Analysis of the Mechanical Failure of Polymer Microneedles by Axial Force

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A polymeric microneedle has been developed for drug delivery applications. The ultimate goal of the polymeric microneedle is insertion into the specified region without failure for effective transdermal drug delivery. The mechanical failure of various geometries of microneedles by axial load was modeled using the Euler formula and the Johnson formula to predict the failure force of tapered-column microneedles. These formulas were compared with measured data to identify the mechanical behavior of microneedles by determining the critical factors, including the actual length and the end-fixed factor. The comparison of the two formulas with the data showed good agreement at an end-fixity (K) of 0.7. This value means that a microneedle column has one fixed end and one pinned end and that part of the microneedle is overloaded by an axial load. When the aspect ratio of length-to-equivalent diameter is 12:1 at Young’s modulus of 3 GPa, there is a transition from the Euler region to the Johnson region due to the decreased length and the increased base diameter of the microneedle. A polymer having a stiffness of less than 3 GPa would follow the Euler formula. A 12:1 aspect ratio of length-to-equivalent diameter of the microneedle is a mechanical indicator determining the failure mode between elastic buckling and inelastic buckling at Young’s modulus of less than 3 GPa for polymer. Microneedles with an aspect ratio of length-to-equivalent diameter below 12:1 and Young’s modulus of more than 3 GPa are recommended for reducing sudden failure by buckling and for successfully inserting a microneedle into the skin.

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I. INTRODUCTION

Tapered micro-columns are generating increasing interest for drug delivery applications. These structures are usually called microneedles, which are used to pierce the outer layer of skin and thereby provide a minimally invasive method of drug delivery that avoids the complications and safety concerns associated with hypodermic needles.

Arrays of microneedles have been created to act as a bridge between conventional injections and transdermal patches [1-3]. Microneedles have been fabricated from polymers, which offer safety, versatility, and cost-effectiveness [4-7]. Replicate microneedle arrays have been made out of various kinds of polymers, including non-biodegradable polymers and biodegradable polymers, for example, by filling a micro-mold with a polymer melt and solidifying it [2,8]. Microneedles made in this way can be intentionally or unintentionally broken off in the skin.

Microneedles require proper design to be inserted into the skin without breaking. Insertion is achieved largely by using needles with sharp tips and with sufficient length to overcome the deflection of the skin’s compliant surface that occurs before insertion. Needle integrity during insertion has been achieved primarily by minimizing the required insertion force by using sharp-tipped needles and by maximizing the mechanical strength through increasing Young’s modulus and the needle’s diameter [2]. These studies have quantitatively measured the force required to fracture microneedles pressed against a rigid surface and the force required to insert microneedles into the skin of human subjects. The goal of these studies was to assure the robust design of a microneedle so that it could be inserted without breaking.

Previous studies have provided analyses of the expected failure force by using an elastic buckling model for the specified geometries based on the Euler formula [9-11]. However, the ideal elastic buckling mode, which
assumes that the structures are “long,” cannot explain the failure of microneedle columns that are intermediate-length or short, so other approaches are needed [12].

To increase successful insertion of microneedles, a comprehensive analytical model of failure is needed to estimate the mechanical behavior of various geometries of tapered columns of solid microneedles made of various kinds of polymers. Inelastic stability of intermediate-length and short columns should also be considered as the critical failure mode of tapered microneedles, given that microneedles tend to be short. The ratio of length-to-equivalent diameter should be considered as the critical factor determining the mechanical failure mode because it can vary with application, such as in transdermal drug delivery and ocular drug delivery [4,13].

II. EXPERIMENTS AND DISCUSSION

Various geometries of microneedles were designed and fabricated for mechanical analysis by using the lens technique and the inclined rotation method, as described previously [2]. Briefly, UV light incident at a fixed longitudinal angle was applied to an SU-8 (SU-100, MicroChem, Newton, MA) slab through a clear glass window in a dark-field photomask. UV (i-line, 365 nm) exposure was carried out at an angle of 20° while the sample was rotated for 900 min, which resulted in a conical shape of non-crosslinked SU-8. Using this approach, various geometries of microneedles were prepared by the inclined rotation and lens technique, and mechanical failure forces were measured. To predict the failure force of the tapered-column microneedles, we first considered theoretical approaches to predicting failure of straight columns and then adapted the solutions to tapered columns. We assumed that the applied force acted parallel to the microneedle axis. In the case of an axial load on the column structure, an analytical solution based on failure due to buckling caused by inelastic or elastic instability of the structure was developed. To predict the force required for needle failure due to buckling, the transition slenderness ratio (column constant, $C_c$), defined by Eq. 1, should be determined:

