Is There a Doctor in the House?

Expert Product Users, Organizational Roles, and Innovation

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Abstract

We explore the impact on innovation that professional end-users of a product have as inventors, executives, and board members in a young organization. In contrast to prior literature, which has emphasized technology roles, we put the spotlight on executive and governance roles that many professional users take in young firms. Using an extensive custom-collected dataset of 231 surgical instrument ventures over a 25-year period combined with qualitative fieldwork, we find that professional physician-users (surgeons) strengthen innovation in some roles but block it in others. Surgeons are related with the increase in a firm's innovation when they take a technology role as inventors, and particularly when they take a governance role on the young 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 professional users as a critical external dependency for a young firm's innovation, but show that a mismatch with a particular organizational role may have unanticipated negative effects on innovation. A key finding is that users are more helpful in suggesting a broad variety of solutions to the firm's innovation problems but less helpful in selecting the best ones for the organization to pursue. Our findings have implications for research on evolutionary perspective on user innovation, organizational roles in young firms, and entrepreneurial policy.

Keywords: innovation, user-innovation, new products, organizational roles, entrepreneurship.

"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 describes product innovation in Burlingham & Gendron, 1989.

Innovation makes or breaks organizations. Because successful innovation depends on ensuring that customers choose the firm's products rather than those of another provider, 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*, i.e., users that employ a particular product in their professional life, as a particularly effective influence on firm innovation (Shah & Tripsas, 2007; Laursen, 2011). 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 et al., 2008). Similarly, two thirds of UK 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

[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.

and so present an interesting puzzle for research. One stream of research emphasizes the benefits (Afuah & Tucci, 2012; von Hippel, 2006). The key argument is that users can increase the breadth of perspectives brought to bear on solving challenging innovation problems (particularly in technology-focused startups), i.e. increase *variation*. Overall, this stream emphasizes 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 (Christensen, 1997). 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. As a result, users may blind firms from pursuing emerging market opportunities.

More recent research 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 2006: 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 firm's innovation, hurting variety. While prior research focuses on established firms' partnering with user-organizations or third-party brokers to address these limitations and ensure more effective transfer of knowledge (Hargadon & Sutton, 1997; Dahlander & Wallin, 2006; Winston Smith & Shah, 2013), our focus is on resource and time-constrained young firms that often find that embedding users within their own ranks is more attractive (c.f. Hillman & Dalziel, 2003). Consistent with this view, evidence suggests that user-roles in young firms have practical import. Two out of three young firms in the medical sector, for example, employ professional users in organizational roles[2] (Zenios, Burns & Denend, 2013). 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 argument that tasks inherently related to a particular role can selectively *activate* (i.e. call to mind) different parts of a user's expertise and so influence the behaviors and the choices about innovation the role occupant makes, we are interested in whether 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. That is a research gap that we address.

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 rely on 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

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

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. First, there are rich implications for the evolutionary perspective on innovation. Consistent with the variation-selection view of innovation (Nelson & Winter, 1982; March, 1991; Katila & Chen, 2008), we classify each organizational role's innovation tasks by their *variation* vs. *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, and a wide range of robustness tests) 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 the 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 also contribute to research on *user innovation.* We find that professional users can add to the firm's innovation process, above and beyond their contributions to just generating inventions that 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 as a CEO slow innovation down. Thus, we identify a more nuanced relationship between professional users' (i.e. surgeons') 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 presence or absence of expertise.

Our findings are potentially also relevant for *policy*. Recent legislative efforts in the U.S. (the 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-firm 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 et al., 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 (Nelson & Winter, 1982; March, 1991). One stream of user innovation research suggests that professional users can help the firm with both variation and selection. Professional users can help increase *variety* of ideas (e.g., re-connect 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 (Franke & Shah, 2003; Dahlander & Frederiksen, 2012). Professional users can also potentially help *selection* of ideas by providing information about product use. Because of their deep knowledge of products and their applications, professional users can help the 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 the firm dislodge innovation trajectories and guide the firm to select solutions that are desirable to implement.

