

IS THERE A DOCTOR IN THE HOUSE? EXPERT PRODUCT USERS, ORGANIZATIONAL ROLES, AND INNOVATION

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We explore the impact on innovation that domain experts, i.e., professional end users of a product have as inventors, executives, and board members in a young organization. Using a dataset of 231 surgical instrument ventures spanning a 25-year period alongside in-depth qualitative fieldwork, we find that professional physician–users (surgeons) strengthen innovation in some roles but block it in others. These experts are related to an increase in a firm’s innovation when they take a technology role as inventors, and particularly when they take a governance role on a fledgling firm’s board. However, despite their frequent involvement in executive roles, surgeon–executives are less likely to be helpful, and especially likely to block innovation, as chief executives. Our results emphasize expert users as a critical external dependency for a young firm’s innovation, but show that expertise can backfire when there is a mismatch with a particular organizational role. A key finding is that expert users are more helpful in suggesting a broad variety of solutions to a firm’s innovation problems but less helpful in selecting the best ones for the organization to pursue. Our findings have implications for research on the evolutionary perspective of innovation, user experts and their organizational roles in young firms, and entrepreneurial policy.

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“You can’t just ask customers what they want and then try to give that to them. By the time you get it built, they’ll want something new. [And] you can get into just as much trouble by going into the technology lab and asking your engineers, ‘OK, what can you do for me today?’ That rarely leads to a product that customers want or to one that you’re very proud of building when you get done. You have to merge these points of view, and you have to do it in an interactive way over a period of time.”

—Steve Jobs describing product innovation (in Burlingham & Gendron, 1989)

Innovation makes or breaks organizations. Successful innovation depends on ensuring that customers choose the firm’s products rather than those of another provider. Thus, understanding how the products that the firm aspires to create are actually being used becomes critical.

Research on end users of products points to “professional users”—that is, users who employ a specific product in their professional life—as a particularly effective influence on firm innovation (Laursen, 2011; Shah & Tripsas, 2007). For example, professional users’ deep knowledge of the use of products may help identify new applications and desirable attributes, and avoid potential oversights in design (Ahuja & Katila, 2004). Firms can then use the information to develop a product that better fits the customer experience. When the professional user is further connected to a community of *peer* experts using the product, such ties can provide even wider access to networks of diverse and user-relevant information (Afuah & Tucci, 2012), help firms unravel end-user trends, and assist in innovative product positioning.¹ Overall, research shows that about 20% of the technologies that underlie medical devices are developed by or with professional end users (i.e., practicing physicians) (Chatterji, Fabrizio, Mitchell, & Schulman, 2008). Similarly, two thirds of U.K. manufacturing firms indicate that customers are a key source of innovation (Laursen & Salter, 2006).

Yet, the nature of the relationship between users and innovation is not obvious. Theoretically, professional users of products are tied to two opposite influences on innovation, and so present an interesting puzzle for research. One stream of research emphasizes the benefits. The key argument is that users can increase the breadth of perspectives brought to bear on solving challenging innovation problems (particularly in technology-focused start-ups)—that is, they increase *variation* (Afuah & Tucci, 2012; von Hippel, 2005). Overall, this stream highlights the benefits to firms’ R&D activities—including refreshing entrenched innovation trajectories—if the variation-increasing breadth of user knowledge can be effectively captured.

In contrast, a second stream emphasizes the limits of user impact. It points out that, despite the promise of user input, as experts, professional users may particularly have trouble accepting ideas outside their immediate expertise, and, as executives, may only have bandwidth to pay attention to a narrow range of user input, thus making *selection* of ideas too narrow and future investments in innovation too redundant and path dependent to bring in new knowledge (Christensen, 1997). As a result, users

may blind firms from pursuing emerging market opportunities.

Recent research on established firms sheds light on this variation–selection tension by suggesting that the benefits of user involvement in innovation may be contingent on the particular way in which firms engage with users. Some work highlights that, while professional users are a potentially valuable source of information for product innovation, in many cases, they reside outside the firm, and, thus, the firm may have limited means to interpret their information, lowering their actual impact. For example, users may provide comments that are too numerous to sort out the relevant ones (von Hippel, 2005: 144), or they may not provide enough richness in contextual information to interpret their comments correctly (Aral & Van Alstyne, 2011; von Hippel, 1994). Thus, selection of the best ideas may be hampered. Or, users simply may not have enough time and interest to be comprehensive or accurate enough to be helpful for a firm’s innovation. As a solution, prior research focuses on established firms’ partnering with user organizations or third-party brokers to address these limitations (Dahlander & Wallin, 2006; Hargadon & Sutton, 1997; Winston Smith & Shah, 2013).

In this study, our focus is on resource- and time-constrained young firms that often find that embedding users *within their own ranks* ensures a more effective transfer of knowledge. Consistent with this view, evidence suggests that user roles in young firms have practical import, although we have more limited theoretical understanding of them. Two out of three young firms in the medical sector, for example, employ professional users in *organizational roles*² (Zenios, Burns, & Denend, 2013). The roles that users take in these new firms vary in their demands, however, which suggests that attention to these differences may help us reconcile the variation–selection tension that is prevalent in prior work on user innovation.

Given these findings, the question then becomes how users can be best engaged in appropriate organizational roles in a young firm. Drawing from roles research, we suggest that tasks inherently related to a particular role can selectively *activate* different parts of a user’s expertise and so influence the behaviors and the choices about innovation the role occupant makes. In particular, we examine whether

¹ While studies on casual users of products provide considerable insight (e.g., recent work on crowdsourcing), casual users differ from professional ones and are not our focus.

² Organizational roles comprise of a set of tasks that the occupant of a role takes responsibility for (Mintzberg, 1979).

placing an expert user in a particular role in an organization can help activate the beneficial (variation-increasing) effects of user input and avoid the harmful (selection-narrowing) ones.

To address this question, we draw from prior research on innovation and organizational roles to ask: *How are professional users in various organizational roles related to product innovation in young firms?* We refer to an extensive customized panel dataset of 231 surgical instrument ventures over a 25-year period to investigate this question. As specially designed tools and devices used by surgeons during operative and invasive procedures (Nemitz, 2013), surgical instruments are utilized by highly educated professional users (i.e., physicians), making the setting especially appropriate for testing our research question. The field of surgical instruments is also an opportune research setting because it has many new firms and particularly reliable measures of innovation. We supplement the data with fieldwork, including interviews with physicians, investors, and venture executives, to deepen our understanding of the phenomenon.

There are several contributions made by our study. First, there are rich implications for the *evolutionary perspective* on innovation. Consistent with the variation–selection view of innovation (Katila & Chen, 2008; March, 1991; Nelson & Winter, 1982), we classify each organizational role's innovation tasks by their *variation* versus *selection* emphasis, and generate theory and empirical support about how typical tasks in a role activate different parts of professional user's expertise, with performance consequences for innovation. Innovation benefits when the role's tasks emphasize variation over selection (user–inventor) or combine the two (user–board member). Strikingly, innovation is undermined when the role's tasks are reversed to emphasize selection over variation (user–CEO).

One alternative explanation for these empirical findings is of course that the quality of users drawn to a particular role goes hand in hand with the innovation quality of the firm. However, our empirical analyses (using firm fixed effects, a rich control set, inverse probability of treatment weighting (IPTW), and a wide range of other robustness tests including instrumental variables) suggest that this is probably not the chief explanation. Rather, an explanation that emerges is that users can be helpful by expanding the variety of ideas to solve a firm's innovation problems, but are significantly less helpful (or not helpful) in just improving their selection. These mechanisms are then likely to explain why innovation is most significantly

related to user–inventors and user–board members, but not to user–executives.

The findings contribute to research on *user innovation*, and particularly to research on the benefits and the curse of domain *expertise*. We find that expert users can add to a firm's innovation process above and beyond their contributions to just generating inventions, which is more commonly studied. They play a host of significant roles that span product development and can help the firm transform inventive ideas into products. But, because they do not have all the skills needed for innovation, user expertise also carries limitations that we identify. One particularly interesting finding is that physicians in the role of a chief executive officer (CEO) slow innovation down. Thus, we identify a more nuanced relationship between professional users' involvement during the early years of an organization's life and innovation. Overall, our findings show that innovation influence varies with one's organizational role, not only with the presence or absence of expertise.

Our findings are potentially also relevant for *policy*. Recent legislative efforts in the USA (i.e., the Physician Payments Sunshine Act) have resulted in reduced involvement of physicians in medical device firms. Yet, our findings suggest that physicians play a host of significant roles in young firms' product development, and so a more nuanced policy would likely be more effective to sustain innovation. Because early decisions about which types of people to hire have staying power (Baron, Hannan, & Burton, 1999), blocking physician–users from early roles may have a particularly damaging effect on diversity, and on innovation in the long run.

