A study into the use of tolerance analysis in the mechanical design of medical devices

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Citation: PAGE, T., 2015. A study into the use of tolerance analysis in the mechanical design of medical devices. International Journal of Design Engineering, 6(2), pp.116-139.

Additional Information:

- This paper was accepted for publication in the journal International Journal of Design Engineering and the definitive published version is available at http://dx.doi.org/10.1504/IJDE.2015.076376

Metadata Record: https://dspace.lboro.ac.uk/2134/19265

Version: Accepted for publication

Publisher: © Inderscience

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A Study into the Use of Tolerance Analysis in the Mechanical Design of Medical Devices

Abstract The medical device industry is fast becoming the most regulated design sector, despite this evidence; the employment of tolerance analysis is scarce. Research conducted into tolerance analysis in the medical device industry and the barriers affecting its use would provide methodology to increase the use of tolerance analysis, consequently improving product quality, reliability, cost-effectiveness and patient care. Telephone interviews and questionnaires were used to collect both qualitative and quantitative research from industry professions. Three industries provided detailed qualitative responses highlighting that complexity and lack guidance were the industry specific factors deterring the use of the tolerance analysis. Research indicated that the primary barrier deterring the wide spread adoption of tolerance analysis was the confusion caused from a lack of guidance. This encouraged the development of a procedure workflow checklist to aid designers through the often misunderstood process of performing a tolerance analysis study.

Keywords medical device design, tolerance analysis

1 INTRODUCTION

Frequently ignored and misunderstood, tolerance analysis is a vital tool in improving products and their design processes. Since every manufactured part is subject to deviation, designers and engineers must consider the impact of variation on device performance (Fischer, 2011). The aim of this research is to understand the effectiveness and barriers deterring designers of medical devices from adopting tolerance analysis. To achieve the desired aim the following objectives need to be realised: understand the significance of tolerance analysis; assess the importance of tolerance analysis within the medical device industry; assess the effectiveness of tolerance analysis; review factors that currently deter the use of tolerance analysis; review of current methods and their respective impacts upon a drug delivery device.

2 LITERATURE REVIEW

Although several researchers have studied how to balance tolerances in order to minimise manufacturing cost (Peters, 1970), (Spotts, 1973) and (Wilde and Prentice, 1975), little research is present in relation to the medical industry. Research concluding the effects of tolerance on mechanical performance is limited; evidence of the employment of tolerance analysis methods in relation to specific drug delivery devices is scarce (El-Haik and Mekki, 2008). Applying tight tolerance limits to a medical device, carries such high initial costs the use of tolerance analysis and the selection of critical tolerances is essential to device performance. The review evaluates and provides reasons for the need for using tolerance analysis and the most appropriate methodology from which to assess the tolerance stack up, on drug delivery devices. It considers and evaluates the conflicting views of the effectiveness of the methods available to designers during the robust design process of complex mechanical devices such as auto-injectors.

Tolerance analysis is deemed one of the most important robust design tools to ensure quality and consistency for mechanical assemblies (Zhang and Wang, 1997). Wysk and Niebel et al. (2000) explained that by using robust design methods the quality of a device can be controlled by reducing the component variation, they argue that addressing the root cause of the problem is too difficult or too costly to directly control. As advocated by (Chase and Greenwood, 1988) the careful selection of an appropriate tolerance analysis method has a significant impact on the cost of production and levels of productivity if adopted early in the design process. As cited by (Johnson, 2012) the high cost of developing new medical devices
and bringing successfully to market and through the legislation of the Federal Drug Administration (FDA), is a factor in some products not making it to market and therefore denying consumers of the benefits.

The cumulative effect of individual tolerance on an assembly affects the total assembly tolerance. This method is commonly referred to as worst-case analysis, first presented by (Fortini, 1967) it has been heavily refuted for use in assembly critical products, (Padmanabhan, 1991) argues that the method relies on the assumption that, the probability of all components occurring at their worst case simultaneously is very low when component variations occur in the form of normal distribution. Assembly variation in the vast majority of cases will be less than that predicted by worst-case analysis. A similar conclusion that the method would lead to “exaggerated” and “pessimistic” tolerance accumulation was held by (Pawar and Chavan et al., 2011).

Consequently statistical calculations are commonly used to assess the likely effects of tolerance build up and defects per million. Statistical tolerance analysis determines the probable or likely variation possible for a selected dimension (Fischer, 2010). This method, more realistically assumes that it is highly improbable that all the dimensions in the tolerance stack-up will be at their upper or lower extent at the same time. However it is argued by (Pawar and Chavan et al., 2011) that using statistical methods leads to conservative results because individual tolerances could be correlated between the same machining methods. They go on to discuss the root cause of tolerance variation, namely, manufacturing errors, are not taken into consideration. The impact of tolerance analysis on multiple facets of design and manufacturing are illustrated in figure 1, which shows the effects of applying tight or loose tolerances.

