bone flap resorption	8% of patients in the cryopreservation group experienced post- operative bone flap infection, which was statistically significant. No patients in the subcutaneous pocket group experienced post-operative infection after cranioplasty. Bone flap resorption rate was higher in the CP group compared to SP technique. No other risk factor was found attributable to a higher bone flap resorption rate. Older age and cryopreservation method at higher storage temperature (-18 degrees C) may be associated with infection's development after performing cranioplasty. BFR is more prevalent in the use of cryopreservation than subcutaneous pocket method. The best method of preservation should also be determined by the local hospital facilities and due to the patient's condition.	IB



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14. Almendárez-Sánchez CA, Solorio-Pineda S, Ramírez-Sosa MA, et al. Cranioplasty with cryopreserved autologous bone in craniectomized patients due to brain trauma, a current and safe option: experience of 97 cases. Cir Cir. 2022;90(4):529-533.	Nonexperime ntal	97 cranioplasties performed over 4 year period involving cryopreserved autologous bone	n/a	n/a	Complication rates	Complication rate was 16.49% with the most significant being SSI (8.24%), presence of intracranial hematoma (3.09%), and reabsorption of the autologous bone (2.06%). Cryopreserved autologous bone is a valid option with an acceptable rate of complications, good biocompatibility, osteogenic potential, and lower surgery costs.	IIIC
15. Caruso JP, Griffin S, El Ahmadieh TY, et al. Surgical site infection after autologous cranioplasty for decompressive craniectomy in traumatic brain injury: a retrospective review of two level 1 trauma centers. J Craniofac Surg. 2021;32(8):2728-2731.	Nonexperime ntal	71 cranioplasties with cryopreserved autologous bone flap after decompressive craniectomy in TBI patients	n/a	n/a	SSI rate	The mean interval from craniectomy to cranioplasty was 99 days. Bone flaps were cultured at the time of reoperation for SSIS to confirm the presence of infection and identify the specific pathogens involved. 4.2% of patients developed SSIs after cranioplasty. Postoperative drain placement and intrawound vancomycin powder were not predictive of infection risk. <5% autologous cranioplasty infection rate in TBI patients across two centers. Authors recommend attempting to preserve native skull and perform autologous cranioplasty in this patient population whenever possible.	
16. Celik H, Kurtulus A, Yildirim ME, et al. The comparison of autologous bone, methyl-methacrylate, porous polyethylene, and titanium mesh in cranioplasty. Turk Neurosurg. 2022;32(5):841-844.	ntal	85 cranioplasties using autologous bone (33), methyl-methacrylate (32), porous polyethylene (12), or titanium mesh (8)	n/a	n/a	Complication rates	Complications were observed in 16 patients, with the highest complication rate (21.9%) in methyl-methacrylate. Infection rate of autologous bone cranioplasties was 9.1%; rate of inability to fix well due to resorption was 9.1%. No major complications observed in cranioplasty with titanium mesh. Porous polyethylene and titanium mesh had the lowest complication rates but are more expensive. Authors conclude that autologous bone and methyl-methacrylate are still the best options and most widely used in most clinics, due to cost considerations.	IIIC
17. Hersh DS, Anderson HJ, Woodworth GF, Martin JE, Khan YM. Bone flap resorption in pediatric patients following autologous cranioplasty. Oper Neurosurg (Hagerstown). 2021;20(5):436-443.	Literature Review	n/a	n/a	n/a	n/a	Description of the materials currently available for pediatric cranioplasty, the advantages and disadvantages of autologous calvarial replacement, the incidence and classification of bone resorption, and the clinical risk factors for bone flap resorption. Cryopreservation represents the storage mode of choice for pediatric patients. Subcutaneous storage is typically not recommended in pediatric patients given large head-to-body ratio and the surgical trauma that would be required to create an adequate abdominal pocket. Attempting to sterilize the bone using alcohol soaking, autoclaving, or calcination, which devitalizes the bone and destroys the osteocytes, is not recommended.	VA
18. Do TH, Lu J, Palzer EF, et al. Rates of operative intervention for infection after synthetic or autologous cranioplasty: a National Readmissions Database analysis. J Neurosurg. 2022;138(2):514-521.	Nonexperime ntal	2295 synthetic and 2072 autologous cranioplasties	n/a	n/a	clinical utilization, costs, and infection risks of autologous bone flap versus synthetic flap cranioplasty	Data were analyzed, focusing on elective cranioplasties after TBI or stroke. Readmissions for infection-related neurosurgical interventions were also examined. Synthetic flap use increased over time, especially in male patients and those with TBI, despite higher costs and infection risks. Median total hospital charge for synthetic cranioplasty was \$31,200 more than autologous cranioplasty. Female patients, those discharged non-routinely, and patients who underwent synthetic cranioplasty were more likely to be readmitted for reoperation for infection. 5.3% of synthetic flap patients and 3.4% of autologous bone flap patients required reoperation for infection.	IIIB



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19. Son Y, Chung J. Risk factor analysis of cryopreserved autologous bone flap resorption in adult patients undergoing cranioplasty with volumetry measurement using conventional statistics and machine-learning technique. J Korean Neurosurg Soc. 2024;67(1):103-114.	Nonexperime ntal	94 patients >18 years of age who underwent autologous bone cranioplasty	n/a	n/a	risk factors for bone flap resorption using conventional statistics and machine learning	The degree of bone flap resorption varies among patients. Risk factors for bone flap resorption are not clearly understood. The initial autologous bone flap of over 60 mL could be a possible risk factor for bone flap resorption. Artificial bone flaps may be considered for patients with large decompressive craniectomy.	IIIB
20. Göttsche J, Mende KC, Schram A, et al. Cranial bone flap resorption: pathological features and their implications for clinical treatment. Neurosurg Rev. 2021;44(4):2253-2260.	Nonexperime ntal	13 cranial bone graft samples with aseptic bone resorption	n/a	2 cryopreserved cranial bone flaps	structural changes, bone volume and bone flap thickness	Typical layering of the cortical and cancellous bone was largely eliminated in the grafts. Histological examination showed coexistence of osteolytic and osteoblastic activity, with fibrosis or necrosis in marrow spaces. Residual fatty bone marrow may obstruct osteogenesis, leading to bone necrosis. No correlation between time interval between decompressive craniectomy and explantation, and bone thickness was found. Structural changes of the bone is a distinct osteopathological feature of aseptic bone necrosis. Authors suggest thorough lavage of the implant to remove bone marrow as a potential treatment, requiring further investigation.	IIIB