RESEARCH BACKGROUND

Variation, Selection, and User Innovation

Research in evolutionary theory confirms that successful solutions to a firm's innovation problems result from generating a variety of new ideas and skillfully selecting a few to commercialize (March, 1991; Nelson & Winter, 1982). One stream of user innovation research suggests that professional users can help the firm with variation and possibly also with selection. Professional users can help increase *variety* of ideas (e.g., reconnect a technology-focused firm with the market), including information about what new products should look like and who might buy them. This is because, as experts, professional users typically have broad understanding of

emerging user needs through their own professional experience and through their professional networks, and a high propensity to share and test ideas with other users within their professional communities (Dahlander & Frederiksen, 2012; Franke & Shah, 2003). Professional users can also potentially help endorse ideas that are likely to be received well by many other users. Because of their deep knowledge of products and their applications, professional users may help a firm develop and test products more effectively before they reach the market and prevent the firm from proceeding down poor development paths that may be costly to reverse. Altogether, this stream of research suggests that users may help a firm dislodge innovation trajectories and guide the firm to develop solutions that are desirable to implement.

In contrast, other research warns about users' tendency to *select* familiar choices that kill innovation. As experts in their domains, professional users may struggle to put aside entrenched problem-solving patterns when they try to create something new (Dane, 2010; Hinds 1999; Nelson & Irwin, 2014). To make decisions, experts have a tendency to rely upon background expertise—that is, “knowledge structures” and shortcuts they have developed through prior experiences (Ocasio, 1997; Walsh, 1995). While it can expedite decision-making, such expertise can also prove limiting as entrenched knowledge structures have trouble accommodating new or changed pieces of information. Such negative influences particularly block innovation when firms narrowly pay attention to the wishes of their “best” user—customers and, in the process, become blind to new and different opportunities (Christensen, 1997).

Overall, background expertise (i.e., in use of a product) is likely to influence the skills and resources as well as the biases and dispositions individuals bring to a particular role. Our argument is that a user's organizational role can determine when each influence (positive or negative) is dominant.

Organizational Roles and Innovation

To deal with the tasks of a growing organization, young enterprises typically turn responsibility for specific tasks over to particular organizational roles (Jung, Vissa, & Pich, 2017; Sine, Mitsuhashi, & Kirsch, 2006). Having formal roles enables firms to increase decision-making speed because “everyone knows exactly what to do” (Mintzberg, 1979: 83) and whose role it is to do which task (Higgins & Gulati,

2006; Merton, 1957). Having formal roles also makes coordination about resources with other roles effective (Beckman & Burton, 2011; Ferguson, Cohen, Burton, & Beckman, 2016).

Much organizational roles research on young firms centers on “role competence”—that is, finding an individual whose expertise matches the tasks of a particular role. The argument is that, when an individual possesses appropriate expertise and resources (Ferguson et al., 2016) and when their background helps them effectively interpret situations they face in a role (Almandoz & Tilcsik, 2015), they are more likely to succeed in it. In Higgins and Gulati's (2006) study, for example, the authors linked favorable investor outcomes to a match between an individual's role in the new biotechnology venture and their past experience in similar roles (such as a chief scientific officer position being filled by someone with a background in engineering).

Although the role competence perspective dominates, a stream of organizational roles research has emerged to look at how a particular role anchors the role occupant's attention and behavior. This stream implies that tasks inherently related to a particular role can selectively activate (i.e., call to mind) different parts of the role occupant's expertise and so influence the behaviors and the choices about innovation the role occupant makes. In a study involving established firms, Dahlander, O'Mahony, and Gann (2016), found, for example, that tasks in a role that an individual held determined which professional network ties (variation vs. selection oriented) individuals reactivated to get information relevant to performing a particular innovation task.³

The key argument about organizational roles relevant to innovation is that, when a role does not give enough opportunities to practice variation-seeking creativity, these skills are not called to mind and thus stay dormant, and, rather, the role makes individuals reflexively apply past practices. For instance, Mizruchi and Stearns (2001) found that, when a particular organizational role emphasized breadth of perspectives (finding out information), experts were likely to interact with a wide range of other people and tap into a diverse network of ideas

³ Dahlander et al. (2016) observed how engineers at IBM changed their innovation search behaviors to match the particular role they held, such as allocating more time to cultivating external, and cutting internal ties as their role changed.

to get a task done. In contrast, when the emphasis of a role was to get consensus to pursue a course of action (select an idea and reject several others), the same individuals tended to turn to a few trusted ties to seek confirmation, and, in the process, inadvertently missed probing and criticism from the wider network to question habitual practices and potentially make higher-quality decisions. Berg (2016) extended these findings to show that expert individuals who changed from creative to managerial roles started to make tried-and-true choices that killed variety (and stopped making choices that promoted it). Although Mizruchi and Stearns (2001) examined bankers who made decisions about high-uncertainty deals, and Berg (2016) experts who predicted the success of new circus acts, it seems likely that different aspects of being an expert user of a product can be similarly activated to contribute to innovation, depending on the organizational role the user is embedded in. This is the research gap that we address.

Innovation Roles in Young Firms

Three types of organizational roles are particularly relevant for innovation in a new firm: technical, executive, and governance.

Technical roles. As part of an organization's "technical core," occupants of technical inventor roles influence a young firm's innovation. Inventors are expected to generate *variety*—that is, to find novel and different solutions to the firm's technology and customer problems. In their role, access to and understanding of diverse domains of knowledge and expertise is emphasized and tied to more innovation (Hargadon & Sutton, 1997).

Executive roles. A young firm's executives mediate between the organization's technical core, which generates ideas for products, and the customers who buy them. Executive roles thus center on *selecting* from a variety of technical solutions a few feasible alternatives for the organization to implement.⁴ CEOs in particular are responsible for a broad spectrum of such tasks, including crafting a product strategy, building a brand, and visiting and nurturing first customers. In their roles, executives also assume responsibility for formalizing processes for implementation—that is, they manage the flow of innovations through a firm's product pipeline to the market.

⁴ Typical executive roles in a young firm include chief marketing officer, vice president of engineering, and the CEO.

Governance roles. Venture boards help firms as they generate a *variety* of ideas for innovation, and participate in the *selection* of relevant ideas to execute. In a young firm, a board member is often asked to join in order to bring in specific expertise related to a technology or a product (Garg, 2013) or a critical interface to an early customer (Wasserman, 2012). Boards thus add variety to the firm's in-house expertise of spotting technology and market opportunities and recognizing product voids in the current market. Second, boards are in charge of monitoring executives' decision-making (Hillman & Dalziel, 2003). Board members' role is to ensure that major decisions about innovation and new products are aligned with interests of investor-owners and the firm. Because venture boards meet frequently, they ratify or turn down a range of decisions from resource provision and spending actions (such as major product launches) to operations and strategy (Daily, McDougall, Covin, & Dalton, 2002; Garg, 2013). Altogether, the innovation task of board members involves both variation and selection seeking.

HYPOTHESES

The hypotheses below propose arguments about the innovation influence of professional users in organizational roles. We examine the key innovation roles in a young firm: users as inventors (technical role), users as members of the executive team and as the CEO (executive role), and users as directors on the firm's board (governance role).

User-Inventors

Because new variations are necessary to provide a sufficient amount of choice to solve a firm's innovation problems (March, 1991), success in the inventor role depends on an individual's ability to source *diverse, new raw material* for innovation. Because user-inventors have direct experience and knowledge within the product domain, and also frequently rely on their network connections to seek and share information (Dahlander & Frederiksen, 2012), they are a good source of fresh ideas for product development, especially in technology-focused start-ups. The variety that users provide is also relevant. In the words of an interviewee, user-inventors provide "the interface between the rest of the physicians you interact with and the engineering." In an extreme case, one interviewee explained to us how product

development can be derailed if user perspective is ignored:

I have a friend who is [a founder] of another company . . . very experienced [non-physician entrepreneurs] creating a surgical device. But, they were so focused on developing the product that they didn't get out with the customer. Once they got out to the market, the customers didn't like the product . . . You need the physicians on the back end.

Overall, because inventors are expected to generate a variety of solutions in their role, user-inventors can assist innovation by exposing the firm to a broad range of relevant user problems and solutions.