![Figure 1: The effects of tolerances are far-reaching (Chase and Parkinson, 1991)](image)

(Johnson, 2012) highlighted the high number of medical device-related injuries, malfunctions, and deaths and questioned if sufficient legislation, process control and resources were in place. Considering this alongside the significant findings (see Figures 2 & 3) from (Cumbum, 2013) who performed retrospective analysis of auto-injector performance. The study emphasised the effects on critical functions of not having used tolerance analysis, prior to production. The graphs show post manufacture test results for injection time, deliverable volume and the variation between performances over 2350 units. This highlights that no
two devices perform exactly the same and in these examples some fail to meet the upper and lower performance requirements (red lines).

Figure 2: Run chart, showing effects of tolerance on drug delivery time (Cumbum, 2013)

Figure 3: Run chart, showing effects of tolerance on deliverable volume (Cumbum, 2013)

In several instances injection time was observed to be >1 second over the specified time, potentially resulting in the device being removed before the drug had been fully administered, causing an under dose.
Furthermore the deliverable dosage ranged between -0.01 and +0.21 over the specified 1mL. If this work was cross referenced with the standards stated by (British Standards Institution, 2012) “The deliverable volume shall not have an absolute error more than 0.01 mL in more than 5% of all cases”. Consequently the majority of units assessed would fail both BSI and FDA approval. If released it could lead to costly recalls, re-designs and possible litigation.

(Cumbum, 2013) concludes his analysis by advocating the use of tolerance analysis before the production for medical injector pens. Further reading discovered that (Chase and Greenwood, 1988) suggested that prior to manufacture limited information is available on distribution type and calculation assumptions are relied upon; these assumptions can affect the relative cost of changing tolerance. Even with detailed quality control records like those provide by (Cumbum, 2013) advanced parametric tolerance analysis is not used to calculate assembly deviation shape. Figure 4 shows how component deviation data can be combined from all parts within the assembly to calculate the total stack deviation, allowing a defects per million (DPM) to be calculated.

![Figure 4: Advanced parametric tolerance analysis (Chase and Greenwood, 1988)](image)

The importance of an effective tolerance analysis is widely recognised: (Whitney, 2004) states significant problems may arise during the assembly process if the tolerance of a part or subassembly was not performed to a satisfactory standard or indeed if any such analysis was even attempted. Another author (Delchambre, 1996) stated that a device could be subjected to significant and costly redesign if the unforeseen effects of tolerance stacked up unfavourably.

Contrastingly an opposing view was noted (Chase and Greenwood, 1988) believing that tolerance analysis is highly computation-intensive and difficult to understand. In addition they concluded that the most important issue to address is the collaboration between design and manufacturing. Furthermore another author (Merkley, 1998) whilst referring to the aerospace industry, which manufactures many complex mechanical devices, concludes that the use of tolerance analysis does not provide sufficient data when dealing with compliant assemblies. Instead he proposes a complicated mix of tolerance analysis, finite element analysis, computer-aided geometric design, and statistics. Similarly auto-injectors are a complex
mechanical device not unlike aerospace components; therefore the same points are applicable. Figure 5 shows an example of a typical auto-injector and its complex, confined linear and axial component stacks.

Figure 5: Auto-injectors compliant assembly (Bergens, 2002)

Limited research was available regarding influences deterring the adoption and sustained use of tolerance analysis, however (Chase and Parkinson, 1991) and (Peng, H.P, and Jiang et al., 2008) both suggest balancing cost versus quality and time versus complexity as factors discouraging companies and individuals from using tolerance analysis alongside other robust design tools.

(Peng, H.P, and Jiang et al., 2008) argue that a dimension with a relatively tight tolerance will inevitably cost more to manufacture, but the possible variation range will be small and lead to fewer rejected parts. This was countered by the notion that optimising the tolerance and foreseeing potential effects can provide significant savings (Bhachu and Raphael et al., n.p). Figure 6 shows the relative increase in cost of specifying tight tolerances which affects the chosen machining and finishing processes.

Figure 6: Relative cost of specifying tight tolerances (Chase and Greenwood, 1988)

(Graves, 1997) concurs, suggesting that saving a penny on each of a thousand units per day roughly equates to £1,500 over a year. However when compared to the cost of buying software, annual license fees and the cost of a trained individual, it is arguably a hard cost for small companies to justify. (Ptc.com, 2009) suggests that the use of tolerance analysis software is historically complicated. Furthermore, many
small and medium-sized enterprises (SMEs) do not have the resource to employee tolerance analysis specialists and subsequently expect design engineers to perform such analysis. (Larsen, 1989) argues that once an employee is trained the two most common methods are conceptually simple and time efficient. (Chase and Parkinson, 1991) strongly support the notion that there is no other robust design tool that yields greater benefits and cost savings than carefully performed tolerance analysis study. (Tolerance Analysis for Medical Devices, 2011) believe the medical industry measures success in terms of people rather than defects per millions. However to achieve the necessary high quality levels demanded by both regulatory bodies and practitioners, assessing potential defects plays a crucial role to ensure successful medical devices.