21. Belzberg M, Mitchell KA, Ben-Shalom N, et al. Cranioplasty outcomes from 500 consecutive neuroplastic surgery patients. J Craniofac Surg. 2022;33(6):1648-1654.	Nonexperime ntal	500 adult neuro-plastic surgery cranioplasties	n/a	n/a	outcomes from cranioplasty surgeries	Cranioplasty has a high risk of complications, with a reoperation rate of 15.2%, primarily due to infections (7.8%). The use of autologous bone flaps was associated with a significantly increased odds of having a major complication whereas synthetic implant material was associated with a significantly decreased odds. The results suggest it is critical to optimize outcomes at the first cranioplasty surgery, and a multidisciplinary collaborative approach may improve outcomes.	IIIA
22. Gousias K, Stricker I, Hoyer A, et al. Explanted skull flaps after decompressive hemicraniectomy demonstrate relevant bone avitality: is their reimplantation worth the risk? Brain Sci. 2023;13(9):1277.	Quasi- experimental	17 stored skull flaps	8 at -23 degrees Celsius and 9 at -80 degrees Celsius	n/a	Bone avitality-precursor to ABR	Preservation at -23 degree Celsius and longer storage times (>3 months) were prognostic factors for higher rates of bone avitality. Storage at -80 degrees Celsius was more beneficial in terms of bone vitality. However, a relevant degree of bone avitality was identified in all skull flaps, even after storage for only several weeks. High rates of bone avitality in stored skull flaps suggest it may be beneficial to reconsider the use of autologous bone for cranioplasty.	IIA
23. van de Vijfeijken SECM, Groot C, Ubbink DT, et al. Factors related to failure of autologous cranial reconstructions after decompressive craniectomy. J Craniomaxillofac Surg. 2019;47(9):1420-1425.	Nonexperime ntal	254 patients who underwent decompressive craniectomy and cranioplasty with autologous bone in separate procedures	n/a	n/a	factors related to bone flap failure	A neoplasm as an initial diagnosis, longer hospitalization after decompressive craniectomy, larger time interval between decompressive craniectomy and cranioplasty, and longer follow-up duration are associated with a higher risk of failure of autologous bone flaps for cranioplasty. Resorption was more common in younger patients and in those with larger cranial defects. Study only included autologous bone that was stored in the freezer at -80 degrees C. Early recovery programs and the use of alloplastic materials may benefit high-risk patients	IIIC
24. Korhonen TK, Tetri S, Huttunen J, et al. Predictors of primary autograft cranioplasty survival and resorption after craniectomy. J Neurosurg. 2018;130(5):1672-1679.	Nonexperime ntal	207 patients who underwent primary autologous cranioplasty	n/a	n/a	all-cause autologous bone flap removal and complications	Complication rate of 39.6% with a bone flap removal rate of 19.3%. Smoking and younger age (<45 years of age) predicted complications leading to bone flap removal. Very young age (<30 years of age) predicted bone flap resorption. Smoking and younger age are significant predictors or cranioplasty.	IIIB
25. da Costa Benalia VH, Pedrozo CAG, Kormanski MK, et al. Spontaneous bone flap resorption following cranioplasty using autologous bone. J Craniofac Surg. 2021;32(1):293-296.	Case Report	1 cranioplasty with autologous bone patient (Female, 64 years of age)	n/a	n/a	n/a	Bone cryogenically stored at -70 degrees Celsius, cranioplasty 4 months after craniectomy with autologous bone. Bone flap almost completely absorbed within 12 months. Authors conclude that the 6 week period after craniectomy should be the optimum amount of time required to correct cranial defect.	VA



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26. Signorelli F, Giordano M, Caccavella VM, et al. A systematic review and meta-analysis of factors involved in bone flap resorption after decompressive craniectomy. Neurosurg Rev. 2022;45(3):1915-1922.	Systematic Review w/ Meta-Analysis	n/a	n/a	n/a	n/a	Bone flap fragmentation, TBI etiology, and young age significantly increase the risk of aseptic bone resorption in patients undergoing cranioplasty with autologous bone flap.	IIIB
27. Rashidi A, Sandalcioglu IE, Luchtmann M. Aseptic bone-flap resorption after cranioplasty: incidence and risk factors. PLoS One. 2020;15(1):e0228009.	Nonexperime ntal	303 cranioplasties with autologous bone flap	n/a	n/a	bone flap resorption and complications	3% experienced autologous bone flap resorption requiring a subsequent cranioplasty with synthetic skull implants. Timing of cranioplasty and Karnofsky Performance Scores (KPS) were identified as significant factors with an impact on development of resorption. A later cranioplasty is associated with a lower risk of resorption.	IIIB
28. Lee JH, Chough CK, Choi HJ, et al. Bone flap changes after cranioplasty using frozen autologous bone flaps: a three-dimensional volumetric reconstruction study. Yonsei Med J. 2019;60(11):1067-1073.		97 patients who underwent cranioplasty with frozen autologous bone flaps	n/a	n/a	changes in bone flap volume	22 patients had CT imaging showing bone flap preservation and 76 patients had CT imaging showing bone flap resorption. The use of a 5-mm burr for central tack-up sutures was significantly associated with bone flap resorption.	IIIC
29. Di Rienzo A, Colasanti R, Dobran M, et al. Bone flap resorption after cranioplasty: risk factors and proposal of the flap integrity score. World Neurosurg. 2024;181:e758-e775.		281 decompressive craniectomies with cranioplasty using autologous bone at single institution	n/a	n/a	bone flap resorption	Authors proposed clinicoradiological scoring system to differentiate no, partial, and advanced resorption. Bone resorption is multifactorial, primary (directly acting on bone resorption) and secondary (participating only when a major cause is present) factors may differ significantly.	IIIC
30. Barzaghi LR, Parisi V, Gigliotti CR, et al. Bone resorption in autologous cryopreserved cranioplasty: quantitative evaluation, semiquantitative score and clinical significance. Acta Neurochir (Wien). 2019;161(3):483-491.	Nonexperime ntal	27 cranioplasties with cryopreserved autologous bone flaps	n/a	n/a	bone flap resorption in cryopreserved autologous bone flap cranioplasties	Moderate and severe absorption occurred in 51.9% and 33.3% of patients, respectively. BFR occurred almost always in patients who have undergone CP with autologous cryopreserved flap, frequently without major clinical consequences, but in about one third of patients with loss of cerebral protection. Authors suggest that age <30 years, fragmented flap, shunting presence, and long cryopreservation time may be considered in association with other risk factors when selecting optimal material for cranioplasty.	IIIB
