Automation of Autologous Bone Processing Saves Time and Mitigates Task Fatigue and Sharps Exposure

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Abstract

There are over 2 million bone grafting procedures performed annually worldwide, 500,000 of which are performed in the United States. The Stryker Bone Mill is a mechanically powered milling tool that efficiently and consistently reduces harvested autologous bone into appropriately sized particles with a single-pass cutting action. Stryker's new Bone Mill+ has an added component, the Prep+, which is designed to remove excess tissue from extracted bone prior to milling. The new Prep+, along with the Bone Mill+ milling component, provides an automated process from start to finish.

To fully evaluate the potential benefits of the Prep+ and Bone Mill+ application, a study was conducted to compare the devices to manual processing by experienced scrub technicians (techs).

During the study, it was observed that the majority of manual preparation time is expended on cleaning the bone by removing excess soft tissue. On average, 60% of overall time was dedicated to cleaning (approximately 27 minutes). With an added average of 14 minutes for manual bone grinding, an overall average of 41 minutes was required to fully process the bone manually. Comparatively, the Prep+ consistently and significantly reduced this processing time with a soft tissue removal time of 10 minutes and an average automated milling time of 8 seconds. In a blind evaluation, expert scrub techs rated the quality of cleanliness of the Prep+ sample at 15% higher quality than manually processed samples. Notably, 50% of participants experienced a nitrile glove perforation event while processing samples manually.

Overall, the Stryker Bone Mill+ and Prep+ can increase scrub tech availability by removing a time-consuming manual task, thereby allowing them to reengage with the surgical team. Bone Mill+ and the Prep+ provided a more standardized solution, resulting in a reliable and predictable processing time. As the health care sector experiences a serious skill shortage, protecting and retaining skilled staff is of the utmost importance for both staff morale and the bottom line. Bone Mill+ and Prep+ provide another solution to workplace environment safety by eliminating a potentially hazardous risk through sharps injury and avoiding costly follow ups.

Background

Autologous bone is considered the gold standard of bone-grafting material. Bone harvested from the patient's own body has a lower risk of rejection and disease transfer than bone harvested from a donor. Autologous bone naturally contains viable cells such as osteoprogenitor cells as well as essential molecular components such as bone morphogenetic proteins. Furthermore, autologous bone can provide a calcium scaffold required to support the new bone growth (Schmidt, 2021).

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: anatomic proximity, the volume of graft desired, the need for structural graft, and the intrinsic biology of the donor site. The most commonly used donor sites are the anterior

and posterior iliac crest of the pelvis (Pape et al., 2010; Robinson et al., 2018).

Allograft, or bone 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 an autograft. Instead, the allograft works as a bridge that allows natural bone to grow through its surface. Over time, natural bone replaces the donor bone (Bauer & Muschler, 2000).

Overall, autograft is considered superior because of its excellent and cost-effective combination of biologic and mechanical properties. Autologous bone grafts continue to be important tools in the management of certain bone defects or nonunions. In one study comparing bone-graft treatment in 182 patients with long-bone nonunion, the autograft populations showed a significantly shorter union time with fewer surgical revisions and significantly lower postoperative infection rates (Flierl et al., 2013).

There are over two million bone grafting procedures performed annually worldwide, 500,000 of which are performed the United States (Campana et al., 2014; Sohn & Oh, 2019). Retrieval and processing of the autologous bone requires the extracted autologous bone to be cleaned and processed by an operating room (OR) scrub technician (tech). This procedure often requires the scrub tech to manually remove excess tissue and mill the bone into smaller particles before reimplantation into the patient. This process can be time consuming, requires physically repetitive motions, and is dependent on individual scrub technician skill and efficiency (Pape et al. 2010; *Stryker Bone Mill Case Study | Medical Device Product Development*, n.d.)

In the post-COVID-19 era, 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 as high as 52% of hospitals with critical staff shortages (*More than 19% of US Hospitals Critically Understaffed—OR Manager*, n.d.). As of May 2021, University of Pittsburgh Medical Center, a well-respected National Referral Centre, implemented a five-phased approach to ensure it could continue to provide essential surgical care when its surgical tech and OR nurse vacancy rate reached 30%. These phases saw a 15% reduced OR availability to compensate for the lack of skilled staff members (*Thoughtful Approach to Reducing OR Time for Elective Surgeries Helps Address Significant Pandemic-Induced Staffing Shortages Safely*, n.d.).