(Fischer, 2010) provides detail for the use of manual calculations whether they are performed by hand or within CAD systems. He concludes that the effectiveness of these hand calculations using the route sum squared calculation can be very effective and simple to perform. However (Harry and Stewart, 1988) dispute Fishers claims and believed that performing such a study manually is too time consuming, open to misinterpretation and errors. To reduce the likelihood of occurrences they propose the use of spread sheets. Employing the use of programs such as Excel® can produce graphs like that in Figure 7, providing quick comparisons between different methods and tolerance allocations. Furthermore (Bhachu and Raphael et al., n.p) suggest that they offer the best balance between cost and quality, yielding the same results as expensive software packages.

![Figure 5: Tolerance stack-up, method comparison](image)

However (Arya and Kumar et al., 2012) contest the use of manual calculations and spread sheets and indeed the use of all previously mentioned statistical methods, instead they advocate the adoption of the Monte Carlo method. The authors define the Monte Carlo method as being a stack-up of multiple randomly selected points from a normal distribution curve that has been generated by the root sum squared method. Once enough samples have been made the simulation becomes a statistical analysis. (Chase and Greenwood, 1988) argue that because the method relies on thousands of randomly selected points, a large
sample needs to be analysed across the distribution curve, the process could take a significant amount of
time and resource.

As previously stated, tolerance analysis can be highly computation-intensive and the Monte Carlo method is
the most demanding of all approaches and cannot be performed by ordinary computers. This reliance on
specialist workstations provides the first issue for companies wanting to adopt the approach. However
(Harry and Stewart, 1988) believe the investment is warranted and suggest that this method can provide the
most realistic predictions when used appropriately. Despite this (Chang, 2011) makes the case that experts
struggle to fully comprehend and agree on the correct application of the method and the use of this by
untrained design engineers is not recommended. The final approach presented is the use of standalone or
add-on software packages; these allow users to perform tolerance analysis within a CAD assembly, see
figure 8. (Sigmetrix, 2014) advise that one of its main advantages is the dynamic, visual results it quickly
generates.

Moreover designers can quickly generate revisions to see side by side effects of both design and tolerance
changes. (Bartenstein and Morak et al., 2006) raise the decisive argument that although large organisations
may be able to afford the software and the personnel to use the programs; however British medical device
design is dominated by SMEs, 77% of which are turning over less than £118,000 per annum and 59%
employ fewer than 5 people, as seen in figure 9. Consequently, the seldom used and expensive software
does not present a feasible proposition to the majority of the industry.
The literature review provided knowledge to the use, application and methodology taken when using tolerance analysis. Research from many authors has confirmed the importance of tolerance analysis and a specific importance to the medical industry. (Bell, 1995) further verifies this claim by presenting a direct comparison between the aerospace industry which is considered the most quality lead commerce, to that of the medical.

Table 1. Comparison between the aerospace and medical device industry (Bell, 1995)

<table>
<thead>
<tr>
<th>No.</th>
<th>Aerospace Equipment Reliability</th>
<th>Medical Device Reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Costly equipment</td>
<td>Relatively less costly equipment</td>
</tr>
<tr>
<td>2</td>
<td>A well-established reliability field</td>
<td>A relatively new area for the application of tolerance reliability principles</td>
</tr>
<tr>
<td>3</td>
<td>Large manufacturing organisations with an extensive reliability engineering departments</td>
<td>Relatively small manufacturing organisations with much less established reliability engineering departments</td>
</tr>
<tr>
<td>4</td>
<td>Reliability professionals with extensive related past experience who use sophisticated reliability approaches</td>
<td>Reliability professionals with relatively less related past experience, which employ simple reliability methods.</td>
</tr>
<tr>
<td>5</td>
<td>Wellbeing of a human is a factor directly or indirectly</td>
<td>Lives and wellbeing of patients are involved</td>
</tr>
</tbody>
</table>
Bell suggests that the requirements for reliability in the medical industry are comparable to that of aerospace and yet receives less attention. Bell, the only author to make this thought-provoking comparison also describes how the industry has to adapt to more commercial standards in response to market demand. However (Tolerance Analysis for Medical Devices, 2011) claims that the medical industry measures success in terms of survival rate rather than defects per million; this shows the ideological conflict to change, that needs to be addressed to improve product quality, reliability, cost-effectiveness and patient care. It was consequently decided that the focus of the investigation would be on auto-injectors; by concentrating on this highly susceptible market as it was deemed to demonstrate the most significant effects of tolerance build up and its outcome on drug delivery.

3 METHODOLOGY

Telephone interviews were used as the primary research method due to the sensitive nature of the information in this competitive industry, where individuals may not commit to answers in writing due to commercial constraints. The medical design sector is secretive and hard to access; its busy professionals are likely to have little time for formal interviews. Participants needed encouragement and discussions become reliant on the interviewer guiding the interview. Consequently a series of pilot interviews were performed to highlight any potential problems with the outlined questions and to gain valuable experience.