31. Mirabet V, Garcia D, Roca A, et al. Cranioplasty with autologous bone flaps cryopreserved with dimethylsulphoxide: does tissue processing matter? World Neurosurg. 2021;149:e582-e591.	Nonexperime ntal	74 patients who underwent cranioplasty with cryopreserved autologous bone after decompressive craniectomy	n/a	n/a	complication rates (infection, bone flap resorption, reoperation, hematoma, and hydrocephalus) and cell viability	Hydrocephalus was significantly more frequent in pediatric patients. No significant differences were found in the incidence of positive microbiological cultures associated with the cause indicating craniectomy. The use of a disinfection protocol was effective in reducing microbiological load. Surgical site infection after cranioplasty was observed in 6.8% of patients. The outcome after autologous cranioplasty is a multifactorial process, which is modulated by patient-related and surgery-related factors. An early start of bone flap processing at the tissue bank had a positive effect on cell viability.	IIIB
32. Klieverik VM, Miller KJ, Han KS, et al. Cranioplasties following craniectomies in children: a multicenter, retrospective cohort study. Childs Nerv Syst. 2019;35(9):1473-1480.	Nonexperime ntal	64 patients who underwent cranioplasty after craniectomy	n/a	n/a	SSI, wound breakdowns, bone flap resorption, and inadequate fit/disfigurement	62.5% used autologous bone re-implant and 57.5% of these showed resorption. 37.5% used cranial implants with one of ten different implant types of which 8.3% required revision due to implant loosening. Cranial implants were associated with low morbidity and lower reoperation dates compared to autologous cranioplasties. No consensus on optimal material to use in pediatric cranioplasty.	IIIA



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33. Melin S, Haase I, Nilsson M, et al. Cryopreservation of autologous bone flaps following decompressive craniectomy: a new method reduced positive cultures without increase in post-cranioplasty infection rate. Brain Spine. 2022;2:100919.	Quasi- experimental	61 bone flaps from 53 consecutive decompressive craniotomy surgery patients	new handling method (surgical glove change, rinse the bone flap with pulse lavage with saline solution, and culture swab prior to cryopreservation)	routine handling of bone flaps (piece of bone for deep tissue culture, no swab culture)	SSI rate	Pulse lavage prior to culture swab and cryopreservation resulted in a significant reduction in positive cultures without any increase in the frequency of post-cranioplasty infections, thus reducing the number of bone flaps being unnecessarily discarded. The new handling method reduced positive bacterial cultures without increasing SSI rates.	IIB
34. Hoang T, Daneman N, Leis JA, et al. The utility of routine autologous bone-flap swab cultures in predicting post-cranioplasty infection. Infect Control Hosp Epidemiol. 2023;44(4):631-637.	Nonexperime ntal	282 patients that underwent craniectomy followed by delayed autologous bone-flap replacement with swab culture at time of cranioplasty	n/a	n/a	utility of autologous bone flap swabs cultures in predicting post-cranioplasty SSI	High positive culture rates. 66.7% of bone-flap cultures were positive at the time of craniectomy and 59.5% were positive at the time of cranioplasty. Poor predictive value (sensitivity 0.07 and specificity 0.4). Only 5.6% of the patients developed SSI after cranioplasty. Common organism was predominantly Cutibacterium acnes and coagulasenegative staphylococci. Low Concordance. Poor match between organisms in bone-flap cultures and SSI pathogens. Bone-flap swab culture had poor sensitivity, specificity, and is a poor predictor of post cranioplasty SSI. Routine autologous bone-flap swab cultures have poor utility in predicting post-cranioplasty SSI. Eliminating this practice could reduce workload and healthcare costs.	IIIB
35. Rao V, Burket N, Christodoulides A, et al. Lowering cranioplasty infection incidence with novel bone flap storage protocol: a retrospective cohort study. World Neurosurg. 2024;183:e454-e461.	Quasi- experimental	119 autologous bone flaps	dry cryopreservation (storage in gauze soaked in 80 mg gentamicin and 2 g nafcillin within a 3- layer sterile bag system)	wet cryopreservation (storage in 1 L of lactated Ringer's solution containing 80 mg gentamicin and 2 g nafcillin in a sterile plastic container secured in an unsterile plastic bag)	infection outcomes	Dry cryopreservation significantly decreased infection after cranioplasty when compared with wet cryopreservation. Overall, 10.9% became infected, requiring subsequent surgery; 18.4% of 49 bone flaps stored using wet cryopreservation became infected compared with only 5.7% of 70 dry cryopreservation bone flaps.	IIB
36. Yeap MC, Chen CC, Chen CT, et al. Predictive value of swab cultures for cryopreserved flaps during delayed cranioplasties. World Neurosurg. 2022;157:e173-e178.		422 patients categorized into two groups, swab and no swab during cranioplasties	n/a	n/a	Accuracy, sensitivity, and specificity of swab cultures for SSI	The overall infection rate was 7.58%. No difference was seen in infection rates between the two groups. The results showed high specificity but low sensitivity for swab cultures to predict SSI occurrence and the pathogens. Authors conclude that routine swab cultures of cryopreserved autografts should not be performed during delayed cranioplasties.	IIIB
37. Day JG, Childs KH, Stacey GN. Implications of a catastrophic refrigeration failure on the viability of cryogenically stored samples. Protist. 2022;173(6):125915.	Case Report	n/a	n/a	n/a	n/a	Discussion of a failure in refrigeration event in a cryostat holding >600 strains of cyanobacteria and eukaryotic microalgae.	VB
38. Göttsche J, Fritzsche F, Kammler G, et al. A comparison between pediatric and adult patients after cranioplasty: aseptic bone resorption causes earlier revision in children. J Neurol Surg A Cent Eur Neurosurg. 2020;81(3):227-232.	ntal	18 children/adolescents and 118 adult patients that underwent cranioplasty following decompressive craniectomy		n/a	frequency and time of occurrence of complications following cranioplasty procedures	Young age and a higher number of fragments in autologous bone flaps were associated with the occurrence of aseptic bone resorption. Children and adolescents showed significantly higher rates of aseptic bone necrosis and revision cranioplasty. Young age is the most important risk factor for the development of aseptic bone resorption as a frequent and early complication with a shorter revision-free time interval in children.	