Second, filling an inventor role with a user is helpful because the variety that users can provide is more *contextualized* than what non-users provide, which helps engineers in the development of a firm's products. One of our interviewees explains, "Everything the physician says is potentially valuable, but a lot of it is potentially irrelevant if you don't put structure around their feedback." Non-user inventors are thus less likely to receive and transmit equally rich and well-rounded understanding of user preferences, because external users are not likely to devote substantial time and energy to communicating to them what they know and feel. A related issue is that users often possess intricate and hard-to-communicate (i.e., "sticky") knowledge about products and their usage that is critical to developing viable products but challenging to source (von Hippel, 1994; Sánchez-González, González-Álvarez, & Nieto, 2009). A non-user entrepreneur described the challenge of developing a device without a background in medicine as follows: "The first technical challenge is understanding the actual nature of the problem. There's often a lot of guesswork involved, because we can't observe [anatomical problems] directly . . . [You have to] ask the doctor what the problem is." It may be especially difficult for external users to communicate all of the necessary contextual details of this "sticky" knowledge when their interaction with a firm is limited. In contrast, because of their background as users, user-inventors are able to "unstick" and interpret this information faster. Our interviews relayed that physician-inventors within the organization's own ranks could more effectively communicate to designers ways to optimize the product, such as specific material properties that an instrument needed to have (e.g., where it needed to be stiff, where it needed to be flexible). Physician-inventors were also able to identify "predictable" problems that would otherwise stymie successful product development, ultimately

requiring fewer design iterations and a more effective overall development. As one physician stated:

I think I have a better perspective than the engineers. I know a lot about the products and materials. [Start-up engineers typically] have never practiced medicine. I can integrate because I handle these things [use medical devices]. I know how doctors think because I am one . . . It's easier for me to assimilate design concepts.

Thus, by incorporating users directly into the firm's product development process in inventor roles, engineering and product development can more directly and continuously draw on a richer understanding of user information.

However, after a certain point, we propose that the presence of more user-inventors in a young firm will become a liability for innovation. First, user-heavy inventor teams risk losing the idea *variety* that underlies effective innovation. There are now diminishing returns to adding yet another user expert because the likelihood of adding qualitatively different ideas is lower. Moreover, because the "accepted" view to think about innovation increasingly becomes that of a product user's, and, in the process, the team is less frequently exposed to other perspectives, it is likely that teams staffed by many users become more limited in their exploration of new innovation alternatives and less likely to add alternatives that diverge from their shared past experience. Consistent with this argument, research shows that teams of experts that share the same background are prone to being trapped in "local peaks" and rarely take "long jumps" to new areas because searching information that is familiar to the majority is faster and easier (Katila & Ahuja, 2002), hurting innovation. Overall, information that user-heavy inventor teams source is likely to become too narrowly focused on the familiar, killing variety, and thus making extensive user influence problematic for innovation.

Second, when the proportion of user-inventors reaches high levels, the team loses skill *diversity*. It will not have enough attention or expertise to evaluate the technical feasibility of ideas—that is, counterbalance the ideas generated from the demand perspective with expertise related to technology and engineering. Consequently, in user-heavy teams, technical feasibility is less and less frequently considered with rapidly escalating consequences for innovation. Parallel examples from consumer electronics suggest that, when products become packed with "too much innovation" and are driven mainly

by employees who do “not necessarily understand how product technologies work,” technology problems may become excessively complex and uncontrollable (Chen & Sang-Hun, 2016: B5), suggesting that costs of user expertise will rise at high levels and eventually exceed the benefits. As one interviewee explained to us, “Some physicians . . . may have ‘pie in the sky’ ideas that aren’t [feasible].” Chasing such “false positives” is particularly damaging for resource-constrained young firms, leading to negative effects on innovation at high levels of user embeddedness. Thus, we propose:

Hypothesis 1. The proportion of users in technical roles is curvilinearly (taking an inverted U-shape) related with a young firm’s innovation.

User–Executives

User–top executives. In their role, executives are the “gatekeepers of innovation” in a young firm. Because the value of product ideas is ultimately decided by the market, it seems likely that filling some executive roles with users who understand demand trends can help a firm make better decisions about which product ideas to select for implementation. As a venture CEO explained, “We are operating in a new segment of the market, so it’s helpful to have a [physician] executive who knows the customer population well. This helps us better identify who the best customers for our product are.”

Furthermore, because they understand the firm’s resources, a user in an executive role is uniquely positioned to triangulate user needs with the firm’s existing commitments, and so enable a more effective selection of which solutions to endorse for innovation. For example, user–executives know the typical evolution of patient conditions and potential complications, as well as the firm’s product strategy and resource position, and how the two factors might interact. As a physician–executive explained, “[Being a physician–entrepreneur] makes the clinical implications of what we’re doing real, and what the ramifications are if something goes wrong. It gives me more confidence and ability to do risk–benefit tradeoffs.” Altogether, because they know the firm and the user, user–executives can effectively evaluate the consequences of the firm’s project choices making innovation more effective.

However, after a certain level, the presence of more user–executives in a young firm is likely to start to obstruct innovation. First, executive teams staffed by users in high proportions are at risk of making

habitual choices without critical evaluation of alternative strategies, thereby reducing novelty. This is because a product offering that overlaps with past products is processed more fluently (and more shallowly) by a team dominated by those who have used similar products in the past, biasing consideration of alternatives more toward those that are familiar and less toward those that would offer fundamentally different solutions for the market. By contrast, we expect teams that retain multiple viewpoints to make better decisions about innovation because they consider more alternatives and evaluate the alternatives more carefully, and so are more likely to retain diversity in selection. Consequently, user-heavy teams are likely to underestimate the value of ideas that are new to them (i.e., reject or completely overlook new, potentially promising product concepts) and to overestimate the value of ideas that they know well (i.e., embrace familiar, less novel ones). These errors particularly hurt innovation that depends on novelty (March, 1991).

Second, users may simply have less skills with which to formalize processes that have been linked to high-performing commercial innovation, and so underestimate the business challenges linked to implementation. As one interviewee explained:

Being an MD doesn’t always help with the business side. I have two cofounders who I’m constantly educating on the business side of it. They get frustrated when doctors don’t buy products right out of the gate. Things like that are constantly a surprise to them.

Another entrepreneur observed, “You are trying to make business-driven decisions, but [physician–users in the executive team] aren’t helpful.” As a consequence, then, user-heavy top teams are unlikely to take product ideas to market effectively because their skill set is too narrow for them to be effective executives. Overall, while more users in executive roles initially increase innovation, at very high levels, rapidly escalating challenges in business evaluation and implementation begin to hamper innovation, reducing the number of products that reach the market. Therefore, we propose:

Hypothesis 2. The proportion of users in executive roles is curvilinearly (taking an inverted U-shape) related with a young firm’s innovation.

User–CEO. The CEO is the most senior, and likely the most central and influential, single role in a young firm’s executive team. At the helm of a young firm, it is the CEO who makes the ultimate selection, should competing market and technology ideas

emerge from lower levels of the organization. The CEO role is also unique because, relative to others in the executive team, the CEO deals with the most diverse cognitive load and with the most time pressure to converge on a single path for the organization to follow—a challenging task, given the ambiguity and chaotic decision environments in young firms. In light of the tasks, we argue that the CEO role is particularly likely to highlight the liabilities of user expertise, and make user-CEOs prone to selecting in a narrow way, possibly damaging innovation.

First, the flexibility in thought that is required of a CEO to make strategic decisions about future products is often lost when a user is placed in the CEO role. Due to the role's pressures and decision ambiguities, especially in a fledgling, young organization, the CEO is particularly likely to "manifest personal preferences and energies into organizational outcomes" (Hambrick & Fukutomi, 1991) and thus be influenced in selection by past experiences, including as user of products. By contrast, new product alternatives that are less familiar to the user-CEO, but potentially offer more novelty for innovation, require more analytical processing and more time (Alter, Oppenheimer, Epley, & Eyre, 2007), which CEOs typically do not have. Therefore, they are less likely to be carefully considered by a user-CEO, and more likely to be underestimated and falsely rejected. Consistent with these arguments, one physician-CEO proffered, "If you show me a prototype, I can say, 'Well, you could do this better . . . I know very well how to help a company optimize its product . . . but I don't know how to invent something that was never invented before.'"

Second, the firm's "best" customers often keep the CEO (and the user-CEO in particular) captive with existing user and technology trajectories even when new and better ones exist (Christensen, 1997; Laursen, 2011). This is because alternatives related to such key customer experiences are processed more fluently and with fewer resources and less time, particularly by the user-CEO who typically interacts extensively with the first customers. This biases decisions toward alternatives that are familiar (e.g., corresponding to the young firm's first customers), but are too redundant and local to bring in new knowledge.

Third, selection of innovation alternatives is inherently multifaceted and requires skills (e.g., business, administrative) that users typically do not have—although many user-CEOs we interviewed believed they had them—leading to poor

decisions about implementation. As one investor explained:

[Physicians] don't have much business acumen, and you're constantly having to educate them about what you're doing and why . . . I think the risk of being an MD is that you don't have the right set of skills and experiences to be a CEO.

Another interviewee noted:

There are some skillsets that full-time entrepreneurs have—business plans, projections, budgets, etc.—that most physicians don't have. As a physician-entrepreneur, it's hard to develop all of those skills. Others are better suited to run the company . . . There are very few MDs who make great day-to-day CEOs . . . the nitty-gritty of business, that is probably [an MD's] greatest weakness.