The aim of the interview was to address how designers currently use tolerance analysis to highlight areas for improvement. It was hypothesised that reasons for neglecting the use of tolerance analysis would be attributed to its complexity and financial investment. The purpose of performing pilot interviews was to identify any problems or faults with the interview prior to questioning industry experts. This would allow any highlighted faults to be addressed prior to industry expert interviews. Performing meaningful pilot interviews in such a technical and specific field provided difficulty as questions could not be fully explored. Consequently mechanical and design engineering participants were selected, although no in depth or industry related experience was present, a basic understanding of tolerance was fundamental. To provide impartial advice and improvement recommendations a third party individual was used to analyse the recorded pilot interview sessions.

Recording the audio dialect from both parties allowed post assessment analysis to be performed. In doing this every fault could be identified, discussed and resolved. Consent was provided prior to recording. A total of 3 pilot interviews were performed over an average, 15 minute period. Having highlighted the importance of predefined counter questions a process flow (see figure 10) was developed in tandem with the third party observer to provide cues and suggested responses to participant’s replies, this was constantly referred to during the interviews. they were often closed and limited the participant’s opportunity for response. Further reading and practise was conducted following the guidelines outlined by (Robson, 2007).

The major limitation of the pilot study was the lack of participant understanding around the topic; this limitation prevented any in depth studies to be performed. It was recognised that the three participants selected were not ideal for the pilot study, however given both the industry and the difficult nature of finding participants able to talk about the subject, it was deemed inappropriate to trial the interview on an industry expert.
Figure 8: Telephone question workflow
4 FINDINGS

Preceding the pilot study and changes to the interview in the form of a robust interview question workflow, a series of primary and secondary industry contacts were contacted. It was believed that the changes made to the interview process would maximise the quality of response from participants. It was also important to contact participants by email prior to the telephone interview to ensure they were well prepared and the interview time was convenient for them. All participants were sent a copy of the Universities participant consent form, which were signed and returned prior to the interviews being performed and available on request. Three interviews were organised across different companies and sectors, with their details remaining anonymous, allowing them to talk freely about their companies practise and use of tolerance analysis. Table 2 provides a description of these three companies and the participants.

Table 2: Summary of interview participants and backgrounds

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Industry/Company Description</th>
<th>Participant/Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.</td>
<td>Small/medium sized medical device design company specialising in injection devices</td>
<td>Head of medical device engineer, 15 years industry experience</td>
</tr>
<tr>
<td>B.</td>
<td>Industry leading provider of aerospace systems for large commercial aircraft</td>
<td>Mechanical design engineer, 21 years industry experience</td>
</tr>
<tr>
<td>C.</td>
<td>Design consultancy specialising in the medical and aerospace industry</td>
<td>A team of mechanical design engineers and a product designer (3 people)</td>
</tr>
</tbody>
</table>

Unfortunately obtaining more interviews was not possible, despite contacting 32 primary and secondary contacts from the medical and aerospace industry, see figure 11. Those that replied typically provided one of two responses; ‘we cannot disclose company procedures’ or ‘we don’t use or have access to tolerance analysis.’ The second of the two responses which represented two thirds of the total replies was believed to be interesting. All of the companies and participants contacted where carefully selected as they were believed to be in roles where tolerance analysis would typically be used. Furthermore it was documented that only the medical companies replied with the response that they do not use tolerance analysis. This response further questions why companies in the medical device sector where seemingly not using tolerance analysis.

![Figure 11: Participant response graph](image-url)
Despite the low response rate it was believed that the breadth of companies and participants provided suitable and detailed information from which to proceed further. The aim of the telephone interview research was to establish why designers in the medical device industry were either not using or struggling to use tolerance analysis with the aim of establishing a method to improve the situation. Telephone interviews were recorded and notes were taken with the participant’s consent allowing the transcript to be evaluated post interview. The transcript and interview notes were analysed following each individual interview so not to confuse responses. The analysed document was then checked for a second time before re-analysing the response with an experienced qualitative researcher who provided impartial analysis. This process was performed a further two times over a two week period with the remaining participant responses. Once all of the responses had been analysed another independent research was used to compare and contrast the three interviews and help to draw impartial conclusions. Participants were informed that they could withdraw from the interview at any point and their responses would remain anonymous. Preceding the evaluation of the interview the interview audio recordings were safely destroyed to maintain confidentiality.

All of the participants answered this question in reference to their company design process. Participant A described tolerance analysis as being the most important tool in their robust design arsenal, the participant felt that the use of tolerance analysis was one of their companies’ major advantages over its competitors. However Participants C believed that it had its place but knowing when to apply it, wasn’t always clear. On further investigation it was revealed that the company was resistant to selling the service unless they were very confident in achieving a definitive answer from which to make an informed decision and take accountability. Participant B described tolerance analysis as being primarily used to ensure that assembly variation had been accounted for and could be controlled. Furthermore he suggested that every critical assembly would be analysed fully as the repercussions for not doing so were too significant to risk not performing the analysis.