39. Romagna A, Eckert A, Scherg F, et al. Cryopreserved bone flaps from decompressive craniectomies: a microbiological analysis. Acta Neurochir (Wien). 2024;166:224.	Quasi- experimental	63 bone flaps from decompressive craniotomies	disinfection of preserved bone flaps with octenidine- pnenoxyethanol and saline	no disinfection	contamination rates	54% infection rate of all bone flaps. After disinfection of the preserved bone flaps, all but one case showed no bacterial growth in swab testing.	IIB



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40. Marion A, Lévesque S, Touchette C, et al. So the bone flap hit the floor, now what? An in vitro comparison of cadaveric bone flap decontamination procedures. Neurosurgery. 2024;96(5):1146-1154.	Quasi- experimental	15 cranial bone flap fragments	simulation of a dropped bone flap on OR floor, contamination of bone flap fragments with select bacterial species, subject to 1 of 5 decontamination procedures, culture of samples after decontamination, and residual antibiotic and chlorhexidine mass spectrometry analysis	bone flap fragment that underwent no decontamination procedure	reduction in bacterial load on the contaminated bone flap fragments after each decontamination protocol	The effectiveness of each decontamination procedure was quantified by the percentage reduction in bacterial contamination: Saline wash 95.7%; Mechanical debridement 97.5%; antibiotic wash 99.5%; alcohol-chlorhexidine antiseptic wash 99.9%; flash sterilization in autoclave 100%. The researchers concluded that alcohol-chlorhexidine solution followed by saline washes offers the best balance of effectiveness, safety, and simplicity for decontaminating dropped bone flaps.	IIB
41. Sahoo NK, Thakral A, Janjani L. Cranioplasty with autogenous frozen and autoclaved bone: management and treatment outcomes. J Craniofac Surg. 2019;30(7):2069-2072.	Nonexperime ntal	12 patients who underwent calvarial reconstruction with frozen and autoclaved autogenous bone	n/a	n/a	infection, bone resorption, clinical outcomes based on skull shape and symmetry, cosmesis and scars. Radiological outcomes	All cases had satisfactory healing and no incidence of bone graft infection. The skull shape and symmetry, cosmesis and scars revealed excellent to moderate improvement in 75% of the patients. Radiological outcomes revealed none of the patients had severe resorption requiring surgical revision with excellent to good implant alignment in 92% of cases. Authors concluded that frozen autogenous cranial bone flaps sterilized by autoclaving is safe and effective material for cranioplasty.	IIIC
42. American Association of Tissue Banks. Standards for Tissue	Consensus	n/a	n/a	n/a	n/a	AATB Standards for tissue banking	IVC
Banking. 15th ed. AATB; 2024. 43. Donnelly BM, Smolar DE, Baig AA, et al. Analysis of craniectomy bone flaps stored in a neurosurgical cryopreservation freezer: microorganism culture results and reimplantation rates. Acta Neurochir (Wien). 2023;165(11):3187-3195.	Nonexperime ntal	148 cryopreserved cranial bone flaps	n/a	n/a	culture results and reimplantation rates of cryopreserved bone flaps	53.4% of flaps were reported to be positive for microorganisms, the most common genus being <i>Propionibacterium</i> and second being <i>Staphylococcus</i> .16.9% were reimplanted, 78.4% were discarded, and 4.7% remained in storage. The authors found there was low utilization of cryopreserved autologous bone. The economics of cryopreservation can vary between hospitals and different countries and the optimal material and method for post craniectomy reconstruction is not clear.	IIIC
44. Code of Federal Regulations. 42 CFR 493. Laboratory requirements. Accessed July 25, 2025. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part 493	Regulatory	n/a	n/a	n/a	n/a	laboratory requirements	n/a
45. Abdelfatah MA. Management of dropped skull flaps. Turk Neurosurg. 2017;27(6):912-916.	Nonexperime ntal	31 dropped cranial bone flaps	n/a	n/a	Reasons for dropped cranial bone flaps, decontamination treatments, and patient complications	The reasons for the dropped 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
46. Jankowitz BT, Kondziolka DS. When the bone flap hits the floor. Neurosurgery. 2006;59(3):585-590.	Nonexperime ntal	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 reasons for dropping included elevation, handing off the field, during plating, and unknown (n=2). After contamination the following treatments were applied: soaking in betadine and/or antibiotic solution, autoclaving, discarding, and unknown (n=1). There were no infections reported. During a poll, 66% of neurosurgeons reported experiencing a dropped flap and 83% would replace the bone flap	IIIB



## Clin Orthop Relat Res. 1993;(290;310-311. ## Source 8, Shelbani-Rad S, Appleperd D, et al. Are dropped observatiously borned using 17% point of autologistic form or the CRR from the C	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
Decontamination was performed using 10% providence indimined solution. Ay EC IGS, 70% topopolyal alcohol with 2% ECRE (Cilcinosproyil), or 0.9% normal saline in solutions from the story mechanical contamination and the story of the study included solution, and the story of the study included solution, predefine and providence and bone damage. I) Orthor Trauma. 40. Bhandari M, Schemittich EH, Adill A, et al. High and low pressure pulsatile layage of contaminated bone grafts. Plast Reconst Surg. 1981;88(3):411-414. 40. Brandari M, Schemittich EH, Adill A, et al. High and low pressure pulsatile layage of contaminated bone grafts. Plast Reconst Surg. 1981;88(3):411-414. 41. Multiple part experiment. The first part of the study produced solution, or cefazion by surface and bone damage. I) Orthor Trauma. 42. Guideline for sterile technique. In: Guidelines for Perioperative experiments. He could solution, or cefazion layage. The street of the study included solution, or cefazion layage. The street of the study included solution, or cefazion layage. The street of the study included solution, or cefazion layage. The street is chinque. In: Guidelines for Perioperative environment. All Part of the study included solution, or cefazion layage. The street is chinque. In: Guidelines for Perioperative environment. All Part of the study included solution, or cefazion layage. The street is chinque. In: Guidelines for Perioperative environment. All Part of the study included solution, or cefazion layage. The street environment and prevention. Surged alse infection. It is solution. The study included solution, or cefazion layage. The street environment and prevention. Surged alse infection. It is solution. The study included solution, or cefazion layage. The street environment and prevention. Surged alse infection. It is solution. The study included solution or cefazion layage and the solution of the study included solution. The study included solution or cefazion layage and the solution of the study included solution. The stu	47. Presnal BP, Kimbrough EE. What to do about a dropped bone graft. Clin Orthop Relat Res. 1993;(296):310-311.	Quasi- experimental	bone from neurosurgical	placed on the OR floor by the instrument table	·	Microbial contamination	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	
49. Bhandari M, Schemitsch EH, Adili A, et al. High and low pressure pulsatile lavage of contaminated tibial fracturers: an in vitro study of bacterial adherence and bone damage. J Orthop Trauma. Quasi-experimental 550. Cruz NI, Cestero HJ, Cora ML. Management of contaminated bone grafts. Plast Reconstr Surg. 1981;68(3):411-414. Multiple part experiment. The first part of the study included 120 rib bone grafts, the second part included 60 liliac bone fragments, and the third part of the study included 120 rib bone grafts. Plast Reconstr Surg. 1981;68(3):411-414. So. Cruz NI, Cestero HJ, Cora ML. Management of contaminated bone grafts, the second part included 60 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 60 liliac bone fragments, and the third part of the study included 120 rib bone grafts. Presence of infection noted by erythema, inflammation, or pus. So. Cruz NI, Cestero HJ, Cora ML. Management of contaminated bone donated bone donated included 120 rib bone grafts, the second part included 60 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 60 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 10 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 10 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 10 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 10 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 10 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 10 liliac bone fragments, and the third part of the study included 120 rib bone grafts, the second part included 120 rib bone grafts, the second part included 120 rib bone graft	osteoarticular bone fragments safely reimplantable in vivo? J Bone	-	osteoarticular bone fragments dropped on the OR floor. Phase 2: 340 osteoarticular bone fragments for	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	purposefully inoculated bone had no decontamination	chondrocyte viability	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	
