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Micromachined needles and lancets with design adjustable bevel angles

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Abstract

A new method of micromachining hollow needles and two-dimensional needle arrays from single crystal silicon is described. The process involves a combination of fusion bonding, photolithography and anisotropic plasma etching. The cannula produced with this process can have design adjustable bevel angles, wall thickness and channel dimensions. A subset of processing steps can be employed to produce silicon blades and lancets with design adjustable bevel angles and shaft dimensions. Applications for this technology include painless drug infusion, blood diagnosis, glucose monitoring, cellular injection and the manufacture of microkeratomes for ocular, vascular and neural microsurgery.

1. Introduction

The delivery of drugs has been accomplished for many years using cannula or hollow needles. Metal needles have been shrunk to increasingly small size but there are limits as to how small a traditional hollow metal needle can be made. Due to the ductile nature of small metal needles, they tend to bend. Silicon needles can be micromachined to a much smaller size and are not ductile at temperatures below 700 °C. Because of this, micromachined silicon and deposited films have been used to fabricate cannula and drug delivery devices [1–8]. Researchers at the University of California [1–5] have fabricated polysilicon and single crystal needles using a combination of wet etching and chemical vapor deposition (CVD). At the University of Michigan, single crystal silicon structures were sealed with CVD films of oxide, nitride or polysilicon to form cannula [6, 7]. While silicon is not prone to bending at room temperature it can fail by fracture, which is a concern for medical needle applications. Initial studies by Henry *et al* [8] have found that the silicon microneedle arrays can pierce the skin repeatedly without breakage of the needle tips or shafts.

As with microneedles, small surgical blades have been fabricated from stainless steel, steel and sapphire [9]. Like microneedle, metal ductility and hence blade bending is a problem. To avoid blade bending, the application of micromachined silicon to surgical blade fabrication has also been explored using wet etching along crystallographic planes and isotropic etching to form fine blade edges [10, 11]. Wet etching of (100) silicon wafers limits the angle of the blade bevel to 54.7°, while an angle of 25° or less is required for efficient surgical cutting.

In this paper, a new method of forming both hollow needles and blades using single crystal silicon is described. The micromachining methods used to form the hollow needles have been used to form resonant microtubes employed in density and mass flow sensors [12, 13]. By merging photolithography and anisotropic plasma etching together, the ability to manufacture both needle and blade tips with design adjustable bevel angles has been obtained. Applications for the microneedle and blade technology exist in areas of painless blood typing, diabetes or glucose monitoring, blood diagnosis, transdermal drug delivery, microinjection into cells, neural stimulation, ocular, vascular and neural microsurgery [1–11, 14].

2. Experimental procedure

The process used to fabricate the single crystal silicon needles is illustrated in figure 1 [15]. A silicon wafer, with or without an etchstop layer, is first patterned and etched to form the fluidic channel for the cannula as shown in figure 1(*A*). An SOI wafer is used in figure 1(*A*), an illustration of the process flow. After this etch step, the wafer is cleaned and fusion bonded to another silicon slice. The internal microneedle channel is formed of silicon. Next, as illustrated in figure 1(*C*), the

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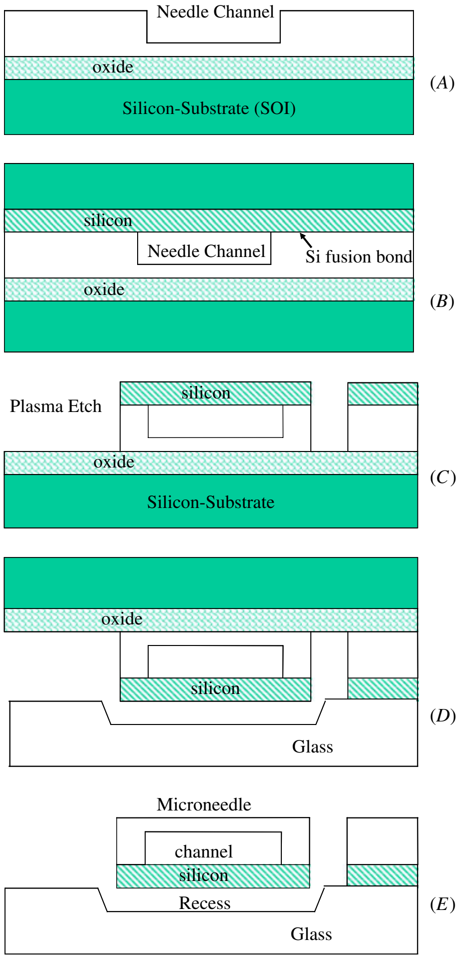