The literature review provided little non-theoretical reasoning for not employing the use of tolerance analysis, therefore this primary data provided new information to help answer the key questions. Participants C described how using their aerospace background and ethos of “getting it right first time every time”, had provided a significant marketing advantage allowing them to move into the medical device sector. The company recognised that being able to ensure quality was fast becoming pivotal in the increasingly legislation driven medical world. In contrast both participants A and B believed that they used the tools not just for their marketability but because they also produced the products on behalf of their clients so any failures would directly impact on them both financially and effect their industry reputation.

Participants C used a comparison between their experiences in the aerospace industry to that of medical. It was believed that performing the analysis on small complex medical devices was often more confusing than that of much larger aerospace assemblies. One group member believed that this was due to the nature of the work they had become involved in. He suggested that there was often more parts within a study and they were rarely static, moving in opposing directions to one another which made deciding upon the critical tolerance stacks difficult. In addition, group members concluded that they often became confused and unsure as what to do next when performing a tolerance analysis study. However participant B thought there was little resistance as the techniques had been engraved into the company’s procedures for many years and had become an everyday encounter.

Both participants A and B suggested that tolerance analysis wasn’t being used to simply improve the product quality, but to control it. They made the interesting point that they are only interested in meeting the performance and quality criteria rather than beating it. Participant A went on to explain that the studies occasionally had an adverse effect, particularly when parametric tolerance analysis was being used to
determine the process capability. He attributed this to human error and the engineer making mistakes as to when it is appropriate to use the known data. Participants C believed that although their tolerance analysis assessments had driven design changes they were still not confident that the re-design would meet the clients’ expectations. They went on to explain how they had been tasked to perform such a study on an existing failing device, bringing it up to the required quality level. This was understood to be successful but was described to be a “painful” process.

When asked whether the selected method or calculations affected the results participant A said that it had been heavily debated with the company as they wanted to ensure they were using the most appropriate calculations. They also believed the Monte Carlo method to be unclear, with them not understanding how many samples should be taken for it to produce relevant data. Both Participants A and B also believed that the assemblies’ tolerances are unlikely to change significantly. Participant B suggested that performing the analysis would not change the choice of production method. Using the example of the difference between the turning and the grinding process, which offer contrasting levels of accuracy at significant cost differentials as outlined in figure 6, a sudden change of method is highly unlikely. They believed that the changes tended to be small because they design with tolerance in mind. This notion disputes the claims of (Chase and Greenwood, 1988) that performing the analysis can dramatically increases the cost of machining.

Participant A raised the interesting opinion that many of their staff were new to using tolerance analysis, although they usually understood the mathematical principles they struggled to implement the data effectively and found it “confusing”. This notion was also suggested by participants C. However they also believed that one of the foremost reasons why tolerance analysis was not being well adopted was the lack of industry specific methodology. They believed that following the approach used in the aerospace industry wasn’t always applicable to medical devices, suggesting that the results sometimes left them unclear whether the design needed to be adjusted or not.

Participant B believed that tolerance analysis being adoption by every medical device design company would simply be a matter of time once legislation caught up with the aerospace industry. There were notable correlations between the views held by the telephone interview participants and that from the literature review. The complexity and confusion of performing tolerance analysis studies was observed to be a decisive factor deterring the use of tolerance analysis. This had also been suggested by (Chase and Parkinson, 1991), however unlike their study which highlighted balancing cost and quality as being a deterring factor the industry participants disagreed. It was recognised that as long as the assessment was performed correctly and appropriately, the potential increased tooling cost necessary to meet their own or clients desired quality levels was not regarded as an issue.

Despite reservations they believed that the investment was necessary to establish a long term footing in the industry. Participants were also asked if an alternative could be used such as physical testing, however this was disputed and not believed to be representative of production parts. Participant A explained that physical testing only represents a single device not millions which tolerance analysis can be used to predict. The aerospace participant made an interesting conclusion believing that the two industries would need different guidance and procedures due to the dramatic differences in scales of production. It was understood that the likelihood of there being a large disparity between the DPM of hundreds units and a million units was likely to be more significant in the larger manufacturing volumes encountered in the medical industry.

The theme of individual and company accountability was also recognised as being a decisive factor which wasn’t highlighted in the literature review. It was understood that companies would be prepared to turn
away significant contracts if the device quality and public liability was dependant on their ability to perform tolerance analysis correctly, taking full accountability. This suggests that the company could not only save their clients’ money by performing tolerance analysis studies well but generate additional revenue for themselves if the confusion can be addressed. Question seven asked if the participant had any further comments or questions didn’t provide any further information or benefit to the investigation. This could have been improved if suggestions were provided, as they were for the more structured questions.