$$C_c = \sqrt{\frac{2\pi^2E}{S_y}}$$

where $E$ is Young’s modulus of the material and $S_y$ is the yield strength of the material. The slenderness ratio of a column is computed from Eq. 2:

$$SR = \frac{L}{r_g} = \frac{KL}{r_g}$$

where the effective length, $L_e$, and the radius of gyration, $r_g$, for a solid circular sectional column are defined as $L_e = KL$ and $r_g = D/4$, respectively [12], where $L$ is an
The end-fixity factor is a measure of the degree to which each end column is restrained against movement. The values of K are 1.0, 0.7, and 0.5 for a pinned-pinned column, a fixed-pinned column, and a fixed-fixed column, respectively [12]. A fixed column is one where the end and the angle of the column at the end do not move. A pinned column is one where the end does not move, but the angle is free to rotate. For the microneedle mechanical analysis, end-fixity factors from K = 0.5 to K = 1.0 were scanned because the needle bases were fixed to a support, and the tips of the needles were not allowed to rotate in any direction about any axis due to friction with the contacting surface.

If the actual slenderness ratio, SR, is greater than the column constant, $C_c$, then the column is considered “long,” and the Euler formula, defined in Eq. 3, should be used to predict the critical load, $P_{cr}$, at which the column would be expected to buckle:

$$ P_{cr} = \frac{\pi^2 EI}{L_e^2} = \frac{\pi^2 EA}{(L_e/r_g)^2} \quad (3) $$

where I is the moment of inertia for a circular section, defined as $I = \pi D^4/64$ (D is the diameter of a circular section), and A is the area of a circular section [12].

As the column gets shorter, it exhibits a tendency to fail at loads less than predicted by using the Euler formula, and this has led to the development of a companion expression to properly account for failure in the intermediate region. This parabolic equation was first suggested by Johnson, and the point at which the Euler formula is shifted to the Johnson formula is governed by the column constant, $C_c$. If the slenderness ratio, $KL/r_g$, is less than the column constant, $C_c$, then the column is considered “short,” and the Johnson formula, as shown in Eq. 4, should be used [15]:

$$ P_{cr} = AS_y \left[ 1 - \frac{S_y(L_e/r_g)^2}{4\pi^2 E} \right] \quad (4) $$

For a tapered column, the surface area, A, varies with the height of the column. To evaluate the mechanical failure of the tapered microstructure, the general buckling formula for a straight column needs to be adapted to a tapered column by introducing an equivalent diameter. The equivalent diameter of a linearly tapered column can be calculated from Eq. 5 to analyze a tapered member [16]. This equivalent value can be used for computing the slenderness ratio and the critical load from the Euler formula and the Johnson formula.

$$ D_{eq} = D_{tip} + \frac{(D_{base} - D_{tip})}{3} \quad (5) $$

Microneedles can fail by different modes. In some cases (e.g., Fig. 1b), microneedles fail by elastic buckling, consistent with the Euler formulation (Eq. 3) used in previous models [10,17]. However, in other cases (e.g., Fig. 1c), failure of the microneedle occurs at the tapered section, which cannot be explained by the elastic buckling model. The Johnson formula (Eq. 4) should be used to evaluate the inelastic stability of this tapered column. The calculated failure force of a PLGA microneedle with 25 $\mu$m of tip diameter, 200 $\mu$m of base diameter and 500 $\mu$m of height is 0.57 N from the Euler equation (Eq. 3) and 0.24 N from Johnson equation (Eq. 4). When 0.4 N of force is applied to a microneedle, as shown in Fig. 1c, the failure of the microneedle occurs at a lower force than calculated value by the Euler equation, as shown in Fig. 1d. Because the Johnson formula was developed for straight columns, Eq. 5 is needed to determine the equivalent diameter, which should be utilized to correct the formula to account for the tapered column of the microneedle.

