Methods and Considerations for Autologous Bone Graft Processing

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With over two million bone grafting procedures performed annually worldwide – 500,000 of those in the United States alone – the demand for this surgical procedure continues to grow. As the healthcare sector experiences a severe skill shortage, protecting and retaining skilled staff is of the utmost importance for patient care, staff morale, and the bottom line.

Understanding the implications of time, quality, safety, and costs in the operating room when it comes to autologous bone grafting is crucial to meeting surgical demand and reducing the risk of surgical technologist burnout.

Overall, automation of autologous bone processing by devices such as Bone Mill+™ and Prep+™ can increase OR personnel availability by removing a time-consuming manual task, thereby allowing them to reengage with the surgical team. This provides a more standardized solution, resulting in a reliable and predictable processing time. In this period of skill shortage, protecting and retaining skilled staff can be achieved by eliminating a potentially hazardous risk through sharps injury and avoiding costly follow ups.

AUTOGRAFT BONE TISSUE: THE GOLD STANDARD FOR GRAFTING

Bone grafting is the process of transplanting bone material to repair or replace complex bone tissues during surgical procedures, such as spinal fusion and orthopedic reconstruction.

Bone graft material options today include the following:

- Autograft – Patient's own bone tissue
- Allograft – Human donor bone tissue
- Xenograft – Bone tissue from another species
- Synthetic – Engineered bone tissue

With over a century of successful clinical utilization, autograft, also known as autologous bone, is considered the "gold standard" of bone-grafting material. Autogenous bone is the only graft material that fulfills all three components of the tissue regeneration triad: osteogenesis, osteoinduction, and osteoconduction.[1] It is also biocompatible, which means that bone harvested from the patient's own body has no risk of rejection or disease transfer. Autologous bone naturally contains viable cells such as osteoprogenitor cells, as well as essential molecular components like bone morphogenetic proteins (BMPs). Furthermore, autologous bone can provide a calcium scaffold required to support the new bone growth.

Autologous bone can be harvested as a tricortical graft for structural support or as a vascularized bone graft for restoration of large bone defects or avascular necrosis. A variety of sites can be used for bone-graft harvesting. The decision as to which harvest site to use is made on a case-by-case basis and depends on several factors. These factors include anatomic proximity, the volume of graft desired, the need for structural graft, and the intrinsic biology of the donor site. The most common donor sites are the anterior and posterior iliac crest of the pelvis.[2,3]

Allograft, which is harvested from a donor person or cadaver, can also be used, and is typically acquired through a bone bank. Unlike autografts, allografts do not form new bone because they lack viable cells and cannot provide the osteogenic properties of autografts. Instead, the allograft works as a bridge that allows natural bone to grow through its surface. Over time, natural bone replaces the donor bone.[4] Immunological reactions from an allograft may interfere with the process and can lead to graft rejection. Additionally, they carry the added risk of transmitting bacterial and viral diseases.[5]

Bone grafting is a widely used form of tissue transplantation, second only to blood transfusion.

Overall, autograft is considered superior to allograft because of its excellent and cost-effective combination of biologic and mechanical properties. Autologous bone grafts continue to be an important tool in the management of certain bone defects or nonunions. In one study compar-

Table 1

Manual vs Automated Processing - Average time

	Manual			Automated Processing		
	Clean	Mill	Overall	Clean	Mill	Overall
Average Manual Time – (Mins)	27	14	41	10	0.14	10.14
Standard Deviation (Mins)	±14	±9	±23	±0	±0.01	±0.06

Table 1: Average time ± StDev (Mins) taken to clean and mill 25g porcine bone across 16 participants compared with Automated Processing

ing bone graft treatment in 182 patients with long-bone non-union, the autograft populations showed a significantly shorter union time with fewer surgical revisions and significantly lower postoperative infection rates.[6]