The Stryker Bone Mill is a well-established tool in the field of spinal fusion procedures. It is a mechanically powered milling tool that efficiently and consistently reduces harvested autologous bone into appropriately sized particles with a single-pass cutting action while providing consistent sized bone that is viable. Upon release into the market, demand for the Stryker Bone Mill was triple the original expectations, demonstrating the need to provide automated solutions to relieve surgical teams of traditionally time-consuming and unnecessary manual techniques (*Stryker Bone Mill Case Study | Medical Device Product Development*, n.d.).

Recently, Stryker's new Bone Mill+ has taken this automation one step further, developing the Prep+, which is designed to remove excess tissue from extracted bone prior to milling. This provides an automated process from start to finish.

Method

Participants

To fully understand the potential benefits of the Bone Mill+ and Prep+, 16 experienced scrub techs evaluated current manual processing techniques in comparison to Bone Mill+ and Prep+. Of the 16 participants, 14 were previous Bone Mill users, one utilized the Medtronic bone mill, and one did not use an automated mill. The scrub techs' range of experience was between 5 and 27 years with an average of 12 years' experience across the cohort. On average, the 16 participants represented an average of 38 procedures per month (range of 2–100 procedures per month). Each participant was surveyed independently and participated in a single attendance session.

Manual Cleaning of Bone

The study objective was to evaluate the quantity and quality of bone material cleaned and milled using the Bone Mill+ platform in comparison to manual processing by experienced scrub techs.

To achieve this, each participant was instructed to clean and mill 25 grams of porcine bone manually to a level of

cleanliness expected in their respective ORs. There was no time limit issued to the participants, and they were blinded to the overall objectives. An independent investigator recorded times and sample weights, took photographic evidence, and monitored safety events over the course of the investigation.

After the initial 10 minutes, the participant was instructed to cease cleaning, and the investigator recorded the weight of the manually cleaned bone. Following the pause, the participant was once again asked to continue cleaning manually to the level of cleanliness expected in the OR. Once the participant determined the bone to be sufficiently cleaned, the time and weight were again recorded, and the sample was photographed before progressing to milling.

Manual Milling of Bone

Once cleaning was completed and the results were recorded as outlined above, the participant was instructed to manually mill the cleaned bone to the level of quality expected in the OR. The overall time, weight, and photographs were recorded by the investigator once completed.

Automated Cleaning and Milling

Three comparison samples of 25 grams of porcine bone were processed using Bone Mill+ and Prep+. First, the bone was cleaned using the Prep+, and an independent investigator recorded times, sample weights, and photographic evidence.

Once measurements were recorded, the three samples were then milled by the Bone Mill+, and once again the independent investigator recorded times, sample weights, and photographic evidence.

Survey and Quality Assessment

Three randomly selected scrub techs were asked to assess photographs of cleaned bone samples and rate the quality of cleaning on a scale of 1 to 10 (1 = very poor, 10 = excellent). Scrub techs were blinded to the bone processing method (Prep+ or manual).

Participants were then instructed to complete a survey. Survey questions are listed below. A combination of free text and yes/no answers were required.

Background Questions	Answer Format
How many procedures/month are you involved in?	Free text
Have you used an automated mill?	Yes or no
If yes, what brand?	Free text
How long do you think it took you to complete manual cleaning?	Free text
How long do you think it took you to mill the bone manually?	Free text
Have you ever experienced hand fatigue while cleaning bone manually?	Yes or no
Have you ever experienced hand fatigue while manually grinding bone?	Yes or no
Have you ever experienced an injury while manually cleaning bone?	Yes or no
Have you ever experienced an injury while grinding bone manually?	Yes or no

Results

Time and Quality

Overall, manual processing of 25 grams of bone took on average 41 (± 23) minutes, 27 (± 14) minutes of which were dedicated to cleaning. When compared with the Bone Mill+, the overall process was consistently 10 minutes, 8 seconds. See Table 1 and Graph 1.