In contrast, other research warns about users' tendency to make familiar choices that kills 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). When they lack full information, or face uncertainty regarding the relevance of different pieces of information, experts have a tendency to rely upon background expertise, i.e. "knowledge structures" and shortcuts they have developed through prior experiences to make decisions (Walsh, 1995; Ocasio, 1997). 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 (e.g. 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 specific organizational roles (Sine et al., 2006; Jung, Vissa, & Pich, 2016). 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 (Merton, 1957; Higgins & Gulati, 2006). Having formal roles also makes coordination about resources with other roles effective (Beckman & Burton, 2011; Ferguson et al., 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. A case in point is a study by Higgins and Gulati (2006) in which 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 CSO 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 role occupant's expertise and so influence the behaviors and the choices about innovation the role occupant makes. In an established-firm study, Dahlander et al. (2016), found, for example, that tasks in a role that an individual held determined which professional network ties (variation vs. selection-oriented) individuals re-activated 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 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 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 with whom they were close to seek confirmation, and in the process inadvertently missed probing and criticism from the wider network to question habitual practices and 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 the young firm: technical, executive, and governance.

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[3] Dahlander, O'Mahony and Gann (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.

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*, i.e., 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. Young-firm executives mediate between the organization's technical core that 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 (Aldrich & Ruef, 2006). In their roles, executives also assume responsibility for formalizing processes for implementation, i.e., they manage the flow of innovations through a firm's product pipeline to the market.

Governance roles. Venture boards help firms as they generate *variety* of ideas for innovation, and participate in *selection* of relevant ideas to execute. In a young firm, a board member is often asked to join 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

[4] Typical executive roles in a young firm include chief marketing officer, VP of Engineering, and the CEO.

operations and strategy (Daily et al., 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 the CEO (executive role), and users as directors on the firm's board (governance role).

User-Inventors

In Hypothesis 1 we propose that up to a point, a young firm with more users in inventor roles will achieve higher product innovation. Greater proportion of user-inventors will initially increase innovation because the inventor role taps into users' ability to source, pass on, and help interpret diverse information about the user community more effectively than non-users do. But, when the proportion of user-inventors reaches high levels, returns to building on the same expertise start to diminish, and technology and engineering skills to develop feasible products become sparse, leading to rapidly increasing problems for product development.

First, because new variations are necessary to provide a sufficient amount of choice to solve the 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), user-inventors 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 how product development can be derailed if user perspective is ignored, *"I have a friend who is [founder] of another company … very experienced [non-physicians 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 the 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."* In contrast, non-user inventors are 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. Moreover, 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 et al., 2009). A non-user entrepreneur describes the challenge of developing a device without a background in medicine, "…*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."* The tacit nature of this "sticky" knowledge can make it difficult for external users to communicate all of the necessary contextual details when their interaction with the firm is limited. In contrast, because of their background as users, user-inventors are able to "unstick" and interpret this information quicker. Our interviews relayed that physician-inventors 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). User-inventors were also able to identify “predictable” problems that would otherwise stymie successful product development, ultimately requiring fewer design iterations and more effective overall development. A physician stated, *"I think I have a better perspective than the engineers. I know a lot about the products and materials. [Startup 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 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, 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. 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, i.e. counter-balance the ideas generated from the demand perspective with expertise related to technical implementation. As a consequence, 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. 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. We propose:

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

User-Executives

User-top executives. Hypothesis 2 argues that up to a point, young firms with more users in top executive roles will achieve higher product innovation. Higher proportions of user-executives will initially increase innovation because user-executives are likely to endorse solutions that are valuable for users of a product and therefore provide balance especially in technology-focused start-ups. However, at high levels, top teams' choices become overly colored by user experience, at the expense of business skills which are also required for implementing innovation.

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 is likely that filling some executive roles with users who understand demand trends can help the firm make better decisions about which product ideas to select for implementation. 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, user in an executive role is uniquely positioned to triangulate user needs with firm's product portfolio, and so enables 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. 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 and decisions about them more toward alternatives that are familiar and less towards 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 are so more likely to retain diversity in selection. Overall, we propose that user-heavy teams are likely to underestimate the value of ideas that are new to them (i.e., reject or completely overlook potentially new 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 skill to formalize processes that have been linked to high-performing commercial innovation and so underestimate the business challenges linked to implementation. One interviewee explained, "*Being an MD doesn't always help with the business side. I have two co-founders 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 described to us, *"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 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. We propose:

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

User-CEO. Hypothesis 3 proposes that young firms with a user in the Chief Executive Officer (CEO) role will have lower innovation. The CEO is the most senior, and likely the most central and influential single role in a young firm's executive team. In the helm of the 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. Given 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 in a young firm - with limited resources and often under duress and time pressure - is often lost when a user is placed in the CEO role. Due to the role's pressures and decision ambiguities, CEOs are particularly likely to "manifest personal preferences and energies into organizational outcomes" (Hambrick & Fukutomi, 1991) and thus be influenced in selection by their past experiences, including as users 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 et al., 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, a physician-CEO offered, *"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 recent and familiar (e.g. the young firm's first customers), but 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. An 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 offered, *"There are some skillsets that fulltime 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 chief executive officer (CEO) role is negatively related with the young firm's innovation.