Figure 1

Manual vs Automated Processing - Average time

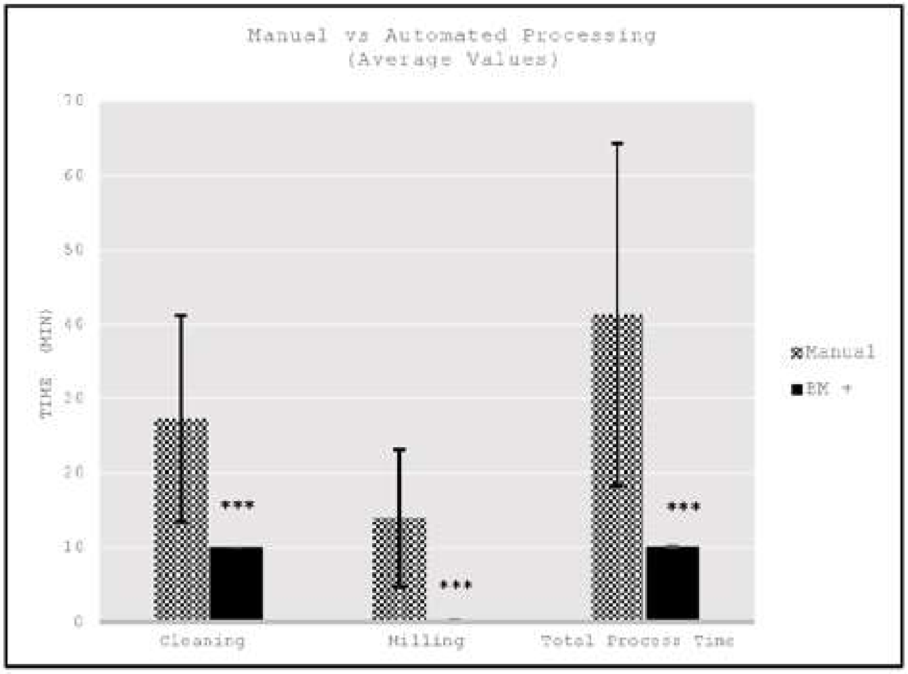

Figure 1: The bar graph representation (mean ± StDev) of average time (Mins) taken to clean and mill 25g porcine bone across 16 participants compared with Automated Processing*** Statistically significant $p < 0.0001$

THE GROWING DEMAND FOR BONE GRAFTS AMID CRITICAL STAFF SHORTAGES

Bone grafting is a widely used form of tissue transplantation, second only to blood transfusion. Worldwide, there are over two million bone grafting procedures performed each year, 500,000 of which are performed the United States alone.[7,8]

The rising incidence of bone and joint disorders along with a rapidly growing geriatric population are fueling the demand for orthopedic surgeries that use bone grafts. During the COVID-19 pandemic, elective surgeries, including most orthopedic procedures, were postponed or canceled, which resulted in even higher demand as COVID-19 restrictions and infection rates diminished.[9]

In addition to procedure backlogs, the global healthcare system has been ravaged by mass resignations and staff shortages, also stemming from the recent pandemic crisis.[10] Healthcare staff are experiencing heavy workloads and are at risk of burnout, a known contributor to turnover.[11] Each turnover percentage point change translates to approximately $270,000 lost or saved per hospital.[12] The rates of burnout are consistently linked with one's role.[13] Although COVID-19 has exacerbated this burnout risk, post pandemic reporting has remained higher than was pre-pandemic numbers. In studies related to burnout, targeting issues such as PPE concerns and meaningful breaks could have a real impact on levels of work-related burnout.[10,13,14]

Hospitals are under increasing pressure with increased volumes of surgeries required and reduced availability of experienced and qualified staff. As of January 2022, 19-21% of hospitals in the United States reported critical staff shortages, with some states reporting percentages of hospitals with critical staff shortages as high as 52%.[15] University of Pittsburgh Medical Center is a well-respected national referral center for many surgical specialties. In May 2021, the organization implemented a five-phased approach to ensure that it could continue to provide essential surgical care when its surgical technologist and operating room (OR) nurse vacancy rate reached 30%. The institution's phased approach decreased OR availability by 15%, compensating for the 30% reduction in surgical services staff members.[15]

TECHNIQUES FOR PREPARING AUTOLOGOUS BONE FOR IMPLANTATION

To achieve the desired bone fusion, or osteogenesis, there must be a "clean" bone-to-bone contact surface between the host bone and the bone graft. Therefore, retrieval and processing of the autologous bone requires the extracted autologous bone to be cleaned and processed by in the OR. In this procedure, any residual connective tissue must be removed and then the bone milled into smaller particles before reimplantation into the patient. There are two methods that may be used during the autograft bone preparation process: manual and automated.

MANUAL CLEANING AND MILLING

To manually scrape the bone, a variety of instruments, including periosteal elevators, rongeurs, curettes, and cautery tools are employed. Manually cleaning autologous bone can be time-consuming, requires physically repetitive motions, and is dependent on the individual's skill and efficiency.[1]

In a recent study evaluating the quantity and quality of bone material cleaned and milled by experienced surgical technologists using manual and automated processing, it was observed that most manual preparation time for autologous bone is expended with the removal of excess soft tissue.[16]

On average, 60% of overall autologous bone processing time—approximately 27 minutes—was dedicated to cleaning. Consistency on timing varied substantially across the participants, with the time spent ranging between 6 and 57 minutes, ± 14 minutes. After cleaning, the bone samples moved directly to manual milling, which required 17 ± 13 minutes. The variability across participants was ± 20 minutes for overall processing (Figure 1, Table 1).