The Prep+ consistently cleaned all 25 grams of bone within 10 minutes. In comparison, 68% of scrub tech participants cleaned 32% (average 4 grams) of their overall processed bone manually in 10 minutes. The Prep+ produced an average of 46% more bone yield than bone cleaned manually when comparing the 10-minute Prep+ cleaning cycle to 10 minutes of manually cleaning.

Following completion of the bone cleaning, samples were photographed and presented to randomly selected scrub techs for assessment. Scrub techs were blinded to the bone processing method (Prep+ or manual) and asked to rate the sample on a scale of 1 to 10 (1 = very poor, 10 = excellent). On average, scrub techs rated the Prep+ at a 15% higher quality cleanliness rating. See Figure 2. The Prep+ consistently cleaned the bone to the level expected in the OR on average ~270% faster than the average scrub tech.

Once cleaned, the sample moved directly to milling, requiring just 8.4 seconds to consistently mill the bone in comparison to 14 (± 9) minutes required for manual milling.

Once manual processing was completed, scrub techs were asked to estimate their overall time cleaning and milling. Fifty percent of scrub techs underestimated their total time by approximately 14 minutes.

Safety

During manual cleaning and manual milling by scrub techs, safety events were observed and recorded by the investigator. Fifty percent of participants experienced nitrile glove puncture, with two participants experiencing multiple events (e.g., glove puncture twice in one session).

When surveyed, 100% of participants self-reported hand fatigue due to cleaning bone, and 75% self-reported hand fatigue due to milling. Thirty-one percent of participants self-reported previously experiencing injury due to either manual cleaning or milling of bone.

Survey Results

Survey Question	**% Positive Response**
Have you ever experienced hand fatigue while cleaning bone manually? Y/N	100%
Have you ever experienced hand fatigue while manually grinding bone? Y/N	75%
Have you ever experienced an injury while manually cleaning bone? Y/N	31%
Holes in gloves while manually cleaning bone. Self-reported/unprompted response; addition—free text	31%
Have you ever experienced an injury while grinding bone manually? Y/N	19%
Holes in gloves grinding bone manually Self-reported/unprompted response; addition—free text	13%