User-Board Members

In Hypothesis 4 we propose that, up to a point, young firms with more users in board member roles will achieve higher product innovation. Greater proportion of users on the board will increase innovation because users can add variety of ideas and select thoughtfully, in particular because they have "skin in the game" because the quality of the board's final solutions depends on good alternatives. But, in excess, user-heavy boards are likely to start to damage innovation as the proportion of new ideas levels off and monitoring that over-emphasizes the role of users may lead to negligence of decision alternatives that depart from the norm and unproductive status struggles among user-experts.

First, 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 the firm's executives and help "*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 venture boards meet often, board members are likely to encounter a wide variety of solutions through their board role on a frequent basis. Further, because the board brings together experts from several domains, user-board members are 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, 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, 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. A 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 helped more directly by testing products and so better position the firm's product offering. A 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, higher proportion of user-board members is likely to impede innovation because adding one more physician is likely to be only incrementally useful, and boards with too many users are likely to face excessive coordination costs eventually making it difficult 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] 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 costs of user involvement to exceed its benefits. We propose:

Hypothesis 4. The proportion of users in board member roles is curvilinearly (taking an inverted U-shape) related with the 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 needs for external resources for innovation, and, because, as resource-poor, of their offers of organizational roles to outside experts. We also chose young firms because of their relatively flat organizations; 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 et al., 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 about five to seven years to experience a liquidation event, such as an initial public offering or an acquisition (Fenn, Liang, & Prowse, 1997). 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*, i.e., 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.

Second, we 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 of 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 U.S. (Kaplan, Sensoy, & Stromberg, 2002). As did prior work (Katila et al., 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 firms 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 cross-checking 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 to accurately assign patents to each firm. Inventors were the individuals listed on each patent. Because prior work notes 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 et al. (2006) and Miguelez and Gomez-Miguelez (2010) matching algorithm that 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), i.e., over 1.4 million individuals who entered medical school, began post-graduate residency training, or obtained a medical license in the United States. The AMA Masterfile is the primary data source for verifying a physician's credentials in the U.S., 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. As did Chatterji and Fabrizio (2016), 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 zipcode to account for potential relocation over time.

We also collected data on each firm's product innovations from the FDA's 510(k) and PMA databases that track medical device product approvals, and tracked exit and restructuring events as well as name changes for sample firms 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. As did 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 FDA approval demonstrates feasibility, effectiveness, and innovativeness of the product concept.[5] 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) and PMA. The type of approval depends on a device's novelty and on potential risks to patient safety. Devices that are substantively similar to previously

[5] 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 executive and governance roles of users did not. These results are available from the authors.

approved ones qualify for a 510(k) approval, whereas radically novel devices require a PMA approval but 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 also analyzed effects of both in aggregate, as well as 510k 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 the 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 the 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 included typical executive positions in a surgical instrument venture, including general business functions (finance e.g. CFO, marketing e.g. VP Marketing, CEO, and R&D e.g. CTO), and roles specific to biopharma firms such as Chief Medical Officer and VP of Clinical & Regulatory Affairs. In a sensitivity test, we dropped the nonlinear term of user-executives and original results remained.

We measured *user-CEO* with a binary variable set to one if the firm's CEO in a particular year was a board-certified physician and zero otherwise. Although co-CEOs are typical in some industries, we checked and found no such pattern in our data. We also ran the results by including a control for user-founders (c.f., Shah et al., 2013).[6] 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 the 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 that we study, 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 (1) by counting each individual in every organizational role that they occupy, and (2) by assigning each individual with multiple roles to a single role. We used

[6] Because we have missing founder data on a large number of firms, and because founders can take many roles including occupying a board seat, 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 analyze an aggregate user-founder variable in a sensitivity analysis only.