grafts. Plast Reconstr Surg. 1981;68(3):411-414. 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 do included for iliac bone fragments, and the third part of the study included experimental 40 rib grafts. S1. Guideline for sterile technique. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:1003-1048. Multiple part experiment. The first part of the study included a local part of the study included solution, power of the study included experimental 40 rib grafts. Decontamination with normal saline solution, powidone-iodine solution, or cefazolin 1gm/liter. No treatment performed inflammation, or pus. No treatment performed inflammation, or pus. No treatment performed inflammation, or pus. No decontaminated with a solution prior to implantation. IIB 1. Guideline for sterile technique in the perioperative experimental with a solution prior to implantation. S2. Centers for Disease Control and Prevention. Surgical site infection (SSI) event. In: National Healthcare Safety Network (NHSN) Patient No treatment performed inflammation, or pus. No treatment noted by erythema, inflammation, or pus. No decontaminated with a solution prior to implantation. No decontaminated with a solution prior to implantation. No decontaminated with a solution prior to implantation. No and Description of CDC wound class for multiple primary sites and tissue harvest sites.	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	Treatment with high and low pressure pulsatile		Microbial detection and identification and evaluation of bone	Low pressure pulsatile lavage led to less structural damage and was equally effective in removing bacteria within a 3 hour debridement	
51. Guideline for sterile technique. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:1003-1048. 52. Centers for Disease Control and Prevention. Surgical site infection (SSI) event. In: National Healthcare Safety Network (NHSN) Patient 6 Guideline on /a n/a n/a Guideline for sterile technique in the perioperative environment IVA n/a n/a Description of CDC wound class for multiple primary sites and tissue n/a harvest sites.	•	Quasi-	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	normal saline solution, povidone-iodine solution, or cefazolin		noted by erythema,	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	
Safety Component Manual. January 2025. Accessed July 25, 2025. https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual current.pdf	Practice. Denver, CO: AORN Inc; 2025:1003-1048. 52. Centers for Disease Control and Prevention. Surgical site infection (SSI) event. In: National Healthcare Safety Network (NHSN) Patient Safety Component Manual. January 2025. Accessed July 25, 2025.	Guideline	n/a	n/a	n/a	n/a	Guideline for sterile technique in the perioperative environment Description of CDC wound class for multiple primary sites and tissue	IVA



CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
53. Kim SH, Kang DS, Cheong JH, et al. Comparison of complications following cranioplasty using a sterilized autologous bone flap or polymethyl methacrylate. Korean J Neurotrauma. 2017;13(1):15-23.	ntal	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
54. Anto D, Manjooran RP, Aravindakshan R, et al. Cranioplasty using autoclaved autologous skull bone flaps preserved at ambient temperature. J Neurosci Rural Pract. 2017;8(4):595-600.	Nonexperime ntal	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, osteomyelitis 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
 Mracek J, Hommerova J, Mork J, et al. Complications of cranioplasty using a bone flap sterilised by autoclaving following decompressive craniectomy. Acta Neurochir (Wien). 2015;157(3):501 506. 	ntal	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
56. Jho DH, Neckrysh S, Hardman J, et al. Ethylene oxide gas sterilization: a simple technique for storing explanted skull bone. Technical note: J Neurosurg. 2007;107(2):440-445.	ntal	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 durations over 10 months were more likely to develop an infection. Discard or re-sterilize bone flaps after 10 months of storage.	IIIB
57. Frye CC, Sullivan J, Sanka SA, et al. Cost-effectiveness of parathyroid cryopreservation and autotransplantation. JAMA Surg. 2024;159(6):634-641.	Nonexperime ntal	591 patients who underwent parathyroid cryopreservation at single institution	n/a	n/a	graft functionality, clinical outcomes, and cost utility	1.7% of patients underwent delayed autotransplantation of cryopreserved parathyroid tissue. 20% were fully functional, 50% were partially functional, and 30% were not functional. Though there is a low replantation rate, when implanted the autografts were at least partially functional 70% of the time. Cryopreservation and autotransplantation were cost-effective compared with the usual care for hypoparathyroidism.	IIIB
58. Moore EC, Siperstein A, Gupta S. Cryopreservation of parathyroid tissue: a white paper on establishing a local service. Endocr Pract. 2019;25(6):605-611.	Expert Opinion	n/a	n/a	n/a	n/a	Review of the process of parathyroid cryopreservation, regulatory issues involved in establishing a local service, tissue processing, billing and reimbursements, outcome, and complications. Includes a detailed description of the technique performed at a single institution.	VA
59. Aiti A, Rossi M, Alviano F, et al. Parathyroid tissue cryopreservation: does the storage time affect viability and functionality? Biopreserv Biobank. 2019;17(5):418-424.	Quasi- experimental	PT samples from 10 patients	cryopreservation of PT samples, thawed at different periods of storage, from a minimum of 10 to a maximum of 66 months	fresh	viability and function of cryopreserved PT tissue	Tissues appear to be viable and able to product PTH even 5 years after storage and cell functionality is maintained after cryopreservation	IIA
60. Yuan H, Zhong Z, Liu Z, et al. Factors influencing the success of cryopreserved parathyroid autotransplantation: a systematic review. Asian J Surg. 2023;46(9):3426-3431.	Literature Review	n/a	n/a	n/a	n/a	Cryopreserved parathyroid autotransplantation operations should be standardized and include such factors as ischemic period time, freezing and thawing methods, and recipient status.	VB
61. Tian L, Ji X, Chen T, et al. Deep hypothermic preservation of autologous skin in the treatment of large-area circumferential multiplane degloving trauma: a pilot study of 2 cases. Cell Tissue Bank. 2019;20(1):109-115.	Case Report	2 patients	n/a	n/a	n/a	Reports of two successful cases of treating large-area degloving trauma through cryopreservation of autologous skin grafts in liquid nitrogen. Authors recommend cryopreservation of autologous skin grafts in the treatment of large-area degloving trauma, especially for the patients in unstable general condition.	VA
62. Yilihamu A, Maimaitiming K, Meierwati, et al. Application of modified skin cryopreservation and delayed replantation technique in the treatment of skin avulsion injury. Arch Clin Psychiatry. 2022;49(4):10-15.	Quasi- experimental	132 patients with skin avulsion	skin cryopreservation and delayed replantation	primary replanting	skin graft survival rate	The improved skin cryopreservation and delayed replantation technique has a higher application value and the risk of necrosis is low.	IIC



CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