Figure 1

Manual vs Prep+ & Bone Mill+ Average time

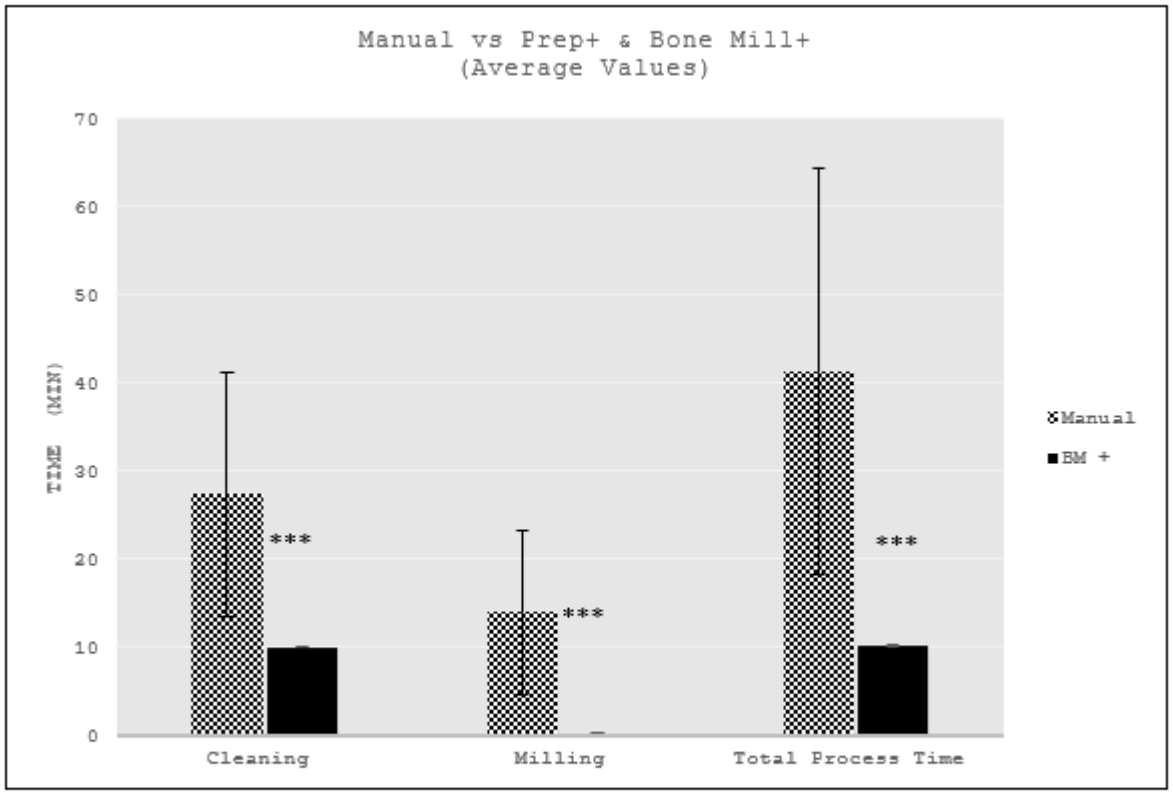

Figure 1: The bar graph representation (mean ± StDev) of average time (Mins) taken to clean and mill 25g porcine bone across 16 participants compared with Prep+ and Bone Mill+. *** Statistically significant $p < 0.0001$

Table 1

Manual vs Prep+ & Bone Mill+ Average time

	Manual			**Bone Mill+**		
	Cleaning	Milling	Overall	Cleaning	Milling	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 Prep+ and Bone Mill+

Figure 2
Manual vs Prep+ Clean

Figure 2: Photographic examples of 25g porcine bone sample following removal of soft tissue. (A) Prep+ Sample (B & C) Manually process by expert scrub techs.

Discussion

Recently, the global health care system has been ravaged by mass resignations, staff shortages, and procedure backlogs owing to the COVID-19 pandemic (Maunder et al., 2022). Health care staff are experiencing heavy workloads and are at high risk for burnout. The rates of burnout are consistently linked with role and are notably highest in nurses (Gemine et al., 2021). Although COVID-19 has exacerbated this burnout risk, even decreased COVID-19 burnout in nurses and other health care professionals remained higher than was reported prior to the pandemic. In studies related to burnout, at least two main risk factors appear modifiable, suggesting targeting issues such as PPE concerns and meaningful breaks could have real impact on levels of work-related burnout (Gemine et al., 2021; Maunder et al. 2022; *Thoughtful Approach to Reducing OR Time for Elective Surgeries Helps Address Significant Pandemic-Induced Staffing Shortages Safely*, n.d.).

Bone Mill+ and Prep+ provide an efficient start-to-finish solution for consistent preparation of autologous bone for reintroduction to the patient. This is a repetitive manual task currently performed in surgery by the scrub tech. During this study we assessed the consistency, time, and safety issues associated with manual cleaning and milling as performed by experienced scrub techs. Currently, solutions for the automated milling of already cleaned autologous bone are on the market, including the original Bone Mill by Stryker. Prep+ is a new addition to the product and alleviates the previously unaddressed issue of cleaning and removal of excess soft tissue from the harvested bone (*Stryker Bone Mill Case Study | Medical Device Product Development*, n.d.)

During the study it was observed that the vast majority of manual preparation time for autologous bone is expended on the removal of excess soft tissue. On average, 60% of overall time was dedicated to cleaning (approximately 27 minutes). Consistency regarding timing also varied substantially across the participants, with an overall range in time between 6 minutes to 57 minutes (or ± 14 minutes). Time required to manually mill samples also varied substantially, with a standard deviation of ± 9 minutes for milling. This inconsistency across participants was recorded at ± 20 minutes for overall processing. Compared with Stryker's Prep+ and Bone Mill+, time was consistently and significantly less, at 10 minutes and 8 seconds for the entire processing from start to finish.

Along with consistency of time, consistency of soft tissue removal compared to manual cleaning can also be considered. The levels of overall quality in cleanliness varied with three of the 10 manually cleaned samples rated with a score less than or equal to 4 out of a possible 10.