The obvious limitation of this investigation was the lack of participants from companies choosing not to adopt tolerance analysis and their rational for the decision. Furthermore the assessment lacked quantifiable data and relied on qualitative assessments that could have been misinterpreted and not directly compared. This was addressed by performing a questionnaire which accessed a much larger audience, designed to validate the telephone interviews and gain access to companies not using tolerance analysis. On balance, it is believed that the complexity and often confusion caused by performing tolerance analysis is the decisive factor deterring the medical device industry from implementing tolerance analysis into their robust design process. Therefore if this can be addressed and the process of performing assessments made simpler and more logical, its adoption could increase. The aim of the questionnaire was to verify the data collected from telephone interviews by surveying new participants. It was recognised that using both qualitative and quantitative methods would be mutually enriching as advocated by (McKinlay, 1993).

Using the insights gained from the telephone interviews it was hypothesised that the online questionnaire would emphasise the low adoption of tolerance analysis in the medical industry compared to aerospace. Furthermore it was theorised that the primary reason for medical device designers not using tolerance analysis would be caused by a lack of guidance and subsequent confusion. The pilot questionnaire was trialled with ten participants and analysed in conjunction with an experienced research expert to identify improvement options. After performing the ten pilot questionnaires using an emailed word document it was recognised that this method restricted the ease of evaluation and identification of patterns. The questionnaire primarily relied on multiple choice responses which would be easy to analyse and compare against the qualitative data collected from the telephone interviews. The responses from the pilot study enabled a re-designed questionnaire (see figure 12) to be established and robustly tested ensuring the participant would always be provided with a relevant question based upon their previous response. The skip logic questionnaire was subsequently integrated into an online survey platform for distribution. These changes would ensure that every answer would lead to an appropriate question, providing a set of informative results whether they use tolerance analysis or not.
Following changes to the questionnaire, the survey was sent to the twenty nine contacts established from the telephone interview that did not partake in the telephone interviews and an additional twenty five from
European companies in the aerospace or medical industry. As with the telephone interview it was important that the questionnaire should only be sent to people believed to be in an appropriate role where using tolerance analysis would typically be expected. This allowed results to be carefully monitored and individual participant's questionnaires assessed, allowing patterns to be identified. The data was analysed with the aid of the third party researcher to remove bias from the one qualitative question and assess individual participant response to identify trends. Thirteen respondents completed the questionnaire, of which seven were from the medical industry and six from aerospace. Figure 13 shows the dramatic difference in use of tolerance analysis as a part of your robust design process between the two sectors.

<table>
<thead>
<tr>
<th>Industry</th>
<th>Using Tolerance Analysis</th>
<th>Not Using Tolerance Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerospace</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Medical</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

Figure 10. Individuals using tolerance analysis within the two assessed industries

Of the five participants that stated that they did not use tolerance analysis, three selected complexity as being the reason why they did not use the analysis tool, see figure 14. One participant stated that the company had chosen not to use it, leaving the remaining participant, believing it wasn’t appropriate for their projects.
All participants who used tolerance analysis including the one medical device designer described performing the studies as either having a positive or very positive effect on the products performance. Having this question was deemed important to ensure that industry professionals acknowledged the benefits highlighted in the literature review. Figure 15 shows the responses provided by participants when asked which tools could improve their ability to perform tolerance analysis studies.

![Figure 11: Medical industry reasons for not using tolerance analysis](image)

Almost all participants selected process workflows and checklist a suggestion also made by participants A. and C. in the telephone interviews. The final written response to the question, what do you think could be done to improve the use of tolerance analysis in the medical device design industry? This question only provided limited in depth responses which had been recognised from studying the works of (Barbour, 2008), (Robson, 2007) and (Murphy and Dingwall et al., 1998). As with the telephone interviews the key message was to reduce the potential for confusion which was also independently recognised by the third part researcher.

<table>
<thead>
<tr>
<th>Method</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written Instruction</td>
<td>2</td>
</tr>
<tr>
<td>Pictorial Instruction</td>
<td>2</td>
</tr>
<tr>
<td>Video Instruction</td>
<td>1</td>
</tr>
<tr>
<td>Process Workflow</td>
<td>12</td>
</tr>
<tr>
<td>Check List</td>
<td>11</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

![Figure 12: Methods of improving the tolerance analysis process](image)
5 DISCUSSION

The questionnaire aimed to both verify and build upon the telephone interview responses. It had been acknowledged that no previous studies published had assessed the factors deterring tolerance analysis; authors had only investigated how to improve the quality of the results. The questionnaire revealed links between low usage of tolerance analysis and participants confusion, despite all respondents recognising the benefits of performing the analysis. The findings opposed the claims made by (Graves, 1997) that cost would be the deterring factor, instead it appeared to be complexity and a lack of available guidance. The companies from which participants responded were also analysed to understand whether if correlations could be made between the size of the company and participant response. Table 3 provides a summary of the participant’s employers alongside their response to whether they used tolerance analysis.

Table 3. Participant company response to whether they used tolerance analysis.

