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Technical paper

A hybrid process for manufacturing surgical-grade knife blade cutting edges from bulk metallic glass

Alex J. Krejcie, Shiv G. Kapoor*, Richard E. DeVor[1]

UIUC, USA

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ABSTRACT

The demand for precision surgical knives is enormous. Currently, diamond knives have been the preferred choice among surgeons for use in precision surgeries, owing to the extreme hardness of diamond and the sharpness that can be achieved in single crystal diamond blades, but material and processing costs are high. Bulk metallic glass (BMG) has the potential to be an economically viable material of similar performance for use in precision surgical knives. To this end, a novel hybrid manufacturing process integrating thermally assisted micro-molding and micro-drawing has been developed for producing BMG surgical-grade knife blade cutting edges with edge radii <50 nm. A hybrid process testbed was designed and used to successfully run tests over a range of the key process variables. Through this testing the deformation of BMG under different strain rates and temperatures was studied in terms of the quality of edge formation. The hybrid process was shown to be capable of producing cutting edges of radius at or below 100 nm.

1. Introduction

Diamond has been the preferred material of choice among surgeons for knives used in surgeries that require precise incisions like ophthalmic surgeries, owing to the extreme hardness of diamond and the sharpness that can be achieved in single crystal diamond blades [1]. However, the cost of a diamond knife used in ophthalmic surgeries is between $2000 and $3000 [1]. Further, owing to the mechanical properties of diamond, careful handling of the diamond knife is needed to maintain the integrity of the cutting edge. Natural diamond is expensive, but a major portion of the cost for surgical knives is incurred while manufacturing the blade cutting edge geometries, particularly the edge radius. While alternative processes and materials are available, achieving high performance at a low cost is still a problem.

The manufacture of various blade geometries is complicated by the fact that surgeons require several different and at times customized angles on their diamond knives [1]. The techniques for manufacturing the diamond knife cutting edge geometry include mechanical lapping, thermo-chemical lapping, chemically assisted mechanical polishing and planarization (CAMPP) and reactive ion etching. All these processes are time consuming and expensive [2–5].

While diamond blades excel due to their reusability and superior edge radius, both stainless steel and silicon have been used to make surgical blades. Stainless steel yields a much larger edge radius than diamond blades (~300 nm) due to the limitation of its crystalline structure. This results in poorer cutting performance and longer heal times [6,7]. Additionally, stainless steel is not tough enough to sustain its cutting edge over multiple uses. Silicon blades can achieve a much smaller edge radii (~40 nm) and thus near the cutting performance of diamond [6,7]. However, like stainless steel, they do not perform as well over multiple incisions.

An economically viable alternative material for precision surgical knives should satisfy the following four criteria: (1) it should be comparable in hardness to alloys like titanium so that the integrity of the knife is maintained; (2) the grain size of the material should be such that the desired edge radius (20–50 nm) can be obtained; (3) the manufacturing costs involved in making knives of various shapes, sizes and edge radii have to be such that it provides a compelling cost benefit over the use of diamond knives; (4) the material should be bio-compatible. Bulk metallic glass (BMG) is a material that has the potential to meet all the above requirements. Therefore, the overall objective of this paper is to develop a manufacturing process for making BMG surgical-grade knife blade cutting edges with edge radii <50 nm. This will be realized using a novel hybrid process involving thermally assisted micro-molding and thermally assisted micro-drawing.

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* Corresponding author at: 1206 W. Green Street, Urbana, IL 61801, USA. Tel.: +1 217 333 3432; fax: +1 217 244 9956.
E-mail addresses: krejcie2@illinois.edu (A.J. Krejcie), sgkapoor@illinois.edu (S.G. Kapoor), redevor@illinois.edu (R.E. DeVor).

[1] Deceased.

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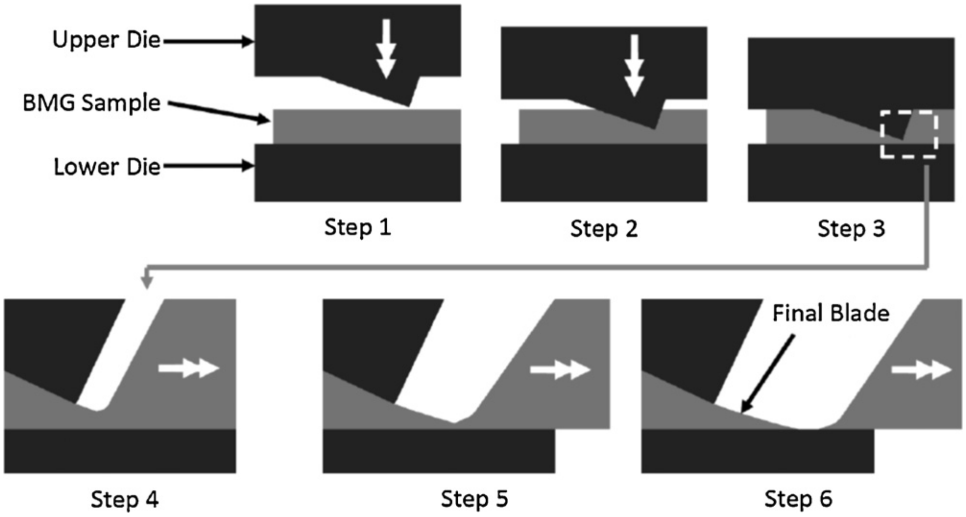

Fig. 1. Hybrid manufacturing process (final blade on left).