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 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 the 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 one when a sample firm gained at least one investment from one of the top 30 most high-status VCs and zero 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. Patents are an effective measure of the firm's technical invention because patents are effective in protecting intellectual property in medical devices (Cohen et al., 2000). 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 user-inventors' influence on innovation without controlling for patents. As expected, the user-inventor coefficient now becomes slightly larger in magnitude while other results are 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, i.e., *Boston*, *San Francisco* and *Los Angeles* (Orange County) *regions*. We measured location by an unreported binary variable coded as one if the new firm was headquartered in one of the metropolitan area zip codes associated with one of the hubs and zero 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 equals one if the young firm is located in a particular MSA and zero 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 what 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 lagged dependent variable, resulting in overstated significance, we also ran a model excluding the variable. Our original findings remained consistent. Because standard errors were almost identical across the models that included vs. excluded the lagged dependent variable, artificially small standard errors seem 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 use is a conditional negative binomial model for panel data, 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 one, making them susceptible to overdispersion or underdispersion, QML models introduce an effect that allows the variance-to-mean ratio to take any value (Woolridge, 1999). 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 (Dahlander et al., 2016; Gourieroux, Monfort, & Trognon, 1984), 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

[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).

primary method was *firm fixed effects* analysis. We also used random effects analysis that does not, unlike fixed effects, drop firms that lack 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 et al., 1995), i.e., 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 do 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). Altogether, our sample contains 231 U.S.-based surgical instrument ventures (1,864 firm-years), observed from 1985 to 2009.

RESULTS

Table 1 reports descriptive statistics and correlations. On average, surgical firms in our sample receive a patent yearly and a product approval every other year. Similar to previous studies on young ventures (Pahnke et al., 2015), patent-intensive firms in the 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 firms 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).

---Insert Tables 1 and 2 about here---

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 and 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, that predicted that firms whose 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 and 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 (H1) and user-board members (H4) 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 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 ($p<0.01$) at lower bound and -2.26 ($p<0.05$) at upper bound of data, and for user-board members 5.27 ($p<0.001$) and -6.70 ($p<0.01$), respectively. We also tested for more parsimonious (logarithmic, exponential) and spline transformations of each variable, as advised by Haans et al. (2016), with strong support for our original inverted U-shaped relationships.

Sensitivity analyses. Because we focus 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 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.

[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.

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 with *presample patents* variable, with consistent results. We also controlled for the size of the executive team because bigger teams, and 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 attempted to model the possible selection process of users to particular organizational roles using two approaches: instrumental variables (IV) (Wallsten, 2000; Li & Prabhala, 2007) and the inverse probability treatment weighting (IPTW) method (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 particularly unable to find a strong instrument for user-CEO), instrumental variables tests broadly support our main findings on user-inventors (nonlinearly increasing) and board members (inverted U), and are described in the Appendix (results available from the authors).

We then ran inverse probability of treatment weighted (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 (Hernan et al., 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 (Yue, Luo, & Ingram, 2013; Almandoz & Tilcsik, 2015). 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 they and their 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 vs. 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 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 vs. 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 H2. 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.

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 sub-segments. This is indeed the case, providing further confirmation for our findings and theory.

DISCUSSION

We started the paper with a question of 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, and modify user influence on innovation in each role. By studying 231 surgical instrument ventures over a 25-year period we find that users in this setting are related with major innovation differences depending on the role they take. Physician-users (at least up to a point) strengthen a firm's innovation when they take a technology role as inventors and a governance role 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 young-firm roles, our analyses suggest that users are a better fit in some organizational roles (variation-seeking) than others (selection-seeking).

Contributions to Evolutionary Perspective and Organizational Roles

There are contributions to *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 both (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 (Jung et al., 2016; Higgins & Gulati, 2006) to *innovation* and to *multiple roles*. We uniquely study the "outside in" effect of embedding users in 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 et al., 2010; Foss et al., 2011) and as a resource to strengthen 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 are drawn to innovation-intensive firms). However, even professional VCs (let alone users) find it challenging to predict which new firms will succeed (Pahnke, Katila & Eisenhardt, 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 to be strongest when the innovation quality of the firm is transparent (more mature, more visible firms) allowing effective sorting by users. Instead, our empirical data show the opposite.