63. Xu Q, Zhu L, Wang G, et al. Application of cryopreserved autologous skin replantation in the treatment of degloving injury of limbs. J Plast Reconstr Aesthet Surg. 2022;75(7):2387-2440.	Case Report	9 cases of degloving injuries of limbs	n/a	n/a	n/a	Description of cases of degloving injuries where skin was prepped, cryopreserved, and replanted in situ when wound condition improved.	VB
64. 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.	Nonexperime ntal	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
65. Titley OG, Cooper M, Thomas A, et al. Stored skin—stored trouble? Br J Plast Surg. 1994;47(1):24-29.	Nonexperime ntal	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 crosscontamination.	IIIB
66. DeBono R, Rao GS, Berry RB. The survival of human skin stored by refrigeration at 4°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
67. Li Z, Overend C, Maitz P, et al. 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
68. Boekema BKHL, 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
69. 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
70. Guideline for preoperative patient skin antisepsis. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:623-676.	Guideline	n/a	n/a	n/a	n/a	Guideline for preoperative patient skin antisepsis	IVA
71. Guideline for medication safety. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:487-540.	Guideline	n/a	n/a	n/a	n/a	Guideline for Medication Safety	IVA
72. van Huizum MA, Hage JJ, Scholten AN, et al. Maximising the preservation of previously irradiated native mammary skin by skinbanking of the autologous flap: outcome after 33 skin-sparing or nipple-sparing salvage mastectomies. J Plast Reconstr Aesthet Surg. 2023;76:145-147.	Expert Opinion	n/a	n/a	n/a	n/a	Review of how autologous flap skin-banking can be used as an approach to manage mastectomy skin flaps.	VB



CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
73. Math N, Hegazi S, Richards T, et al. A novel innovative technique in the management of bilateral critical limb ischaemia: delayed saphenous vein autologous graft. Ann R Coll Surg Engl. 2022;104(6):e177-e179.	Case Report	n/a	n/a	n/a	n/a	Great saphenous vein salvage during emergency limb amputation. Vein storage in University of Wisconsin solution (UWS) with delayed autograft. One-month follow-up revealed no major complications and persistent revascularization.	VB
74. Eqbal A, Gupta S, Bisleri G. Storage solutions to improve grafts preservation and longevity in coronary artery bypass grafting surgery hype or hope? Curr Opin Cardiol. 2021;36(5):616-622.	Literature Review	n/a	n/a	n/a	n/a	Review of different saphenous vein graft (SVG) storage solutions and their impact on SVG function	VA
75. Organ Procurement and Transplantation Network. Policy 16: organ and extra vessel packaging, labeling, shipping, and storage. June 26, 2025. Accessed July 25, 2025. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf	Accreditation	n/a	n/a	n/a	n/a	OPTN policy describing organ and extra vessel packaging, labeling, shipping, and storage requirements for organ transplantation.	n/a
76. Wang W, Salama M, Todorov P, et al. New method of FACS analyzing and sorting of intact whole ovarian fragments (COPAS) after long time (24 h) cooling to 5 °C before cryopreservation. Cell Tissue Bank. 2021;22(3):487-498.	RCT	ovarian fragments from 16 patients	cooling to 5 degrees C for 24 hours then cryopreservation	immediate cryopreservation	follicle count and viability	long time (24 hour) cooling of ovarian tissue to 5 degrees C before cryopreservation has a trend of a cell viability increasing	IC
77. Amorim CA, Leonel ECR, Afifi Y, et al. Cryostorage and retransplantation of ovarian tissue as an infertility treatment. Best Pract Res Clin Endocrinol Metab. 2019;33(1):89-102.	Literature Review	n/a	n/a	n/a	n/a	Review of ovarian tissue cryopreservation and transplantation indications, procedures, efficacy and main results.	VB
78. Dolmans MM, von Wolff M, Poirot C, et al. Transplantation of cryopreserved ovarian tissue in a series of 285 women: a review of five leading European centers. Fertil Steril. 2021;115(5):1102-1115.	Literature Review	n/a	n/a	n/a	n/a	individual patient data from 5 European centers analyzed. Recovery of endocrine function was achieved in almost all women undergoing transplantation of ovarian tissue.	VA
79. Giovannopoulou E, Karakasi MV, Kouroupi M, et al. Safety and efficacy of ovarian tissue autotransplantation: a systematic literature review. Folia Med (Plovdiv). 2023;65(3):362-370.	'	n/a	n/a	n/a	fertility outcomes and procedure-related complications	A total of 3427 patients subjected to ovarian tissue retrieval and cryostorage for fertility preservation. A total of 295 transplantations included. Overall surgical complication rate for tissue retrieval was 0.3%. Ovarian transplantation was associated with a pregnancy rate of 50.7% and a live birth rate of 32.7% per patient.	IIIB
80. Jin F, Ruan X, Juan D, et al. Ovarian tissue cryopreservation: prospective randomized study on thawed ovarian tissue viability to estimate the maximum possible delivery time of tissue samples. Gynecol Endocrinol. 2019;35(7):591-594.		165 ovarian tissue samples (15 samples from each of 11 patients)	cryopreservation, thawed, and randomly divided into seven groups depending on the time after thawing (0, 20, 40, 60, 80, 100, 120 mins)	Fresh sample	follicle counts, steroid hormones, and lactate levels	No significant differences for the three parameters of tissue viability comparing each of the timed groups. Tissue remains viable up to two hours for delivery of tissue samples from the laboratory to the operating room.	IC
81. Khattak H, Malhas R, Craciunas L, et al. Fresh and cryopreserved ovarian tissue transplantation for preserving reproductive and endocrine function: a systematic review and individual patient data meta-analysis. Hum Reprod Update. 2022;28(3):400-416.	Systematic Review w/ Meta-Analysis	n/a	n/a	n/a	n/a	Ovarian tissue cryopreservation and transplantation could restore reproductive and hormonal functions in women.	IIIB
82. Nadesapillai S, van der Velden J, van der Coelen S, et al. TurnerFertility trial: fertility preservation in young girls with Turner syndrome by freezing ovarian cortex tissue—a prospective intervention study. Fertil Steril. 2023;120(5):1048-1060.	Quasi- experimental	93 participants with turner syndrome	laparoscopic unilateral ovariectomy and cryopreservation of ovarian cortex tissue	n/a	presence of follicles in ovarian cortex tissue	Follicles were present in 32% of the girls. Girls with turner syndrome and either a 46,XX cell line, spontaneous onset of puberty, or a combination of measurable AMH and normal FSH levels were most likely to have follicles in their ovarian cortex tissue. Ovarian tissue cryopreservation in girls with turner syndrome remains an experimental treatment.	IIA



CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
83. Schallmoser A, Einenkel R, Färber C, et al. The effect of high-throughput vitrification of human ovarian cortex tissue on follicular viability: a promising alternative to conventional slow freezing? Arch Gynecol Obstet. 2023;307(2):591-599.	Quasi- experimental	ovarian tissue from 30 patients	cryopreservation with slow freezing versus vitrification and rapid warming	fresh	follicular viability	No significant differences regarding follicular viability between slow frozen and vitrified cortex tissue samples 24 hours after thawing and rapid warming. Follicular viability of thawed and rapid warmed samples was not significantly different in comparison to fresh samples, indicating high proportions of follicular survival rates with both methods. Researches concluded that rapid vertical vitrification of ovarian tissue may be equivalent to slow freezing in terms of follicular viability while offering a cost-efficient alternative to conventional slow freezing procedures.	IIA
84. Silvestris E, De Palma G, Canosa S, et al. Human ovarian cortex biobanking: a fascinating resource for fertility preservation in cancer. Int J Mol Sci. 2020;21(9):3245.	Literature Review	n/a	n/a	n/a	n/a	Review of innovative techniques available including ovarian cortex cryopreservation before anti-cancer treatments and subsequent autologous reimplantation and a regenerative medicine approach using oocytes derived in vitro from ovarian stem cells. Both techniques have a major benefit related to the prompt recruitment and processing of the ovarian cortex fragments before gonadotoxic treatments.	