As shown in Fig. 2, experimental data are placed between K = 0.5 and K = 1.0, and they are well fitted to the line calculated at K = 0.7. The end-fixity factor of 0.7 is a combination of one fixed end and one pinned end, and the buckled shape approaches the fixed end with a zero slope while the pinned end rotates freely [18]. Using a value of K = 0.7 in Eq. 3 and Eq. 4 leads to good agreement between theoretical and experimental data. The value K = 0.7 means that part of the microneedle was overloaded by an axial load. The increase in the K value increases the effective length and the slenderness ratio and moves the transition point to the intersection of the solid line from the Euler formula and the dashed line from the Johnson formula.

It is evident from Fig. 2 that over the range of microneedle geometries considered, the failure mode is best calculated using the Johnson formula for shorter needles and the Euler formula for longer ones. To find the transition point, we use Eq. 1 to calculate the column

![Figure 2: Experimental and predicted failure forces of a microneedle with D_{tip} = 25 \mu m and D_{base} = 200 \mu m as functions of the microneedle length and end-fixity (K = 0.5, 0.7, and 1).](image-url)
Fig. 3. Experimental and predicted forces at microneedle failure as functions of the microneedle base diameter for a needle with $D_{\text{tip}} = 25 \, \mu\text{m}$, $L = 0.7 \, \text{mm}$, and $E = 3 \, \text{GPa}$ at $K = 0.7$.

The transition from “long” microneedles to “short” microneedles identified by comparing the slenderness ratio to the column constant can alternatively be expressed as a transitional aspect ratio of length-to-equivalent diameter for a microneedle made of a given material. For the tapered PLGA microneedles considered in the study with $E = 3 \, \text{GPa}$, the transition from the Euler region to the Johnson region occurs at an aspect ratio of 12:1.

Having varied the microneedle length/aspect ratio, we next examined the effect of microneedle base diameter with $D_{\text{tip}} = 25 \, \mu\text{m}$, $L = 0.7 \, \text{mm}$, and $E = 3 \, \text{GPa}$ on the failure force. Fig. 3 compares experimental measurements to predictions made by using the Euler formula and the Johnson formula for $K = 0.7$. The Euler region changes to the Johnson region with increasing base diameter. The transition point, where $SR = C_c$, occurs at a base diameter $D_{\text{base}} = 120 \, \mu\text{m}$. This transition again occurs at an aspect ratio of length-to-equivalent diameter of about 12:1, which is close to the transition point obtained by using the change in the length.

Finally, we studied the effect of Young’s modulus, $E$, on the failure force of a needle with $D_{\text{tip}} = 25 \, \mu\text{m}$, $D_{\text{base}} = 200 \, \mu\text{m}$, and $L = 1 \, \text{mm}$. Fig. 4 shows experimental data compared to predictions by the Euler formula and the Johnson formula with $K = 0.7$. The Euler region transitions to the Johnson region with increasing Young’s modulus, and the transition point, where $SR = C_c$, occurs at $E = 3 \, \text{GPa}$. As expected, the Johnson formula fits the data better than the Euler formula at higher values of Young’s modulus, which effectively makes needles “short.”

### III. CONCLUSION

The calculations from the Euler formula and the Johnson formula with $K = 0.7$ showed good agreement with the measured data. The value of $K = 0.7$ means that the column had fixed-pinned ends and that part of the microneedle was overloaded. Microneedle failure depended on the aspect ratio of the length-to-the equivalent diameter, and the failure mode changed from obeying the Euler formula to obeying the Johnson formula at an aspect ratio of 12:1 when the base diameter was increased and the length was decreased. Most microneedle geometries of interest for drug delivery applications (i.e., short and strong needles) were best characterized by using the Johnson formula.

Overall, this study provided a simple mathematical model to anticipate the mechanical behavior of a polymeric microneedle. Various kinds of microneedles for various applications can be designed based on this model. To avoid sudden failure of a microneedle by buckling and to be able to insert the microneedle into the skin successfully, we recommend geometries with an aspect ratio of length-to-equivalent diameter of below 12:1 and a polymer with Young’s modulus of more than 3 GPa.
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