Toward a heat-curling polymeric needle designed for safe disposal

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Statement of Purpose: Improper and unsafe needle-syringe disposal is a worldwide healthcare issue. It has been well documented especially in developing countries that tens of millions of hepatitis and HIV infections result from this problem each year [1]. Conventional steel needles require a high temperature for incineration and generate a large amount of waste. Even after disabling the needles, they remain sharp hazards and potentially dangerous for recycling workers. Auto-disable needle-syringes have been developed in recent years and most of these devices function by preventing the syringe's plunger from being withdrawn after injection. However, the needle disposal and recycling problem remains unsolved. These limitations could be addressed through the use of shape memory polymers (SMPs). SMPs are a class of stimuli-responsive materials that can undergo a shape change based on and environmental trigger. SMPs have been widely used in biomedical devices such as deployable stents [2] and surgical suture [3]. Meanwhile, some studies [4] have shown the potential to replace the conventional steel needle with a polymeric needle. We reasoned that by introducing the programmable nature of SMP to a needle, the disabling process would be easy, fast and safe. Following use, the needle tip could be thermally curled, removing the stick hazard. The objective of this study was to develop a programmable polymer needle that has requisite sharpness and can be triggered by heat to curl into a non-stick shape for safe and easy disposal. The polymer stiffness is crucial for this application. Thus, buckling analysis was performed to understand the structural characteristics. Puncture forces through a skin model were also measured.

Methods: High molecular weight PMMA (Mw = 540 kDa) was used in this study. The polymer was pre-dried at 100 °C prior to extrusion at 205 °C. The thermal stability and glass transition (T_g) of PMMA fiber before and after extrusion were compared. An annealing process was performed after extrusion at 120 °C before further characterization. The shape memory performance was analyzed, and the ability of hot-pressed PMMA films to fix and recover a tensile strain was examined. A heat-curling PMMA needle was demonstrated by setting a permanent curled shape and then programming a temporary straight shape. Next, a sharp tip was created by a cryogenic fracture process. Finally, heat-triggered recovery to the permanent curled shape was examined. A skin model was developed for needle-buckling analysis containing thick ballistic gel as a mimic of dermis and a layer of nitrile butadiene rubber (nitrile glove) on the top as a mimic of epidermis. Puncture forces were measured with various needle lengths. The effect of needle length on critical buckling force was investigated and compared with theoretical prediction.

Results: The extruded PMMA with predrying at 100 °C before extrusion and annealing at 120 °C after extrusion exhibited good thermal stability and a T_g of 111 °C. It also showed a high elastic modulus of 3.4 GPa at RT. PMMA films exhibited excellent shape fixing with a fixing ratio of 99% but a modest recovery ratio of 68% during the first cycle, gradually increasing to 95% for the third cycle. A curling needle demonstration is shown in Figure 1. With the aid of our skin model, the puncture forces of PMMA needles with a diameter of 0.75 mm were measured. Puncture forces were largely independent of needle length and were comparable to commercial BD 22 gauge needle. The critical buckling force with various PMMA needle lengths was also investigated. The length dependence was well-predicted by Euler's buckling theory.

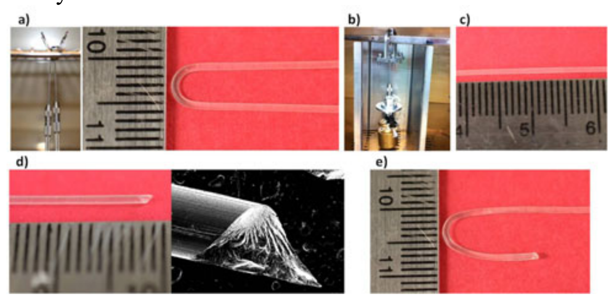

Figure 1. Needle fabrication amd shape memory demonstration: a) Setting the permanent shape, b), c) Programming the temporary shape, d) The freeze fractured tip, and e) Shape recovery of the curled needle.

Conclusions: This work demonstrates the first shape memory curling needle for safe disposal and recycling purpose. High molecular weight PMMA fibers exhibited good shape fixing and recovery ratios. The needle tip sharpness was achieved by freeze fracture. With the help of the skin model we developed, the puncture force was measured and the critical buckling force found to be well predicted by Euler's theory. Our study offers a simple way for fabricating a polymeric non-stick needle for easy and safe disposal. Future developments are needed to create a hollow needle with the same shape memory characteristics.

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