85. Arapaki A, Christopoulos P, Kalampokas E, et al. Ovarian tissue cryopreservation in children and adolescents. Children (Basel). 2022;9(8):1256.	Literature Review	n/a	n/a	n/a	n/a	Discussion of recent advances in ovarian tissue cryopreservation in young women and children.	VB
86. Dolmans MM, Donnez J, Cacciottola L. Fertility preservation: the challenge of freezing and transplanting ovarian tissue. Trends Mol Med. 2021;27(8):777-791.	Expert Opinion	n/a	n/a	n/a	n/a	discussion of ovarian tissue cryopreservation and transplantation	VA
87. Oktay KH, Marin L, Petrikovsky B, et al. Delaying reproductive aging by ovarian tissue cryopreservation and transplantation: is it prime time? Trends Mol Med. 2021;27(8):753-761.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of ovarian tissue cryopreservation and transplantation and proposal of guidelines for selecting patients who are most likely to benefit from elective ovarian tissue cryopreservation and to provide a better risk-benefit ration from the procedure.	VA
88. Lee S, Ozkavukcu S, Ku SY. Current and future perspectives for improving ovarian tissue cryopreservation and transplantation outcomes for cancer patients. Reprod Sci. 2021;28(6):1746-1758.	Literature Review	n/a	n/a	n/a	n/a	Review of various methods and strategies to improve ovarian tissue cryopreservation and transplantation outcomes. Effective multidisciplinary oncofertility strategies that considers cryopreservation methods, thawing processes and devices, surgical procedures for transplantation, and advances in technologies are necessary to provide high-quality patient care.	VA
89. Kilcoyne KR, Mitchell RT. Fertility preservation: testicular transplantation for fertility preservation: clinical potential and current challenges. Reproduction. 2019;158(5):F1-F14.	Literature Review	n/a	n/a	n/a	n/a	Overview of the current status of transplantation of testicular tissue and cells for fertility preservation in males.	VA
90. Braye A, Tournaye H, Goossens E. Setting up a cryopreservation programme for immature testicular tissue: lessons learned after more than 15 years of experience. Clin Med Insights Reprod Health. 2019;13:1179558119886342.	Expert Opinion	n/a	n/a	n/a	n/a	Description of clinical fertility preservation program for young boys at high risk of SCC. Provides information to centers interested in setting up an immature testicular tissue bank.	VA
91. Sung ZY, Liao YQ, Hou JH, et al. Advancements in fertility preservation strategies for pediatric male cancer patients: a review of cryopreservation and transplantation of immature testicular tissue. Reprod Biol Endocrinol. 2024;22:47.	Literature Review	n/a	n/a	n/a	n/a	Review of strategies to optimize the preservation strategy of human immature testicular tissue in the future.	VA



CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
92. 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.	Organizationa I 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
93. Desai MM, Biraris SR, Wade RM. Auto bone banking: innovative method for bone preservation. J Orthop Case Rep. 2014;4(4):16-18.	Case Report	17 patients with resected femoral head preserved in iliac pouch on ipsilateral side	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. None were replanted.	VB
94. Cho BH, Higgins JP. Revascularization and replantation in the hand: ectopic banking and replantation. Hand Clin. 2019;35(2):199-206.	Literature Review	n/a	n/a	n/a	n/a	Clinical indications for ectopic banking, preoperative counseling, ectopic banking location, duration of ectopic banking and proximal wound management, and surgical technical considerations.	VB
95. Erçin BS, Kabakas F, Tatar BE, et al. Salvage of devascularized and amputated upper extremity digits with temporary ectopic replantation: our clinical series. J Invest Surg. 2022;35(7):1451-1461.	Case Report	17 male patients with ectopically banked digits	n/a	n/a	n/a	Ectopic banking success rate was 94.1%, the orthotopic/heterotopic transfer success rate was 100%. Ectopic banking time averaged 19.2 days. Authors advocate for early transfer method.	VA
96. Liaghat O, Shabbooie Z. Ectopic banking and implantation of an amputated hand. Indian J Orthop. 2020;54(5):731-737.	Case Report	n/a	n/a	n/a	n/a	Case report of hand replantation by ectopic banking technique.	VA
97. Faramarzi M, Roosta S, Dianat M. Outcome of incus interposition after preservation in soft tissue. Iran J Otorhinolaryngol. 2017;29(91):83-88.	Nonexperime ntal	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 20 dB air- bone gap (ABG).	A 20 dB ABG was achieved in 78.9% of patients. Researchers concluded that preservation of the autologous incus in the postauricular space between surgeries was safe and effective	IIIB
98. Gyo K, Hato N, Shinomori Y, et al. Storage of the incus in the mastoid bowl for use as a columella in staged tympanoplasty. Auris Nasus Larynx. 2007;34(1):5-8.	Nonexperime ntal	24	ın/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 construction was successful in 65% of procedures. The follow-up period of 5-9 post-procedure showed continued successful hearing outcomes in 57% of the patients.	IIIC
99. 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 replanted successfully during the second procedure with good results.	