The remainder of this paper is organized as follows. Section 2 outlines the material properties of bulk metallic glass. Section 3 explains the hybrid manufacturing process and the experimental testbed. Section 4 presents the experimental investigation and results. Section 5 interprets the results obtained. Section 6 analyzes edge quality and lastly, Section 7 presents the conclusions from this work.

2. Properties of bulk metallic glass

Bulk metallic glasses were originally discovered in the 1960s when a binary Au–Si glass metal was created. However, not until the early 1990s have more stable multi-component alloys with lower critical cooling rates been found. Vitreloy-1, developed by Liquid Metal Technologies [8], is a zirconium-based bulk metallic glass with the chemical formula: $Zr_{41.25}Ti_{13.75}Cu_{12.5}Ni_{10}Be_{22.5}$. It is categorized as an amorphous alloy or bulk metallic glass due to its chemical makeup and atomic structure. Vitreloy-1 would traditionally exist with a crystalline structure as do most materials. However, rapid cooling (1 K/s) during solidification from a melt allows the material to reach a metastable condition in which the amorphous structure that existed in its liquid state is maintained. Vitreloy-1 has a much lower critical cooling rate to maintain its amorphous structure than most metallic glasses, making it usable in a wide range of applications.

Vitreloy-1 is ideal for use as a surgical blade material due to its amorphous structure, high strength (1900 MPa) and high hardness (534 HV). Both the strength and hardness are equivalent to standard tool steels and are ideal for the formation and retention of a sharp edge. Vitreloy-1 also reaches 2% elongation before failure at room temperature, which is greater than similar high strength brittle metals and ceramics. Zirconium-based alloys have been shown to be fully biocompatible [10,11] and unlike many plastic and silicon instruments, can be sterilized with any current medical method. An in-depth study of the material properties of Vitreloy-1 was performed by Lu et al. [9].

Vitreloy-1 transitions to a supercooled liquid state at high temperatures (625 K), still well below the materials melting point (993 K). This supercooled state softens the material and allows the use of several thermally assisted methods of manufacturing not usually available to metals and other hard materials. Through differential scanning calorimetry, the onset of glass transition was found to occur at 625 K [9]. The material has a relatively large stable supercooled region of about 80 K where it follows a time/temperature-dependent relation to crystallization. During this time, the structure of the material slowly reverts to its stable structure through crystal growth. At or above 705 K crystallization is unavoidable. The stable region for Vitreloy-1 is larger than most bulk metallic glasses making it an ideal alloy for working in the supercooled liquid region.

3. Hybrid manufacturing process

In an effort to produce blades with edge radii of less than 50 nm, several manufacturing methods were examined. Machining [12] and micro-molding [13] were found to be viable methods for generating the initial geometry suitable to support a strong stable edge, but do not appear to be capable of producing the required edge radii of <50 nm. Thermally assisted micro-drawing was found to be capable of creating very small features, viz., the edge radius. Therefore, it was decided to further pursue a process that combined thermally assisted micro-molding and thermally assisted micro-drawing to form bulk metallic glass within the supercooled liquid region.

Fig. 1 schematically outlines the proposed hybrid manufacturing process. The dies are heated to a pre-specified temperature within the supercooled region of BMG prior to the beginning of the micro-molding process. Steps 1–3 involve molding the rake face and initial geometry of the blade. At step 3, the upper die is stopped when the remaining material thickness is around 20 μm. Steps 4–6 show a detailed view of the subsequent micro-drawing operation. The BMG sample is drawn to the right, causing the sample to deform plastically until it fails along a sharp edge. The material to the left in step 6 is the final blade.

In order to perform the hybrid manufacturing process, a testbed was created capable of accurately molding the BMG sample within its supercooled region and then precisely drawing the molded blade (Fig. 2). The upper die is controlled by a ball screw actuator capable of outputting over 1000 N of force. An LVDT providing feedback to the process controller is used to measure the gap between the upper and lower die with a resolution of 100 nm. An additional actuator with sub-micron precision is used to draw the BMG sample. This actuator has an adapter plate that allows mounting of the BMG sample and contains a load cell. The critical geometries of both the upper and lower dies utilize tool steel inserts for maximum strength, higher precision and easy maintenance. The lower die is adjustable to allow precise alignment of the upper and lower dies to create a uniform gap thickness during molding. The upper die is designed to produce a 20° rake angle in the final blade.