<table>
<thead>
<tr>
<th>Company Description</th>
<th>Revenue (2013)</th>
<th>Employees</th>
<th>Participant Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>British multinational pharmaceutical healthcare company</td>
<td>£25.6 billion</td>
<td>99,000</td>
<td>Company procedures</td>
</tr>
<tr>
<td>American multinational conglomerate corporation specialising in medical products</td>
<td>£17.8 billion</td>
<td>88,000</td>
<td>Confusion</td>
</tr>
<tr>
<td>Manufactures and markets pharmaceutical products and services</td>
<td>£8.75 billion</td>
<td>35,154</td>
<td>Appropriateness</td>
</tr>
<tr>
<td>German chemical and pharmaceutical company</td>
<td>£8.6 billion</td>
<td>40,676</td>
<td>Confusion</td>
</tr>
<tr>
<td>Subsidiary of American multinational conglomerate specialising in medical products</td>
<td>£11.08 billion</td>
<td>46,000</td>
<td>Confusion</td>
</tr>
</tbody>
</table>

The five companies not using tolerance analysis are all large multinational organisations where the investment of thousands of pounds in adopting tolerance analysis would not represent a significant investment. However they still don’t use the tool despite recognising the benefits to their products. Providing that tolerance analysis was appropriate to the company, participant representatives attributed this decision to confusion, not cost. Because the only apparent barrier deterring these organisations from using tolerance analysis is confusion addressing this problem would increase the adoption of tolerance analysis.

However, these results are not fully representative as respondents only came from large organisations. Inevitably cost will deter some SMEs from investing, but it is Important to remember that normally only large companies actually produce medical devices. Having used skip-logic, the participant’s questions were selected on the basis of the previous question; comparisons could be made between aerospace contributors and medical. It was found that all participants from the aerospace industry were not only all using tolerance analysis but believed it to be a very useful tool.

Participants were asked how the process of performing the analysis could be aided through the use of supplementary tools; this highlighted both process workflows and checklists as potentially being the most
beneficial. This was also advocated by (Helmreich, 2000) who first recognised the use of procedure workflows in the aerospace industry and proposed its practice in the medical industry. Helmreich’s lessons from aviation, details a dramatic reduction in preventable mistakes when workflows were trialled with practitioners. Using the same logic, workflows could be implemented at the other end of the medical industry to help encourage adoption and correct use of tolerance analysis to improve medical device quality.

Assessing only the medical industry responses, a trend was identified that all for mentioned participants selected the use of workflow checklists and tick lists, with only the aerospace contributors choosing other tools. One participant believed that it would only be a matter of time before tolerance analysis would become a legislated requirement. At present there are no documented plans for this to be enforced however it has been recognised by several authors that the medical industry needs similar legislation to that of aerospace where performing tolerance analysis is actively promoted.

The population sample selection was relatively small due to the specific nature of the investigation. Consequently participants were specifically targeted based upon their industry and job title. This raises issues as to whether the results are truly representative as the sample was not selected at random; however given the resources available taking this approach was deemed to be suitable. It is believed that by addressing the complexity of performing a tolerance analysis study its use in the medical design industry could increase. All participants understood the benefits of performing the analysis which provides optimism that if a new approach or method can be developed people would be willing to make the change.

6 CONCLUSIONS

Drawing from the literature review, telephone interviews and questionnaires, conclusions were established based upon the research objectives. The lack of existing research investigating the reasons why the medical industry is seemingly resistant to adopting tolerance analysis makes definitive comparisons and evaluations hard to make. Confusion and limited guidance were highlighted as the areas to address to increase the use of tolerance analysis in the medical device industry.

The primary deterring factor was the complexity of performing analysis opposed to the cost which (Chase and Parkinson, 1991) attributed to be the biggest issue. This was believed to be industry specific, as only very large pharmaceutical companies produce complex devices that warrant tolerance analysis and the necessary financial investment to establish the system. Whereas the aerospace industry has specialists to perform tolerance analysis, such a role hasn’t been observed in the medical industry. Consequently design engineers are being given the responsibility with limited guidance hence their reluctance and confusion.

Secondly the levels of tolerance analysis use between the aerospace and medical industry were observed to be contrasting. Results showed that only 1 in 6 medical industry participants were using tolerance analysis opposed to all participants from the aerospace sector, despite the two industries being recognised as equally quality critical and jointly deserved of tolerance analysis (Bell, 1995). To address the underlining problem, a workflow checklist was highlighted as being the most universal adaptable and cost effective method for improving both user experience and results from such a study.