Altogether, we propose that user-CEOs have a negative effect on innovation in young firms because they lack the flexibility in thought and behavior and the broad administrative skillset required to address the range of higher-order, innovation-related tasks (from product strategy to implementation) that fall under their purview. Overall, users who become CEOs find themselves in an organizational role that de-emphasizes their unique ability to interpret user knowledge and instead highlights their most common deficiencies in management and opportunity evaluation. Therefore, we suggest:

Hypothesis 3. A user in the CEO role is negatively related with a young firm's innovation.

User-Board Members

In a young firm, a significant task of a user-board member is to add variety to the firm's internal efforts to source raw material for innovation. For instance, venture board members can plug critical resource deficiencies in technology, development, and distribution, and add information that top executives may not have but need as they plan the firm's product vision (Thiel, 2014; Wasserman, 2012). Our interviewees told us that a user on the board can, in particular, "provide strategic direction" for a firm's executives and help them "intuitively" understand customers, thereby helping the firm innovate. Our interviewees also described effective board members who brought knowledge of sectors and stage-specific guidance and therefore provided sound strategic advice for product development. Because the board brings together experts from several

domains, and because venture boards meet often, user-board members are also likely to be frequently exposed to uncertainties in what they thought were established cause-and-effect relationships related to product use. Because research shows that such exceptions or counterexamples to what is believed to be true are needed to shake existing knowledge structures and revise them (Starbuck, 1996), we expect that users on a young firm's board may have a more open mind in proposing a variety of alternative solutions, and that they are likely to remain open to probing a wider range of possibilities for product solutions. This is important because the quality of the board's final solution depends on good alternatives.

Second, user-board members can also positively influence innovation by making the firm's selection of product solutions both more relevant and more wide-ranging. For instance, a board's role is to serve as a reality check on the tendencies of founders to be overconfident and passionate about technology or early products (Wasserman, 2012: 273) and expose product-related ideas to early probing and criticism before resources are committed down a particular development path. As one non-physician CEO elaborated, "Our board MDs help challenge us on things such as our clinical study designs, making sure we have clear understanding of endpoints, and whether they will be significant enough to get a fair reimbursement." Some user-board members also help more directly by testing products and so better position the firm's product offering. As one medical device entrepreneur told us:

One of our big supporters was a physician, an electrophysiologist. He came onto the board. He wasn't a business guy, but he was very good at the procedure . . . He gave us a lot of confidence and feedback on the early development. He also did a bunch of clinical cases . . . very important feedback.

He further elaborated, "When you get to the design phase, you need the interested parties involved so you can get their feedback. You don't have the luxury of doing 1,000 cases. [That board member] was critical."

However, after a certain point, a higher proportion of user-board members is likely to impede innovation because adding one more physician is likely to be only incrementally more useful, and unproductive status struggles and excessive coordination costs excessively less useful, eventually making it difficult for the board to effectively carry

out the tasks. In particular, our interviewees pointed to dynamically increasing coordination costs when too many physician-experts were embedded. One of our non-physician CEOs offered this insight: "Having one strong medical voice on the board is adequate . . . [to complement this] we typically need other types of skills among our board members that MDs cannot provide." Our interviews also suggested that having high numbers of users on a board dilutes the perceived importance of any one user's expertise and can lead to disruptive status conflict. A senior partner at a health care consultancy firm explained that high numbers of physicians on a board often led to jockeying for position as the board's "ultimate" medical authority, which severely distracted from the actual purpose of the board meeting. Thus, ventures with too many user-directors may find themselves with undisciplined boards that are less able to put forth new ideas for innovation and less effectively monitor the firm and guide innovation, ultimately leading to the costs of user involvement exceeding its benefits. We propose:

Hypothesis 4. The proportion of users in board member roles is curvilinearly (taking an inverted U-shape) related with a young firm's innovation.

METHOD

Sample and Data Sources

We analyzed the relationship between user roles and innovation in surgical instrument ventures over a 25-year period from 1985 to 2009. The sample of ventures was drawn from the population of U.S. investor-backed medical device firms that received their first round of venture funding between 1985 and 2005. We chose young ventures because of their need for external resources for innovation, and because of their offers, as resource-poor organizations, of organizational roles to outside experts. We also chose young firms because of their relatively flat organizational structures; young firms rarely have deep hierarchies or compartmentalization (Mintzberg, 1979; Sine et al., 2006), which makes it especially likely for executives to be directly involved in innovation. We chose investor-backed firms because their success in attracting external funding indicates that they are technically and strategically viable (Davila, Foster, & Gupta, 2003) and therefore able to gain user ties. We also chose investor-backed ventures because, while not all young firms have formal executive roles and

many do not have a board, as standard practice, investors typically formalize these roles during the first investment round(s) (Wasserman, 2012). This makes our core interest of users in executive and governance roles relevant and consistently measurable across the sample firms.

We began the sample in 1985, because several new technologies that underlie new products in surgery were introduced in the mid-1980s (e.g., minimally invasive surgical tools), making the year 1985 a natural breakpoint in the industry's history and product development opportunities (Xu, Avorn, & Kesselheim, 2012). We concluded our sample selection with the firms founded in 2005, but continued data collection for all firms until 2009 because ventures typically take between five to seven years to experience a liquidation event, such as an initial public offering (IPO) or an acquisition (Fenn, Liang, & Prowse, 1995). Ending with firms founded in 2005 thus enabled us to follow most sample firms through their tenure as private firms and gain a more complete picture of their actions.

We chose "surgical instruments"—that is, specially designed tools and devices for operative and invasive surgical procedures—because they are used by surgeons (i.e., highly educated professional users) (Cassak & Levin, 2006; Wells, 2010). Many other medical devices, such as diagnostic tools (e.g., x-ray machines or wearable monitoring devices), are more often used by technicians, nurses, or patients than by physicians (Barley, 1986). Surgical instruments, in contrast, are primarily used by physicians and are thus open to high levels of professional user influence.

We also chose surgical instruments because their users (surgeons) are part of a professional community of practice and are highly educated. Communities of practice are particularly important in the medical field and allow for the dissemination of information and influence and for the refinement of ideas. High levels of education suggest access to social and human capital that can further contribute to young firm innovation.

To develop a comprehensive and accurate database of surgical instrument firms, we triangulated data from Venture Economics with data from VentureOne. Each database relies on unique yet complementary sources: Venture Economics compiles data from investors, while entrepreneurs are the source for VentureOne data. Both databases have been used extensively in prior research and shown to provide an accurate and comprehensive coverage of investor-backed ventures in the USA (Kaplan,

Sensoy, & Strömberg, 2002). As did prior work (Katila, Rosenberger, & Eisenhardt, 2008), we began by forming the sample from Venture Economics, and then corroborated data and identified missing information with data from VentureOne. By using these two databases, we compiled data on 4,033 investor-backed medical device firms. We identified surgical instrument firms using the category's industry classification (i.e., surgical instrumentation, equipment, and lasers, verified by two industry specialists). We then used business descriptions of the sample firms to identify those that developed surgical instruments and excluded those that only manufactured or distributed devices but did not develop them. The final sample was 231 surgical instrument firms.

Our data collection provided detailed information about firm characteristics, including founding and exit dates, investors, and key personnel. Our primary list of *executives* and *board of directors* for each firm (i.e., name, title, start and end dates of employment) came from the two venture databases. We supplemented our primary data sources with additional information on executives from Capital IQ, FactSet, Thompson/SDC Platinum, Lexis-Nexis, ReferenceUSA, Mergent, D&B Million Dollar Database, the Corporate Technology Directory, and the Medical and Healthcare Marketplace Guide. These additional sources were particularly useful for crosschecking data, as they helped sort out ambiguous terms such as "director" or "founder," and enabled a more accurate picture of each executive's tenure at each firm to ensure accuracy.

We gathered data on the young firms' *inventors* from patent documents from the Delphion patent database and additionally used Who Owns Whom directories to track subsidiaries and accurately assign patents to each firm. Inventors were the individuals listed on each patent. Because prior work has noted that inventors are sometimes not uniquely identified (the same person may appear under different combinations of initials and names in patent documents, and there can be multiple inventors with the same name), we used the Trajtenberg, Shiff, and Melamed (2006) and Miguélez and Gomez-Miguélez (2010) matching algorithm, which has been shown to be robust in correcting for misspellings and identifying a unique list of inventors. As part of this algorithm, the Soundex coding method is applied to check for phonetic spelling variations in the names of inventors listed on patents. We grouped names with similar Soundex codes and then differentiated between them using the middle initial, city, state,

and country to arrive at a unique list of inventors yearly for each sample firm.