As previously mentioned, staff vacancy rates have also reduced OR availability time in some hospitals by up to 15%. Reducing time associated with manual tasks increases staff availability. Rather than focusing on this manual task, scrub techs have the freedom to work more efficiently, reengage with additional intraoperative assistance, and continue to support their OR teams. This

also means that up to 41 minutes of scrub tech time can be recouped. Unnecessary clinical variation leads to increased costs, as seen in many surgical procedures. A key factor in elevated costs are extended OR time and failure to standardize the coordination of care (*Reducing Clinical Variation to Drive Success in Value-Based Care [Part 1]*, n.d.). Surgeons can now rely on a consistent time of 10 minutes to fully process up to 25 grams of autologous bone when planning surgery. In addition, they can recoup up to 30 minutes per level of harvested bone preparation.

Time is a high value commodity within an OR. Given that surgical care accounts for nearly one-third of all US health care spending, the OR alone is valued at $36 to $37 per minute, making it the second most expensive part of surgical care. In other words, every minute counts (Childers & Maggard-Gibbons, 2018). Stanford University has shown the value down to one second, where a "move on two" (moving a patient to an operating table on a count of two rather than three) saved on average $12,000 in OR costs per year (Brodsky, 1998).

One of the more serious risks to any health care worker's well-being is injury sustained during their work. According to a multitude of government legislative and HSE guidelines, improving PPE concerns and removing risk of injury is a core component of establishing a safe work environment (Hambridge et al., 2020). Sharps injuries are one of the leading causes of accidents sustained by health care workers and have been described as an "important public health concern" (Pathak et al., 2012). Sharps injuries can be defined as ". . . skin penetrating stab wounds caused by a sharp instrument and accidents in a medical setting" (Centers for Disease Control and Prevention [CDC] 2008 (*About the Workbook | Sharps Safety | CDC*, n.d.).

Over the course of the study, 50% of the participants were observed to experience one or more glove punctures. Thirty-one percent of respondents to the survey stated that they had experienced fatigue or injury while performing the cleaning task manually in an OR.

It is well accepted that, during surgery, intact gloves act as a protective barrier against blood-borne pathogens such as HIV, hepatitis B, and hepatitis C. We also know that glove perforation is not only frequent but also often unrecognized by surgeons and scrub nurses. One study showed that of 242 glove punctures, 176 (72.7%) were not noticed by the operative team members and were only detected after the operation (Ersozlu et al., 2007). There is not only physical risk to be considered such as exposure to HIV, hepatitis, and other infectious hazards, but also psychological impact to workers, which can result in long-term issues and affect wellness of staff in a number of ways. Reports show post-traumatic stress disorder, anxiety, depression, insomnia, and loss of appetite are because of sharps injury (Hambridge, 2022; Moayed et al., 2016) The aggregate direct and indirect cost of a sharps injury was calculated as being between $650 and $750, encompassing laboratory fees, prophylactic treatment, and lost productivity. The cost is also increased when HIV-infected patients are identified, driving the costs to upwards of $2,456. These figures are conservative because the review did not include the cost of treating an occupational infection, litigation, or compensation. The National Health Service in the United Kingdom paid over £4,000,000 to 1,213 claimants from 2012 to 2017 (Gallagher, 2020; Hambridge et al., 2020).

Cost Considerations

Sharps injury: $650–$2456 (excluding litigation costs)

Cost of OR minutes: $36–$37 per minute per operation

Cost of OR availability reduction due to staff shortage

Conclusion

Overall, Stryker's Bone Mill+ and Prep+ can increase scrub tech availability by removing a time-consuming manual task and allowing scrub techs to reengage with the surgical team. As with any manual task, results will vary from person to person. Bone Mill+ and Prep+ provide a standardized solution to a previously unaddressed OR task, resulting in a reliable and predictable processing time. As the health care sector experiences a serious skill shortage, protecting and retaining skilled staff is of the utmost importance for both staff morale and the bottom line. Each turnover percentage point change translates to approximately $270,000 lost or saved per hospital (*Designing Hospitals That Promote Staff Wellbeing*, n.d.; Lin et al., 2013). Bone Mill+ and Prep+ also provide another solution to ensure safe work environments by potentially eliminating a hazardous risk event due to sharps injury and costly follow up.

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