100. Favaretto F, Compagnin C, Cogliati E, et al. Characterization of human subcutaneous adipose tissue and validation of the banking procedure for autologous transplantation. Int J Mol Sci. 2023;24(9):8190.	Quasi- experimental	samples of adipose tissue lipoaspirates cryopreserved in aliquots	storage in vapor phase liquid nitrogen to test long-term storage	storage in dry ice for 24 h	tissue viability and safety	adipose tissue cryopreserved up to three years maintains its differentiation potential and cellular composition, keeping viable precursors and mature cells.	IIA
101. Ohashi M. Fat grafting for facial rejuvenation with cryopreserved fat grafts. Clin Plast Surg. 2020;47(1):63-71.	Case Report	n/a	n/a	n/a	n/a	Case reports of facial fat grafting using cryopreserved fat grafts.	VB



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102. Gal S, Pu LLQ. An update on cryopreservation of adipose tissue. Plast Reconstr Surg. 2020;145(4):1089-1097.	Expert Opinion	n/a	n/a	n/a	n/a	Description of adipose tissue cryopreservation protocol and techniques	VA
103. You X, Yao Y, Gao J, et al. Corynebacterium bovis infection after autologous fat grafting in breast augmentation: a case report. Front Cell Infect Microbiol. 2023;13:1265872.	Case Report	1 patient	n/a	n/a	n/a	Case study of a rare human bacterium which caused an infection in a patient who had undergone autologous fat-based breast augmentation using cryopreserved fat. The authors recommend further research to understand risks associated with cryopreservation of fat and identify ways to prevent infections in the future.	VA
104. Heo JH, Shin J, Choi GS, et al. Periocular lipogranuloma after cryopreserved fat injection into the forehead. Dermatol Surg. 2019;45(12):1723-1725.	Case Report	single patient	n/a	n/a	n/a	Discussion of a rare case of development of lipogranuloma after cryopreserved forehead fat injection and subsequent radiofrequency treatment. Cryopreserved adipose tissue is more vulnerable to injury than fresh.	VB
105. Guideline for team communication. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:1143-1178. 106. Current Good Tissue Practice (CGTP) and Additional	Guideline Regulatory	n/a	n/a	n/a	n/a	Guideline for team communication in the perioperative environment	IVA
Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Guidance for Industry. US Food and Drug Administration. December 2011. Accessed July 25, 2025. https://www.fda.gov/regulatory-information/search-fdaguidance-documents/current-good-tissue-practice-cgtp-and-additional-requirements-manufacturers-human-cells-tissues-and		n/a	n/a	n/a	n/a	FDA regulatory guidance for establishments that manufacturer HCT/Ps to follow current good tissue practice.	s n/a
107. Standard TS.03.03.01. E-dition – Standards & EPs: Ambulatory. The Joint Commission. Accessed July 15, 2025. https://edition.jcrinc.com	Accreditation	n/a	n/a	n/a	n/a	TJC ambulatory transplant safety standard for organizations to investigate adverse events related to tissue use or donor infections	n/a
108. Standard TS.03.01.01. E-dition – Standards & EPs: Hospital. The Joint Commission. Accessed July 25, 2025. https://edition.jcrinc.com	Accreditation	n/a	n/a	n/a	n/a	TJC hospital transplant safety standard for hospitals to use standardized procedures for managing tissues	n/a
109. Center for Improvement in Healthcare Quality (CIHQ). CIHQ Accreditation Standards for Hospitals. Accessed July 30, 2025. https://cihq.org/acc-default-hospitals.asp	Accreditation	n/a	n/a	n/a	n/a	CIHQ accreditation standards for hospitals including tissue and tissue specimen management.	n/a
110. Center for Improvement in Healthcare Quality (CIHQ). CIHQ Accreditation Standards for Hospitals & Psychiatric Hospitals. Accessed July 30, 2025. https://cihq.org/acc-default-hospitals.asp	Accreditation	n/a	n/a	n/a	n/a	CIHQ accreditation standards (for hospitals that do not wish to participate in Medicare) including tissue and tissue specimen management.	n/a
111. The Joint Commission. Standard TS.03.01.01. E-dition – Standards & EPs: Ambulatory. Accessed July 25, 2025. https://edition.jcrinc.com	Accreditation	n/a	n/a	n/a	n/a	TJC ambulatory transplant safety standard for organizations to use standardized procedures for managing tissues.	n/a
112. Guideline for transmission-based precautions. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:1179-1206.	Guideline	n/a	n/a	n/a	n/a	Guideline for transmission-based precautions in the perioperative environment	IVA
113. Code of Federal Regulations. 29 CFR §1910.1030. Bloodborne pathogens. Accessed July 25, 2025. https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-Z/section-1910.1030	Regulatory	n/a	n/a	n/a	n/a	OSHA bloodborne pathogen standards and definitions	n/a



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114. Lombardo JA, Russell N, He J, et al. Autograft cellular contribution to spinal fusion and effects of intraoperative storage conditions. Spine (Phila PA 1976). 2023;48(16):1181-1189.	Quasi- experimental	48 rabbits (animal study)	posterolateral spinal fusion with autograft groups evaluated with different intraoperative storage conditions	autograft groups evaluated included viable, partially devitalized, devitalized, dried, and hydrated iliac crest	bone cell viability and fusion performance	Bone cell viability and fusion performance were maintained when the graft was stored in saline intraoperatively. Autograft left dry on the back Table showed a rapid decline in cell viability and fusion but was maintained with storage in saline. Viable autograft yielded significantly higher fusion results compared with devitalized graft, suggesting that the cellular component of autograft promotes fusion.	IIA
115. 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. Fed Regist. 2013;78(17):5565-5702.	Regulatory	n/a	n/a	n/a	n/a	HIPAA modifications and regulations for protecting patient information.	n/a
116. Guideline for a safe environment of care. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:165-196.	Guideline	n/a	n/a	n/a	n/a	Guideline for a safe environment of care	IVA
117. Guideline for design and maintenance of the surgical suite. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2025:79-142.		n/a	n/a	n/a	n/a	Guideline for design and maintenance of the surgical suite	IVA
118. The Joint Commission. Standard TS.03.02.01. E-dition – Standards & EPs: Ambulatory. Accessed July 25, 2025. https://edition.jcrinc.com	Accreditation	n/a	n/a	n/a	n/a	TJC ambulatory transplant safety standard to trace all tissues bidirectionally	n/a
119. Benze C, Spruce L, Groah L. Perioperative Nursing: Scope and Standards of Practice. Denver, CO: AORN Inc; 2021. Accessed July 25, 2025. https://www.aorn.org/docs/default-source/guidelines-resources/periop-nursing-scope-standards-of-practice.pdf		n/a	n/a	n/a	n/a	Standards of perioperative nursing	IVB
120. Miranda E, Pye H, Buckingham S, et al. Risk assessment for activity regulated under the Human Tissue Act: a single institution experience. Biopreserv Biobank. 2022;20(3):217-223.	Organizationa I Experience	n/a	n/a	n/a	n/a	Description of one organization's risk assessment activities related to the use of human samples in research. Additional considerations beyond the risk to human health when completing a risk assessment include ethics and consenting during acquisition, damage or breakdown of packaging, delay or loss in transit, malfunction of storage facilities, failure of laboratory equipment, unauthorized access to tissue samples, incorrect or unconsented for procedures being carried out, untrained personnel handling the tissue, and any other hazards that result in tissue loss.	VA