The American Medical Association (AMA) Physician Masterfile was used to identify board-certified physicians (i.e., *professional users* in our executive, board, and inventor data). The AMA Physician Masterfile is a comprehensive listing of doctors of medicine (MD); that is, the more than 1.4 million individuals who entered medical school, began post-graduate residency training, or obtained a medical license in the United States. It is the primary data source for verifying a physician's credentials in the USA, and it is highly accurate. As physicians progress in their careers, completing educational requirements and adding additional certification, their Masterfile records are updated. Records are never removed, and include both current AMA members and non-members. Because education (and the related professional training) regulates access to the profession and to jobs, using the Masterfile to identify professional users is appropriate. We matched our data on venture inventors, executives, and board members with the AMA Masterfile data to identify physician-users in each role. We matched on the first and last names and middle initials to obtain accurate matches. If a middle initial was unavailable, we additionally matched on geographical location. If there was still no match, as a final step, we matched by hand, using the cities within 50 miles from the zip code to account for potential relocation over time.

We also collected data on each firm's product innovations from the U.S. Food and Drug Administration's (FDA) databases that track medical device product approvals. We compiled exit and restructuring events as well as name changes for sample firms in order to correctly assign approvals for each firm.

As part of this study, we also conducted a series of interviews with physicians, medical device entrepreneurs, investors, and industry experts. We spoke with physician-entrepreneurs, medical device entrepreneurs who were not physicians, and physicians who were not entrepreneurs. We spoke with industry participants who were involved in the early stages of the study's time frame, and with those who were involved later. This fieldwork supplemented our quantitative data collection, helped to sharpen the quantitative measures, and assisted the interpretation of our results.

Measures

Innovation. Following Laursen (2011), we measured innovation using yearly counts of *product*

approvals for each sample firm. Product approvals are an appropriate measure of commercial innovation because FDA approval is mandatory for any surgical instrument to be sold in the United States, and it demonstrates feasibility, effectiveness, and innovativeness of the product concept. A new product introduction typically closely follows.

We collected annual data on product approvals received by each firm. There are two types of FDA device approvals: 510(k) (i.e., premarket notification) and PMA (i.e., premarket approval). The type of approval depends on a device's novelty and on potential risks to patient safety. Devices that are substantively similar to previously approved ones qualify for a 510(k) approval, whereas radically novel devices require a PMA approval, but the latter are relatively rare (about 3% in our data). We included both types of approvals that a firm received in a given year to measure products. We analyzed effects of both in aggregate, as well as 510(k) approvals separately, with consistent results.

Independent variables. We operationalized user involvement in roles by four time-varying independent variables. To obtain the data, we first cross-referenced individuals against the AMA Physician Masterfile as described above and flagged as users those individuals who were board certified. As noted above, this is an appropriate measure of professional users because nationwide training and certification requirements draw clear boundaries around which individuals qualify as a physician, and make it straightforward for both firms and other physicians to verify someone's status. It is also a particularly relevant measure of professional users because research views as experts in a domain those who have obtained a membership or certification within a professional community, such as law or medicine (Rothman & Perrucci, 1970). Once certified, physicians join a well-established professional community of practice that brings them into frequent contact with other practicing physicians. In all variables (except the user-CEO), we used percentages to yield proportions of users in a role rather than absolute numbers, as did Higgins and Gulati (2006), because the number of users is likely to co-vary with the size of each team.

We measured *user-inventors* as the yearly percentage of inventors listed on a firm's patents that were board-certified physicians. Because incorrect attribution of patent inventorship may invalidate the patent (Nerkar & Paruchuri, 2005), users listed on a firm's patents are an appropriate measure of user involvement in invention. As did prior work, we

used a firm's patents applied for (and subsequently approved) in a particular year.

We measured *user-executives* as the yearly percentage of a firm's senior executives who were board-certified physicians. User-executives is an appropriate measure of user involvement in executive roles because, as noted above, selection of senior executives is purposeful in investor-backed firms. Executives in our sample encompassed typical executive positions in a surgical instrument venture, including general business functions (finance, e.g., chief financial officer; marketing, e.g., vice president of marketing; CEO; and R&D, e.g., chief technology officer) and roles specific to biopharma firms, such as chief medical officer and vice president of clinical and regulatory affairs. In a sensitivity test, we dropped the nonlinear term of user-executives and our original results remained.

We measured *user-CEO* with a binary variable set to 1 if the firm's CEO in a particular year was a board-certified physician and 0 otherwise. Although co-CEOs are typical in some industries, we checked and found no such pattern in our data. We also ran the results including a control for user-founders (Shah & Tripsas, 2007).⁵ As expected, the effect on innovation of user-founders was positive, while the pattern of original results held.

We measured *user-board members* as the yearly percentage of a firm's board members who were board-certified physicians. User-board members is a particularly appropriate measure of user influence in governance roles because, in investor-backed firms such as those that we studied, every board seat is carefully allocated (Wasserman, 2012). The use of proportions to measure user influence again follows prior work that typically measures board composition as the percentage of total directors with a particular attribute (Almandoz & Tilcsik, 2015).

Because it is possible that individuals in young firms are embedded in multiple roles simultaneously, we ran our results (a) by counting each individual in every organizational role that they occupy, and (b) by assigning each individual with multiple roles to a single role. We used several methods to assign individuals to a single role,

including random assignment and hierarchical ordering by most dominant role (CEO > non-CEO executive > board > inventor; or, inventor > CEO > non-CEO executive > board). We re-ran our models on these different datasets with different assignments and our results held. This indicates that roles rather than individuals are likely driving the results, as we hypothesized.

Controls. Because firms can become more skilled at innovation as they age, we controlled for *firm age* in years between the year the new firm began operations and the current year. We also ran models in which we controlled for *funding round* instead of firm age, with similar results. Because the availability of financial resources is likely to influence a young firm's innovation, we also controlled for *capital raised* by the cumulative inflation-adjusted funding raised by the firm in thousands of U.S. dollars (Stuart, Hoang, & Hybels, 1999). We logged the age and capital raised variables to account for skew.

Because prominent venture capitalists (VCs) may be particularly likely to influence innovation, as they may have better connections and more powerful influence, we also controlled for a firm's relationship with a *high-status VC*. We used a VC's eigenvector centrality in venture capital syndication networks to assess its prominence (Bonacich, 1987) and measured high-status VC partner with a binary variable set to 1 when a sample firm gained at least one investment from one of the top 30 most high-status VCs and 0 otherwise.

Because we wanted to isolate users' (particularly user-inventors') ability to support commercial innovation beyond their ability to assist technical innovation, we controlled for yearly *number of patents* for each firm.⁶ Patents are an effective measure of the firm's technical invention because patents are effective in protecting intellectual property in medical devices (Cohen, Nelson, & Walsh, 2002). We measured patents with a two-year lag because our interviewees described a one- to two-year lag of introducing patented ideas to market in surgical instruments. We logged the variable to account for skew. In a sensitivity analysis, we also tested

⁵ Because we had missing founder data on a large number of firms, and because founders can take many roles, including a board-director role, a key executive role such as the CEO, or no formal role at all (and the data that we have on specific founder roles is not complete), we analyzed an aggregate user-founder variable in a sensitivity analysis only.

⁶ In a sensitivity test, we estimated how user embeddedness in organizational roles influences technical (patents) rather than commercial (products) innovation. As expected, user-inventors had a strong positive relationship with technical innovation while users in executive and governance roles had not. These results are available from the authors.

user–inventors' influence on innovation without controlling for patents. As expected, the user–inventor coefficient then became slightly larger in magnitude while other results were consistently supported.

We also controlled for regional entrepreneurial development. Because localized social capital (Laursen, Masciarelli, & Prencipe, 2012) and knowledge spillovers (Owen-Smith & Powell, 2004) in areas of high entrepreneurial activity may spur innovation, we included unreported variables for three regions known for their medical device entrepreneurial density and sophistication; namely, the *Boston*, *San Francisco*, and *Los Angeles* (Orange County) regions. We measured location by an unreported binary variable coded as 1 if a new firm was headquartered in one of the metropolitan area zip codes associated with one of the hubs and 0 otherwise. The new firm's location was collected from Venture Economics (or, if needed, from VentureOne and Lexis-Nexis). In sensitivity tests, we interacted region dummies with a time trend (of the three regions, San Francisco's influence increased over time) and also added *metropolitan statistical area (MSA) fixed effects* to control for "local shocks" in a venture's local geography that may influence resources and innovation (Samila & Sorenson, 2010), measured with a dummy variable that equaled 1 if the young firm was located in a particular MSA and 0 otherwise. Results (available from the authors) were again consistent.