Given that both telephone interview and questionnaire participants suggested the use of a workflow checklist system to reduce confusion and provide guidance through the process; it was believed that this would be the most appropriate method to address the highlighted problem. The checklist seen in figure 16 has been implemented at the other end of the medical sector for surgeons to use before, during and after the operating procedure; although it may appear simple, it is thought to have saved 1500 lives in its first 18 months of use. (Who.int, 2007)
Building upon the surgical safety checklist, the workflow outlined in Table 4 was designed to provide a top level summary of a typical tolerance analysis study performed using spread sheets. Its design shares the basic principles used by the surgical safety checklist and similarly each stage provides additional guidance and questions to the users. Further research is still required to build upon this workflow checklist proposal to ensure it is relevant to all methods of performing the analysis. The surgical safety checklist has been evaluated and tested in all possible circumstances scenarios to ensure it can be used with all operating procedures without conflicting criteria. This testing and development period would provide significant benefit to the proposed workflow checklist to ensure its effectiveness.

This work recommends the medical device design industry to adopt tolerance analysis, alongside guidance tools to aid unfamiliar designers through the process of performing the analysis. It was highlighted that a workflow checklist would encourage the use of tolerance analysis providing it helped reduce confusion. Furthermore, research suggested that a procedure that could be applied to both CAD packages and spread sheets would allow the tool to be more widely implemented. The limitations of the study have been recognised and highlighted throughout the paper, emphasising the opportunity for additional research. Building upon the proposed Workflow Checklist in Table 4 a robust and dependable procedure could be created, this would benefit from further research assessing each individual stage of the analysis process to ensure the guidance workflow is always providing appropriate direction.

The aim of this investigation was to identify a procedure that could encourage designers of medical devices to adopt tolerance analysis; this has been achieved by producing a workflow checklist which if developed, refined and promoted further would help to improve product quality, reliability and cost-effectiveness.
## Table 4: Proposed workflow checklist

<table>
<thead>
<tr>
<th>Defining Parts for Analysis</th>
<th>Performing Tolerance Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> Confirmed concept design</td>
<td><strong>2.1</strong> Define all critical tolerance stacks <em>Both radial and linear</em></td>
</tr>
<tr>
<td><strong>1.2</strong> Define and list all functions <em>Document those components these should be only the components which have a major, direct influence.</em></td>
<td><strong>2.2</strong> Select a stack and input individual into spreadsheet <em>Proposed tolerance Part dimension</em></td>
</tr>
<tr>
<td><strong>1.3</strong> Break down influencing components <em>Which components have a direct effect on the list of functions</em></td>
<td><strong>2.3</strong> Define upper and lower limits for the assembly stack <em>Ensure that the limit will allow the assembly to work in all states and ranges of movement.</em></td>
</tr>
<tr>
<td><strong>1.4</strong> Is it a proprietary part? <em>If yes stop</em></td>
<td><strong>2.4</strong> Input known process capability figures <em>If actual data is unavailable: Cp 2.0 and Cpk 1.33</em></td>
</tr>
<tr>
<td><strong>1.5</strong> Define influencing features <em>This may remove the need to assess certain features</em></td>
<td><strong>2.5</strong> Perform study <em>Do results appear sensible? If not check individual tolerance allocations and stack limits.</em></td>
</tr>
<tr>
<td><strong>1.6</strong> Refine interactions to simplify design <em>Re-run dFMEA study on changed features before preceding</em></td>
<td><strong>2.6</strong> Do the parts per million fail rate meet with the product design specification <em>If no reconsider part tolerances? Can parts or features be merged to reduce the stack up effect?</em></td>
</tr>
<tr>
<td><strong>1.7</strong> Do you fully understand the feature at the extremes of its tolerance? <em>If yes, no further testing required If no proceed to section 1.8</em></td>
<td><strong>2.7</strong> Repeat procedure until all stacks have been assessed and meet acceptance criteria <em>Are all tolerances realistic? Can some be loosened and still meet the required specification?</em></td>
</tr>
<tr>
<td><strong>1.8</strong> Define testing/analysis <em>Is physical testing appropriate? If yes proceed no further</em></td>
<td><strong>2.8</strong> Verify manufacturer process capability <em>Can this be trusted? consider a factor of safety</em></td>
</tr>
<tr>
<td><strong>1.9</strong> Document results <em>Record all decisions as a part of 510k provision and ISO 13485 standards</em></td>
<td><strong>2.9</strong> Document results <em>Record all results as a part of 510k provision and ISO 13485 standards</em></td>
</tr>
</tbody>
</table>

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1. **Confirmed concept design**
   - **Note:** Check if it is a proprietary part. If yes, stop.
2. **Define and list all functions**
   - **Document those components these should be only the components which have a major, direct influence.**
3. **Break down influencing components**
   - **Which components have a direct effect on the list of functions?**
4. **Is it a proprietary part?**
   - If yes, stop.
5. **Define influencing features**
   - **This may remove the need to assess certain features.**
6. **Refine interactions to simplify design**
   - **Re-run dFMEA study on changed features before preceding.**
7. **Do you fully understand the feature at the extremes of its tolerance?**
   - If yes, no further testing required. If no, proceed to section 1.8.
8. **Define testing/analysis**
   - **Is physical testing appropriate? If yes proceed no further.**
9. **Document results**
   - **Record all decisions as a part of 510k provision and ISO 13485 standards.**
REFERENCES