Figure 1. Cross-sectional diagram of the microneedle fabrication process. (*A*) Etch the needle channel. (*B*) Fusion bond the silicon wafers. (*C*) Plasma etch the external shape of the needle, including the bevel edge. Stop on the SOI oxide layer. (*D*) Anodically bond the silicon needle wafer to a glass handle wafer. (*E*) Etch back the unwanted portion of the silicon substrate.

outer dimensions of the needle, including the bevel and shaft are formed using photolithography and anisotropic plasma etching. A deep reactive ion etch system, manufactured by STS, was used in this study to form the vertical silicon sidewalls required by this step. The etched silicon wafer stack is now anodically bonded to a micromachined glass wafer. The needles that will be singulated are aligned over recesses in the glass wafer as shown in figure 1(*D*). As a final wafer processing step, the unwanted portion of the silicon wafer can now be removed with either the dissolved wafer wet etch process or a plasma etch step.

To produce silicon blades or lancets, a simpler subset of the processing steps is employed. In the case of blades, the needle channel is not required so the fusion bonding steps are not utilized. Scanning electron and optical microscopy were used to study the microstructures.

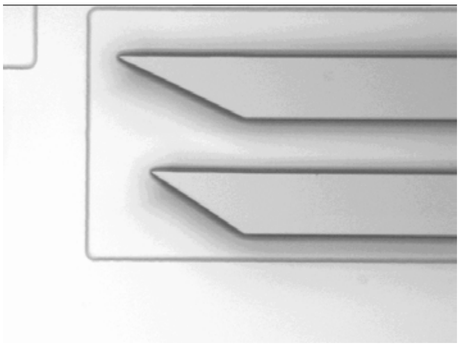

Figure 2. Top view of two blades with different bevel angles.

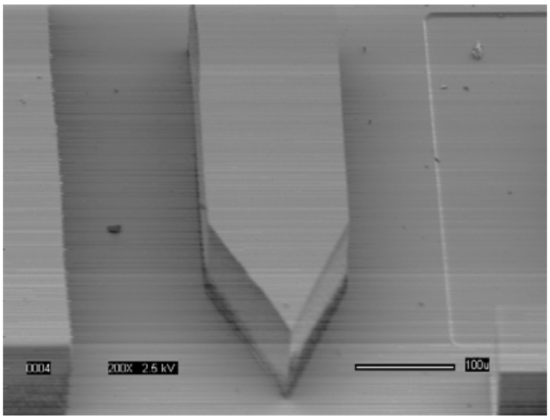

Figure 3. Alternate bevel design. The scale bar is 100 μm in length.

3. Results and discussion

The simplest structures to fabricate with this new process are blades. By using photolithography to define the bevel angle, a blade with a cutting surface perpendicular to the wafer surface can be formed. Figure 2 shows a top-view example of two silicon blades made side-by-side with different bevel angles. The blade angles produced, 25° and 35°, match the angle drawn during mask design. Figure 3 shows how a lancet with a double bevel tip can be fabricated on the same wafer. Using anisotropic etching with vertical sidewalls enables blade edges to be made from single crystal silicon without reference to a crystallographic plane. The primary drawback to this approach is the restriction in blade edge length to that of the wafer thickness. A limit to the cutting edge length is not a problem for lancets, oscillating microkeratomes and cataract slit micro instruments.

The next level in microstructure complexity is the fabrication of a single microneedle. Figure 4 shows how a hollow beveled needle tip can be fabricated with the process. It was noted that the same processing techniques often used to form vertical sidewalls, namely sidewall deposition, can cause problems in opening the microtube at the needle tip. Sidewall deposition can cause completely or partially sealed needle tube tips. Adjusting the etch/deposit cycle or a post etch plasma oxygen clean can be used to open the needle tip orifice.

To enable the release of the blade or needle requires specific design and process consideration. Release of the device can be obtained by bonding the silicon wafer to a micromachined glass wafer prior to plasma etching the outer dimensions of the blade or needle or prior to final etchback of the silicon wafer as illustrated in figures 1(*D*) and (*E*). The

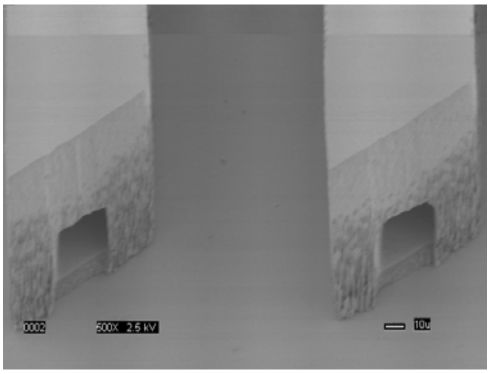

Figure 4. Silicon needle tips. The scale bar is 10 μm in length.