We included controls for the year to capture any *temporal effects* that might contribute to venture innovation, such as macroeconomic conditions, beyond those for which we had directly controlled. We operationalized these effects by unreported year dummies. Lastly, we included a lagged dependent variable (*lagged product approvals*) to control for time-variant unobserved firm heterogeneity and to facilitate causal inference (Heckman & Borjas, 1980).⁷ Adding the lagged dependent variable did not change the pattern in our results, indicating that such alternative explanations are less likely to explain our results. Because standard errors can be inaccurately reduced in models with a lagged dependent variable, resulting in overstated significance, we also ran a model excluding the variable. Our original findings remained consistent. As

standard errors were almost identical across the models that included versus excluded the lagged dependent variable, artificially small standard errors seemed less likely to influence the significance of our main findings.

Statistical Methodology

Because our dependent variable is counts of products, we used a negative binomial regression. To account for venture heterogeneity, we used *firm fixed effects* analysis. The fixed effects model that we used was a conditional negative binomial model for panel data, as proposed by Hausman, Hall, and Griliches (1984) and implemented using the *xtnbreg* command in STATA (Benner & Tushman, 2002). We also used fixed-effects quasi-maximum likelihood (QML) Poisson regression. While standard Poisson models assume a variance-to-mean ratio of 1, making them susceptible to overdispersion or underdispersion, QML models introduce an effect that allows the variance-to-mean ratio to take any value. Although QML Poisson often offers a more conservative estimate of the significance of the coefficients, due to typically larger standard errors compared to negative binomial regressions (Gourieroux, Monfort, & Trognon, 1984), the Poisson regression findings were highly consistent and supported our original findings.

Causal inference. While no research design can completely rule out reverse causality and possible other alternative explanations, we tried to account for these issues in several ways. Our primary method was *firm fixed effects* analysis. We also used random effects analysis, which did not, unlike fixed effects, drop firms that lacked variation in the dependent variable. Findings were highly consistent (available from the authors). To further account for unobserved firm heterogeneity, we ran a model in which we included a *presample products* variable (Blundell, Griffith, & Van Reenen, 1995)—that is, we controlled for products introduced by the firm three years prior to the study period. Because it is plausible that firms that have been active in innovation in the past will continue to be so, the presample variable accounts for such unobserved heterogeneity that may otherwise influence the results (Heckman & Borjas, 1980; Katila & Ahuja, 2002). To further facilitate causal inference, we included a rich control set, lagged our independent and control variables, and included other tests, reported below, to account for selection bias (e.g., instrumental variables (IV) and inverse probability of treatment weighted (IPTW) regressions).

⁷ One possible alternative explanation is, for example, that firms that lack product innovation make a visible change and replace the firm's current CEO with a user expert, thus hoping to gain more investor confidence (and, ultimately, product approvals).

Altogether, our sample contained 231 U.S.-based surgical instrument ventures (1,864 firm-years), observed from 1985 to 2009.

RESULTS

Table 1 reports our study's descriptive statistics and correlations. On average, surgical firms in our sample received a patent yearly and a product approval every other year. Similar to previous studies on young ventures (Pahnke, Katila, & Eisenhardt, 2015), patent-intensive firms in our sample had more funding and more high-status investors than firms without patents, and firms that introduced products in the past were likely to continue doing so. Altogether, of the 231 firms in our sample, 143 were successful in obtaining a product approval. Many firms in the data also had at least one physician–user in an organizational role. Physicians were common in executive (74%) and governance (69%) roles. A large number of firms also had at least one physician–inventor (59%), and many had a physician–CEO (25% of sample firms). Overall, the independent variables show considerable variance, and the correlation matrix indicates low correlations among the independent variables.

Main Findings

Table 2 presents the firm fixed-effects negative binomial and QML Poisson analyses for the innovation effects of users in four organizational roles. Model 1 includes the control variables only. Consistent with the rest of our analyses, we find that new firms receive more product approvals when they have more funding (capital raised) and greater technical invention (patents).

To test Hypothesis 1—that firms with more users in technical roles achieve more innovation (up to a point)—we assessed the linear and squared coefficients for *user–inventors* in Model 2. The coefficient for the linear term of user–inventors is positive and significant while the coefficient for the squared term of user–inventors is negative and significant in Model 2 and in the full Model 6, supporting the hypothesis.

In Hypothesis 2, we argued that users in executive roles similarly have a nonlinear (inverted U-shaped) effect on innovation. To test the hypothesis, Model 3 introduces linear and squared coefficients for *user–executives*, but neither is significant. Exclusion of the squared term in a sensitivity test did not change the results, confirming that Hypothesis 2 is not supported.

To test Hypothesis 3, which predicted that firms at which the CEO is a user achieve lower innovation output, we assessed the coefficient for the binary user–CEO variable in Model 4. The coefficient is negative and significant in Models 4 and 6, supporting the hypothesis.

Hypothesis 4 argued that more users in governance roles yield more innovation (up to a point). The coefficient for the linear term of user–board members is positive and significant while the coefficient for the squared term is negative and significant in Models 5 and 6, supporting the hypothesis.

To probe the curvilinear results for user–inventors (Hypothesis 1) and user–board members (Hypothesis 4), we further checked for the presence of an inverted U-shaped relationship using the *utest* command in STATA (Lind & Mehlum, 2010). The test confirms that the turning point for the inverted U-shape is well

TABLE 1
Descriptive Statistics and Correlations

	Variable	Mean	SD	1	2	3	4	5	6	7	8
1	Product Approvals	0.76	1.45								
2	User–Inventors	0.09	0.18	0.11							
3	User–Executives	0.15	0.15	−0.07	0.11						
4	User–CEO	0.22	0.42	−0.05	0.11	0.40					
5	User–Board Members	0.21	0.23	−0.05	0.03	0.16	0.19				
6	Capital Raised ^a	6.65	3.69	0.17	0.14	0.10	0.12	−0.03			
7	Firm Age ^a	1.78	0.49	0.02	−0.05	−0.01	0.00	0.01	0.17		
8	High-Status Investor	0.34	0.47	0.12	0.17	0.01	0.02	−0.04	0.43	−0.03	
9	Patents ^{a,b}	0.59	0.73	0.20	0.34	0.00	0.04	−0.09	0.26	−0.05	0.33

Notes: $n = 887$. Correlations above 0.06 significant at $p < .05$.

^a logged

^b two-year lag

TABLE 2
Fixed Effects Negative Binomial Models Predicting Product Approvals

	1	2	3	4	5	6	7	QML Poisson
User-Inventors		1.51** (0.58)				1.57** (0.56)	1.55** (0.57)	1.77** (0.57)
User-Inventors squared		-2.01* (0.82)				-1.92* (0.79)	-1.86* (0.78)	-2.19** (0.75)
User-Executives			-2.59 (2.01)			-0.59 (2.19)	-0.78 (2.19)	1.34 (3.09)
User-Executives squared			6.10 (4.57)			3.70 (5.14)	4.10 (5.16)	-0.11 (9.22)
User-CEO				-1.04** (0.32)		-1.23*** (0.36)	-1.27*** (0.36)	-1.50*** (0.28)
User-Board Members					4.49** (1.52)	5.27** (1.64)	5.15** (1.65)	5.75* (2.56)
User-Board Members squared					-5.89** (1.87)	-5.98** (1.90)	-5.95** (1.90)	-9.15 (5.63)
<i>Controls</i>								
Capital Raised ^a	0.13*** (0.03)	0.13*** (0.03)	0.14*** (0.03)	0.14*** (0.03)	0.14*** (0.03)	0.13*** (0.03)	0.13*** (0.03)	0.09* (0.04)
Firm Age ^a	-0.05 (0.23)	0.02 (0.24)	-0.06 (0.23)	-0.01 (0.24)	0.04 (0.24)	0.11 (0.25)	0.17 (0.25)	0.64 [†] (0.39)
High-Status Investor	0.16 (0.31)	0.18 (0.32)	0.19 (0.32)	0.19 (0.32)	0.21 (0.31)	0.27 (0.32)	0.37 (0.32)	0.64 (0.50)
Patents ^{a,b}	0.25*** (0.07)	0.23** (0.07)	0.25*** (0.07)	0.27*** (0.07)	0.27*** (0.07)	0.28*** (0.08)	0.29*** (0.08)	0.24** (0.08)
Lagged Product Approvals	0.04 [†] (0.02)	0.04 [†] (0.02)	0.04 [†] (0.02)	0.03 (0.02)	0.04 [†] (0.02)	0.03 (0.02)		0.04 (0.03)
Presample Product Approvals							0.15 (0.61)	
Constant	-1.79 [†] (0.95)	-1.99* (0.98)	-1.77 [†] (0.94)	-1.66 [†] (0.95)	-1.39 (0.95)	-1.40 (0.98)	-1.55 (1.07)	
χ^2	87.3***	95.4***	87.9***	98.8***	99.0***	125.3***	122.8***	920.4***

Notes: $n = 887$. Year and region fixed effects are included in all models. Standard errors in parentheses.