User-roles may also go hand in hand with other alternative influences on ventures' 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 FDA as a key gatekeeper of product innovation (mandatory FDA approval of new devices), window dressing and legitimacy are generally less likely levers for increased product approvals of firms, 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 (or block innovation) more than others (von Hippel, 1986; Christensen, 1997), Laursen's work (2011) notes that the taken-for-granted assumption is that user involvement benefits firms. Surprisingly little research has yet to examine 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 take away 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 (Foss et al., 2011; Lilien et al., 2002), i.e., 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 foresight to pick the most "high-quality" users and place them in particular roles. Although von Hippel (2005: 144) makes 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 the firm's innovation trajectory towards high end of the market while leaving holes open for disruptive

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

innovation in the other end, c.f., Christensen, 1997 - but it was not significant. 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 startup---especially if the role is 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 describe that most startups rather advice physicians “to keep their day jobs” given the inherent uncertainties in any startup, and so retain both careers. And, as noted above, our empirical tests on early firm-years show 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 confirm with the patterns in the data and rather 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 would hinder the development of lifesaving 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 (e.g., VP 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 the 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 chief executive officer position. Too many doctors – or doctors who become CEOs – can slow innovation down. More broadly, our findings suggest a new "lever" for innovation: careful selection of tasks assigned to an organizational role can help maintain organization's "creative edge," and, perhaps also more fully exploit each individual's potential.

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Table 1. Descriptive Statistics and Correlations

Variable	Mean	Std. Dev.	Min	Max	1	2	3	4	5	6	7	8	9
1 Product Approvals	0.76	1.45	0.00	12.00									
2 User-Inventors	0.09	0.18	0.00	1.00	0.11								
3 User-Executives	0.15	0.15	0.00	0.75	-0.07	0.11							
4 User-CEO	0.22	0.42	0.00	1.00	-0.05	0.11	0.40						
5 User-Board Members	0.21	0.23	0.00	1.00	-0.05	0.03	0.16	0.19					
6 Capital Raised[1]	6.65	3.69	0.00	10.69	0.17	0.14	0.10	0.12	-0.03				
7 Firm Age[1]	1.78	0.49	1.10	3.26	0.02	-0.05	-0.01	0.00	0.01	0.17			
8 High-Status Investor	0.34	0.47	0.00	1.00	0.12	0.17	0.01	0.02	-0.04	0.43	-0.03		
9 Patents[1,2]	0.59	0.73	0.00	3.18	0.20	0.34	0.00	0.04	-0.09	0.26	-0.05	0.33	
10 Lagged Product Approvals	0.73	1.48	0.00	17.00	0.51	0.12	-0.06	-0.04	-0.02	0.15	0.03	0.12	0.17

N=887

[1] logged

[2] two-year lag

Correlations above 0.06 significant at $p<.05$

Table 2. Fixed Effects Negative Binomial Models Predicting Product Approvals

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

[1] logged [2] two-year lag

N=887. Year and region fixed effects are included in all models.

Standard errors in parentheses

† p < .10 * p < .05 ** p < .01 *** p < .001 Two-tailed tests.

Appendix: Instrumental Variables Analysis

In the instrumental variables (IV) 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, 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 (Wooldridge, 2002), finding the most suitable instruments is crucial. 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; Hamilton & Nickerson 2003). We base our selection of instruments on theoretical arguments and test the validity of our instruments using the Anderson canon correlations test for under identification and the Cragg-Donald Wald F-statistic for weak identification. Our instruments were measured at the local geographical level because local variables are more likely to predict user involvement because ties are typically formed with local physicians while the FDA approval process of new medical devices is nationwide (Chatterji & Fabrizio, 2014). 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 are calculated at the level of the focal firm's Metropolitan Statistical Area (MSA) to capture a cluster of adjacent counties with close economic and social relationships.

We instrument *user-inventors* with the *number of physicians per medical device startup* in the MSA yearly. As did prior work, we gathered county-level data on physician density from *Physician Characteristics & Distribution in the U.S.*, an annual publication of the American Medical Association. Physician density indicates the potential pool of physicians available to collaborate (Chatterji & Fabrizio, 2016). Second, we attempted to instrument *user-executives, user-CEOs* and *user-board members* with the number of *surgical instrument startups* 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 startups there are, or, alternatively makes it easier by making physician-users more aware of startup 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 relevance of those instruments.

We then test for instrument strength using the Cragg-Donald Wald F-statistic and comparing the test statistic 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 around 25%. We therefore have a reasonably strong instrument for user-inventors and a somewhat weaker instrument for user-board members. Again, the instruments for user-CEOs or user-executives did not meet the criteria. As explained below, we also tested for several alternative instruments that our interviewees suggested, but were not successful in finding strong instruments for user executives or user-CEOs.

Other Tested Instruments. Because firms near large hospitals may be at an advantage in finding and attracting physicians with which 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 startups in the area are successful, we expected 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 startup, 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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