In the aforementioned study, automated bone cleaning consistently took 10 minutes, whereas automated milling only took 8.4 seconds.[17]

During the study, the quality of soft tissue removal was also assessed on a 10-point scale. The levels of overall quality in cleanliness varied, with three out of the 10 manually cleaned samples rated with a score of less than or equal to 4 out of a possible 10. (Figure 2)

During manual cleaning and manual milling by OR personnel, safety events were observed and recorded. Half of the participants experienced glove puncture, with two participants experiencing multiple events (glove puncture twice in one session). When surveyed, all participants self-reported hand fatigue while cleaning bone manually, 75% self-reported hand fatigue due to manual milling, and 31% had previously experiencing injury while manually cleaning bone.

TIME, SAFETY, AND COST CONSIDERATIONS

As previously mentioned, staff vacancy rates have reduced OR availability time in some hospitals by up to 15%. Reducing time associated with manual tasks increases staff availability. Rather than focusing on manual autologous bone processing tasks, surgical techs have the freedom to work smarter, reengage with additional intraoperative assistance, and continue to support their OR team. This also means that up to 40 minutes of surgical tech time can be recouped. Unnecessary clinical variation leads to increased costs, as seen in many surgical procedures. Key factors in elevated costs are extended operating-room time and failure to standardize the coordination of care.[18] Surgeons can now rely on a consistent time of 10 minutes to fully process up to 25 g of autologous bone while planning surgery and can recoup up to 30 minutes per level of harvested bone preparation.[17]

Figure 2
Manual vs Automated Clean

Figure 2: Photographic examples of 2.5g porcine bone sample following removal of soft tissue. (A) Automated Clean Sample (B & C) Manually process by expert scrub techs.

Time is a high-value commodity in the OR. Given that surgical care accounts for nearly one-third of all U.S. healthcare spending and the OR – valued at $36 to $37 per minute – is the second most expensive part of surgical care, every minute counts.[19] Stanford has shown the value down to 1 second, where a "move on 2" (moving the patient to the operating table on the count of 2 rather than 3) saved an average of $12,000 in OR costs per year.[20]

One of the more serious risks to healthcare workers' well-being is injury sustained at work. Improving PPE and removing risk of injury is a core component to establishing a safe work environment according to OSHA guidelines.[21] Sharps injuries, defined as ". . . skin penetrating stab wounds caused by a sharp instrument and accidents in a medical setting,"[22] are a leading cause of accident sustained by healthcare workers and have been described as an "important public health concern."[23]

Safety is a major concern in the manual process. Over the course of the study by Ersozlu et al, 50% of the participants had experienced one or more glove punctures, and 31% had experienced fatigue or injury while performing the cleaning task manually in an OR environment.

In a recent study evaluating the quantity and quality of bone material cleaned and milled by experienced surgical technologists using manual and automated processing, it was observed that most manual preparation time for autologous bone is expended with the removal of excess soft tissue.

It is well accepted that intact gloves act as a protective barrier against blood-borne pathogens such as HIV, hepatitis B, and hepatitis C during surgery. Glove perforation is frequent but often unrecognized by surgical personnel. One study showed that of the 242 glove punctures, 176 (72.7%) were not noticed by the operative team members and were only detected after the operation.[24]

Not only does the risk of exposure to infectious disease need to be considered, but the psychological impact can also result in long-term issues that affect the wellness of skilled staff in several ways. Reports show that post-traumatic stress disorder, anxiety, depression, insomnia, and loss of appetite may result from sharps injury.[25,26]

The aggregate direct and indirect cost of a sharps injury was calculated to be between $650 and $750, encompassing laboratory fees, prophylactic treatment, and lost productivity. The costs increased when HIV-infected patients were identified, driving the amount up to $2,456. These figures are conservative, as the review did not include the cost of treating an occupational infection, litigation, or compensation. From 2012 to 2017, the National Health Service in the United Kingdom paid out over £4,000,000 to 1,213 claimants.[27,28]

In a value-based health care environment struggling with adequate skilled staffing, the impacts of time, quality, safety, and burnout in the OR must be priority considerations when determining the best method for autologous bone processing. Automated bone cleaning and milling is a solution to meeting the current challenges.

For information about the indications and intended use of the Bone Mill+TM and Prep+TM, visit www.strykerpoweringgold.com

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