^a logged

^b two-year lag

[†] $p < .10$

* $p < .05$

** $p < .01$

*** $p < .001$. Two-tailed tests.

within the data range for both variables, using the Fieller method (Fieller, 1954). Moreover, the relationships are significantly increasing at low values and decreasing at high values within the data intervals. The slope for user-inventors is 1.57 ($p < .01$) at the lower bound and -2.26 ($p < .05$) at the upper bound of the data, and, for user-board members, 5.27 ($p < .001$) and -6.70 ($p < .01$), respectively. We also tested for more parsimonious (logarithmic, exponential) and spline transformations of each variable, as advised by Haans, Pieters, and He (2016), with strong support found for our original inverted U-shaped relationships.

Sensitivity analyses. Because our focus is on the effects of “treatment” (user in an organizational role),

a statistical challenge is to show that differences in innovation can be attributed to the treatment, and not to other factors such as firm heterogeneity or selection of a user to a particular treatment.⁸ We attempt to

⁸ In a randomized experiment—the ideal approach to evaluate treatment effects—randomization takes care of many threats to causal inference. Because each firm is randomly assigned to a treatment or control group, the two groups look alike on average and selection bias is eliminated. But randomization is unavailable to us, and so we attempt to make the treatment and comparison groups comparable by including fixed firm effects and a rich control set. We also use a quasi-experimental design that facilitates causal inference (i.e., IPTW regression).

account for such potential biases by using several approaches. Our main findings are robust to models with alternative specifications and several added controls.

First, we ran alternative specifications to account for firm heterogeneity. While our original specifications used fixed effects negative binomial regression, we also ran random effects as well as fixed effects QML Poisson regressions. These analyses yield strongly consistent findings, with the exception that the squared term of user-board members is negative but does not reach significance in QML Poisson analyses. Closer inspection shows that our board member data are somewhat sparse at the upper bound (i.e., only a few firms overshoot the most productive level of users on the board), which likely explains the minor difference.

Second, we added variables to control for other omitted firm heterogeneity. We replaced the lagged product approvals variable (included in original regressions) with *presample products* (Table 2, Model 7) and *presample patents* variables, with consistent results. We also controlled for the size of the executive team, because bigger teams as well as bigger firms can have larger information processing and problem-solving capabilities, which may aid innovation. The coefficient for *team size* was positive and significant, as expected, while our original results were consistently supported.

Third, we explicitly modeled the possible selection process of users to particular organizational roles, using two approaches: the instrumental variables (IV) (Li & Prabhala, 2007; Wallsten, 2000) and the inverse probability of treatment weighted (IPTW) regressions (Rubin, 1977). In both approaches, the first-stage results showed a pattern in which patent-intensive, well-funded firms were more likely to co-opt users in inventor roles, and younger-tenured firms in executive roles. Although the lack of strong instruments was limiting for our IV second-stage analyses (and we were, in particular, unable to find a strong instrument for user-CEOs), IV tests broadly support our main findings on user-inventors (non-linearly increasing) and board members (inverted U), as described in Appendix A (results available from the authors). The IPTW regressions, reported below, are strongly supportive of our original findings.

We ran IPTW regressions in order to make the treated and untreated samples in the data more comparable (such that they would have, on average, similar rates of innovation absent the treatment; Horvitz & Thompson, 1952). This method is a two-stage selection-on-observables estimation technique that first estimates the probability of each subject

being treated, and then, in the second stage, weighs each subject with the inverse probability of being treated to adjust for the potential selection bias introduced by non-random treatment (Hernán, Brumback, & Robins, 2000). We implemented the IPTW model by first estimating a pooled probit regression with standard errors clustered by firm to predict a likelihood of a user in particular organizational role, and then estimating a weighted fixed-effects Poisson regression with robust standard errors to predict the number of product approvals (Almandoz & Tilcsik, 2015; Yue, Luo, & Ingram, 2013). Our original findings were consistently supported (results available from the authors) and thus further increase confidence on our original findings.

Scope Conditions: Time and Industry Sector

Because the needs of a young firm may change as it and its technologies age, we tested whether our results were sensitive to *temporal variations* to benefits in user involvement. In particular, we tested the effects of users on *early versus late stage* innovation. For example, user-inventors may be particularly helpful in early stages when product development uncertainties are greatest and less pivotal later. We used patents as an early-stage measure of (technical) innovation and products as a late-stage measure of (commercial) innovation. Consistent with temporal variations, user-inventors had a more significant effect, and user-board members a less significant effect, on early-stage innovation (patents). These role effects were reversed for late-stage innovation (products). Overall, then, under resource constraints, young firms should include users in technology roles early, and in governance roles later.

We also tested for temporal variations by splitting the sample by *early versus late funding rounds*. Despite the much smaller sample sizes, the original findings held. User-executives' influence now had the hypothesized inverted U-shaped pattern in early (but not significantly in late) rounds, providing partial support for Hypothesis 2. One possible explanation for this result is that top executive positions in a young firm become more administrative and managerial as the firm ages (Wasserman, 2012), leading to increasingly dominant emphasis on selection over variation (rather than perhaps a more fluid combination of both variation and selection tasks early on) and eventual obstruction of innovation in firms in which users take on executive roles.

We also ran our models on a broader sample of *medical device ventures* (2,754 firm-years) rather

than surgical instruments only. Because surgical instruments are particularly prone to user influence, for our arguments to hold, we expected the influence of user-roles to be particularly strong in surgical ventures and weaker in the other subsegments. This is indeed the case, providing further confirmation for our findings and theory.

DISCUSSION

We started the paper with a question regarding how young firms co-opt end users of products to drive innovation. Our central insight was to unravel the roles that users take in young firms, and the mechanisms (variation vs. selection seeking) that are differently activated to modify user influence on innovation in each role. By studying 231 surgical instrument ventures over a 25-year period, we found that users are related with major innovation differences depending on the role they take. Physician-users strengthen a firm's innovation when they take a technology role as inventors and a governance role as directors on the young firm's board. But, despite their frequent involvement in executive roles, physician-executives do not help young firms innovate (except for very early-stage firms) and are likely to block innovation as chief executives. So, although users whom we studied have the type of expertise that can be relevant for multiple roles in young firms, our analyses suggest that users are a better fit in some organizational roles (variation seeking) than others (selection seeking).

Contributions to the Evolutionary Perspective and Organizational Roles

There are contributions to the evolutionary perspective on innovation. Our empirical findings support the theory that typical tasks in a role activate different parts of individual's expertise, with performance implications for innovation. When the organizational role narrowly emphasizes *selection* over variation (e.g., user-CEO), innovation suffers. In contrast, when the role emphasizes *variation* over selection (i.e., user-inventor) or combines the two (e.g., user-board member), innovation improves. Consistent with our theory, then, our findings indicate that the value of users to young firms is highly related with the specific types of roles that they fill.

We also extend recent research insights about organizational roles in young firms (Higgins & Gulati, 2006; Jung et al., 2017) to innovation and to multiple roles. We uniquely study the "outside in" effect of

embedding users in a venture's technical, executive, and governance roles, and the innovation impact. While prior research that intersects users, organizational roles, and performance often just focuses on financial performance and on users in one role (i.e., technical), or looks at the reverse effects of assigning the firm's employees to work in user communities (Dahlander & Wallin, 2006), our contribution is to respond to calls for research to examine the value of product users in a variety of organizational roles (Bogers, Afuah, & Bastian, 2010) for a young firm's innovation.

There are, naturally, alternative explanations. One is that particular users may self-select to roles in more innovative firms (e.g., user-inventors may be drawn to innovation-intensive firms). However, even professional VCs (let alone users) find it challenging to predict which new firms will succeed (Pahnke et al., 2015), making this type of sorting not fully compelling as an explanation. Our empirical tests further confirmed that sorting is a less likely explanation. In particular, we would expect our empirical results on user-inventors to be strongest when the innovation quality of the firm is transparent (more mature, more visible firms), allowing effective sorting by users; instead, though, our empirical data show the opposite.

User-roles may also go hand in hand with other alternative influences on a venture's innovation such as external legitimacy, but this alternative explanation seems again incomplete. For example, research suggests that young firms may window dress by adding experts to organizational roles that are visible to outsiders, including the board, before critical firm milestones such as an IPO (Chen, Hambrick, & Pollock, 2008), and so mature firms that are ready for an IPO (and also typically then have more innovation) should be particularly likely to add more user-board members. However, when we isolated pre-IPO and IPO-years in analyses, this empirical pattern did not emerge. We also alternatively restricted the sample to firm-years nine and younger and again found the original results strongly supported. Finally, because our setting has the FDA as a key gatekeeper of product innovation (mandatory FDA approval of new devices), window dressing and legitimacy are a less likely explanation for increased product approvals, and user contributions to innovation a more likely explanation.