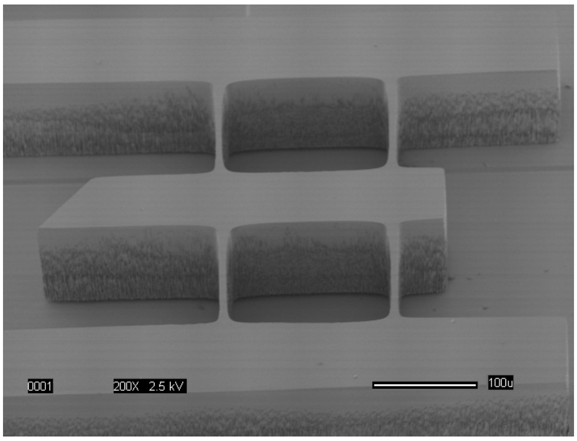

Figure 5. Tabs used to tether a blade or needle to the silicon wafer prior to singulation. The scale bar is 100 μm in length.

recess prevents bonding of the silicon needle to the glass wafer. The glass wafer does not etch during the anisotropic plasma etching of the silicon or the dissolved wafer process. Figure 5 shows how tabs can be employed to produce a singulated needle. The small silicon tabs can be broken or cut to release the individual needle or blade.

Advantages of these single crystal, plasma etch defined needles include the ability to set any wall thickness from 0.5 μm to over 25 μm. Unlike CVD-based microneedles, the wall thickness of these needles can vary along the length of the shaft to provide additional strength to where the cannula is mounted to a syringe or other infusion system. Cannula can also be made with elbows, loops and mechanical support structures since photolithography and plasma etching define the geometries [13]. The basic micromachining process has been in use for manufacturing microtubes for resonant sensors since 2002 and so has proved its repeatability and manufacturability. Since only single crystal silicon is used to form the needle, warpage and film stress often found in CVD films are not factors with these devices. One can also fabricate both hollow needles and solid blades on the same wafer. For the blades the needle cavity is deleted from the design. Dielectric layers and metal runners can also be employed with this technology to enable neural stimulation or sensing capability.

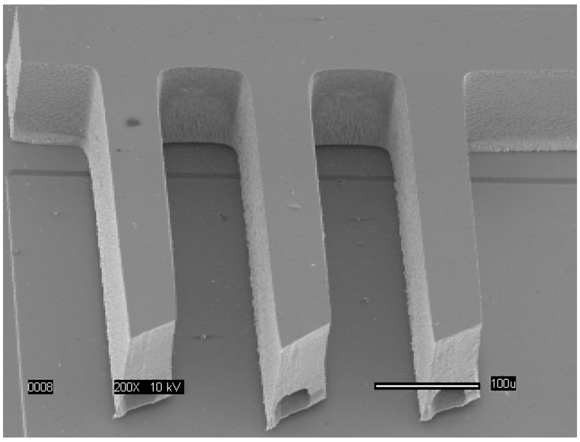

Figure 6. Two-dimensional single crystal silicon needle array. The scale bar is 100 μm in length.

Two-dimensional needle arrays can also be produced with this process as shown in figure 6. Needle size, spacing and number can be varied through design. The array can be supplied from a single reservoir, which can be part of a micromachined glass wafer. Fluid manipulation through anodically bonded silicon microtubes and glass with vertically drilled holes has already been accomplished in density and mass flow meter chips [13]. An array of properly sized, hollow needles offers a method for the painless delivery of higher drug doses.

4. Conclusion

A new micromachining process and design are described in which hollow needles and two-dimensional needle arrays are fabricated from single crystal silicon. The micromachining process involves the use of fusion bonding, photolithography and anisotropic plasma etching. The cannula produced with this process can have design adjustable bevel angles, wall thickness and channel dimensions. By offering thicker walls more mechanically robust microneedles can be produced. Two-dimensional microneedle arrays were also produced with this process, which allows for higher dose rates in drug infusion applications. A subset of these processing steps can be employed to produce silicon blades and lancets with design adjustable bevel angles and shaft dimensions. Applications for this technology include painless drug infusion, cellular injection and the manufacture of microkeratomes for ocular, neural and vascular microsurgery.

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