Contributions to User Innovation

Our key contribution to user innovation research is the finding that professional users can contribute

to the firm's innovation process, above and beyond their contributions to just generating ideas that has been more commonly studied. We show that physicians play a host of significant roles that span product development, from technical to governance roles. In other words, the users' contributions extend to transforming inventive ideas into products.

Another contribution is that we identify scope conditions of user involvement. While some studies examine when user innovation will most likely occur (Baldwin & von Hippel, 2011) and why some users innovate more than others (von Hippel, 1986), Laursen's (2011) work noted that the taken-for-granted assumption is that user involvement benefits firms. Surprisingly little research to date has examined when firms might *not* want to engage users. Our contribution is to show that expertise of professional users carries limitations, and that this trade-off is further influenced by the organizational roles that users are embedded in. Users can become "too much of a good thing" in any role, and *non*-users may be particularly effective in many executive tasks, at least if they are the chief executives. A key takeaway is that, while users bring many benefits to the young firm's innovation process, innovation is likely to benefit by careful decisions about staffing key organizational roles.

We also contribute by extending the domain of user innovation research to organizational roles and to young firms. In most research, users are individuals outside the established firm from whom firms either appropriate inventions (Winston Smith & Shah, 2013) or with whom firms partner to develop products (Lilien, Morrison, Searls, Sonnack, & von Hippel, 2002)—that is, the focus is on external roles. But, while this focus makes sense for established firms, resource-poor young firms are much more likely to have product users in *internal* roles, such as top executives (Zenios et al., 2013). Our contribution was to provide more understanding of such user presence in ventures and the mechanisms whereby it influences innovation.

Again, there are of course alternative explanations related to selection of particular user-innovators. One is that some firms may have the foresight to pick the most "high-quality" users and place them in particular roles. Although von Hippel (2005: 144) made the point that this is somewhat unlikely because predicting in advance which users develop innovations that are valuable for a particular firm is difficult, we created a measure of the invention experience of the users (user's prior patenting) to

account for it.⁹ The coefficient for the variable had a negative sign, perhaps even suggesting that the most sophisticated (i.e., patent-experienced) users may drive a firm's innovation trajectory toward the high end of the market while leaving holes open for disruptive innovation in the other end (Christensen, 1997). Again, our original results remained.

Another explanation is that a more high-quality user would be more reluctant to give up a professional career and a high salary for a full-time role in a start-up—especially if the role is that of one of the executives rather than the more prestigious CEO position—suggesting that more low-quality users would select into executive roles. But, again, our data do not support this explanation. Our interviewees indicated that most start-ups instead advise physicians "to keep their day jobs," given the inherent uncertainties in any start-up, and so retain both careers. And, as noted above, our empirical tests on early firm-years showed a *positive* relation of user-executives with innovation, not a negative one. Again, these reverse causality explanations on roles and innovation do not seem to conform with the patterns in the data which support our original theory.

Contributions to Policy and Entrepreneurship

Finally, our findings are also relevant for policy. Recent legislative efforts (e.g., the "Sunshine Act" in the United States) have sought to reduce the involvement of physician-users in business firms in order to reduce conflicts of interest. Our findings suggest that a more nuanced policy would be more effective to sustain innovation. Completely separating the involvement of professional users from firm innovation efforts will hinder the development of life-saving surgical instruments produced by young firms, such as those in our sample, and could potentially limit the growth of a vital part of the economy.

Our findings also suggest several directions for future research. One avenue to explore is the specific roles that user-founders take post-founding and the possible impact on innovation. In our (limited) data available on founders, user-founders followed three kinds of paths. While some chose, after founding their firms, to become the CEO of the firm, others chose to operate in non-CEO executive roles, often associated with varying degrees of R&D responsibility

⁹ Although we did not have the data to control for it, another worthwhile direction for future work would be to collect data on the medical practice experience of physician-users.

(e.g., vice president of R&D, chief technology officer, chief medical officer). A third group chose not to work in any executive role at all, but instead retained a board position. Following the paths of user-founders presents an interesting avenue for future work.

Another interesting extension of the current research would be to examine how differences in users' capabilities and background influence innovation. If the data were available, future work could, for example, examine how other dimensions of users' educational (e.g., MBA) or professional background moderate the relationships that we proposed and found.

CONCLUSION

Placing the right people in the right roles is key to success in young firms. Our focus was to explore whether filling roles with expert users can plug critical resource deficiencies for ventures. Although users can serve young firms in multiple ways, our findings suggest that, for innovation, professional end users of a firm's products can help in technical and governance roles but prove limiting in many executive roles. In general, users should be involved in moderation, together with non-users, and avoid taking the CEO position. Too many doctors—or doctors who become the CEO—can slow innovation down. More broadly, our findings suggest a new *lever for innovation*: the careful selection of tasks assigned to an organizational role can help maintain an organization's creative edge and fully exploit each individual's potential.

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APPENDIX A: INSTRUMENTAL VARIABLES ANALYSIS

In the instrumental variables analysis, we sought to model unobserved information that drives matches of physician–users with young firm roles (i.e., sorting of physician–users to specific roles). Our goal was to provide more assurance that differences in innovation can be attributed to user involvement in particular roles, and not to other factors such as sorting of users in different positions. Because the instruments must not encompass the same problem as the original regressor, finding the most suitable instruments is crucial. Explicitly, the instruments must be relevant (i.e., must have an effect in the first stage) and valid (i.e., must be uncorrelated with the error term in the second stage). We based our selection of instruments on theoretical arguments, and tested the validity of our instruments using the Anderson canon correlations test for under-identification and the Cragg–Donald test for weak identification. Our instruments were measured at the local geographical level, as local variables are more likely to predict user involvement because ties are typically formed with local physicians whereas the FDA approval process of new medical devices is nationwide. In other words, instruments are likely to be relevant predictors of the focal user involvement in roles but relatively less likely to predict our dependent variable, innovation. All instruments were calculated at the level of the focal firm's MSA in order to capture a cluster of adjacent counties with close economic and social relationships.

We instrumented *user-inventors* with the *number of physicians per medical device start-up* in the MSA yearly. As did prior work, we gathered county-level data on physician density from *Physician Characteristics and Distribution in the US*, an annual publication of the AMA. Physician density indicates the potential pool of physicians available to collaborate. Second, we instrumented *user-executives*, *user-CEOs*, and *user-board members* with the *number of surgical instrument start-ups* in an MSA yearly (excluding the focal firm). Because there is more labor market competition, finding physicians for firm roles may become more challenging the more start-ups there are, or, alternatively, easier by making physician–users more aware of start-up opportunities.

The Anderson test statistic for our user–inventors model is 14.066 ($p < .001$) while the test statistic for our user–board members model is 4.259 ($p < .05$). In both cases, we can reject the null hypothesis that the equation is under-identified, indicating that our instruments for

user-inventors and user-board members predict our endogenous regressors. In contrast, running the same tests on user-CEOs and user-executives did not confirm those instruments strongly.

We then tested for instrument strength using the Cragg–Donald Wald F -statistic and comparing the test statistics to critical values from Stock and Yogo (2005) to estimate the maximal possible bias that might result from using weak instruments. The test statistic for user-inventors is 13.981, suggesting a maximal possible bias of 15%. The test statistic for user-board members is 4.21, suggesting a maximal bias of around 25%. We therefore have a reasonably strong instrument for user-inventors and a moderately strong instrument for user-board members. Again, the instruments for user-CEOs or user-executives did not meet the criteria. We also tested for several alternative instruments that our interviewees suggested, but were not successful in finding stronger instruments, as explained below.

OTHER TESTED INSTRUMENTS

Because firms near large hospitals may be at an advantage in finding and attracting physicians with whom to collaborate, we also tested *hospital and medical school*

density in an area as instruments, using data from USHospitalInfo.com and the American Association of Medical Colleges. We similarly tested whether the number of *surgical procedures performed* in a region might predict firm–surgeon collaboration, using data from the *Dartmouth Atlas of Health Care*, which gathers information on procedures paid for by Medicare. We also tested the *number of IPOs* in the firm’s local geographical area (i.e., MSA) yearly as instrument, using Kenney and Patton’s database of U.S. IPOs. Because a large number of IPOs indicates that start-ups in the area are successful, we expect that a high number of nearby IPOs is likely to attract physicians to take an executive role (and often the related equity position) in a surgical instrument start-up, but would be unlikely to predict venture innovativeness, making it an appropriate instrument. We also tested the viability of *malpractice insurance data* as a possible instrument. Physicians who have to pay higher premiums in liability coverage in a certain area in order to practice may be more likely to look for alternative career paths, such as employment in medical device firms. We gathered data on county-level liability insurance premiums from 1991 onwards from the *Medical Liability Monitor*. Altogether, while the patterns of results were broadly similar, these other tested instruments were ultimately weak.

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